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 CTIA—THE WIRELESS ASSOCIATION® AS AMICUS CURIAE SUPPORTING PETITIONER

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INTEREST OF AMICUS CURIAE

CTIA—The Wireless Association® is an international nonprofit organization representing the wireless communications industry. CTIA's members include wireless carriers, suppliers, and manufacturers; telecommunications service providers; and many other contributors to the wireless communications industry.[1]

CTIA advocates for policies that support the wireless industry's continued growth and contribution to the American economy. CTIA has regularly filed amicus briefs in cases presenting issues of importance to its members, including False Claims Act cases. *See, e.g.*, *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989 (2016); *T-Mobile S., L.L.C. v. City of Roswell,* 135 S. Ct. 808 (2015); *Limelight Networks, Inc. v. Akamai Techs., Inc.,* 134 S. Ct. 2111 (2014); *Sprint Commc'ns, Inc. v. Jacobs,* 134 S. Ct. 584 (2013); *City of Arlington v. FCC,* 569 U.S. 290 (2013).

The question in this case is whether a *qui tam* relator's FCA suit should be dismissed on materiality grounds when the pleadings reveal that the federal government continued to pay claims after learning of an alleged regulatory or contractual infraction, and the pleadings offer no basis for overcoming the inference of immateriality that arises from that continued payment. In CTIA's view, the answer is yes. Like

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[1] No party or counsel for a party authored this brief in whole or in part, and no one other than amicus curiae, its members, or its counsel funded the preparation or submission of this brief. *See* Sup. Ct. R. 37.6. Counsel for petitioner and respondent received timely notice of this filing, and both consented to the filing through blanket consent letters filed with the Court. *See* Sup. Ct. R. 37.2.

other companies that frequently do business with the federal government, CTIA's members have a strong interest in ensuring that courts distinguish between lawsuits prosecuted by individuals with credible knowledge of undisclosed fraud and unfounded cases filed solely to extract large settlements. When the pleadings in a case show that an alleged regulatory or contractual infraction was immaterial because the government knew about the infraction and kept paying claims, the case should be dismissed.

SUMMARY OF ARGUMENT

This Court's False Claims Act jurisprudence has always aimed to find "the golden mean between an inadequate and an excessive scope for private enforcement" of the Act. *Graham Cty. Soil & Water v. U.S. ex rel. Wilson*, 559 U.S. 280, 302 (2010). Consistent scrutiny of materiality at the pleading stage is an essential part of that effort.

Meritorious FCA claims serve the important purpose of deterring and punishing fraud on the government, but the FCA as interpreted by the Ninth Circuit essentially has become a lottery for the plaintiffs' bar. Over the past 30 years, the number of *qui tam* lawsuits filed each year has steadily increased. By 2017, an average of 13 new *qui tam* suits were filed each week. Many of these cases are just the type of opportunistic lawsuits this Court has warned about—efforts by a private citizen to reap a personal financial windfall while producing little benefit to the government. *See Schindler Elevator Corp.* v. *U.S. ex rel. Kirk*, 563 U.S. 401, 412–13 (2011).

Many of these *qui tam* suits are "implied false certification" cases that follow a common pattern: several years after the fact, a relator seeks draconian

monetary penalties based on nothing more than a purported violation of one of the thousands of statutory, regulatory, or contractual requirements applicable to a company that does business with the government. The government does not intervene and, despite having knowledge of the purported violation, continues to pay the contractor (often for years after acquiring such knowledge). Nonetheless, the defendant incurs significant costs in defending against the suit. Those costs end up being passed on to the government—and ultimately to taxpayers—in the form of higher prices paid by the government for goods and services.

To avoid these costs, defendants must be able to get meritless FCA suits dismissed on the pleadings. In *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), this Court recognized that the FCA's materiality requirement provides an important check on non-meritorious suits. The Court explained that when the government has learned of the defendant's alleged noncompliance and nonetheless has continued to pay the claims the defendant submits, that is strong evidence that the noncompliance is immaterial.

Since *Escobar*, however, the federal appellate courts have disagreed about whether a suit must be dismissed when the complaint alleges that the government knew of the defendant's alleged fraud and nonetheless paid the defendant's claims and nothing in the complaint suggests that the alleged fraud was material. The Ninth Circuit's decision in this case provides a vivid example of the lower courts' confusion, because it conflicts with *Escobar* in several important respects. Given the enormous amount of money involved in defending meritless cases and the large vol-

ume of these suits, this Court's review is critical to ensure industries' ability to efficiently and effectively dispense with them.

ARGUMENT

I. MERITLESS FCA SUITS IMPOSE SIGNIFICANT COSTS ON COMPANIES THAT DO BUSINESS WITH THE GOVERNMENT

A. Meritless FCA Suits Are On The Rise

1. The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, imposes significant penalties on those who knowingly present false or fraudulent claims to the government for payment. 31 U.S.C. § 3729(a)(1)(A). The FCA authorizes both the government and private parties to enforce it. *Id.* § 3730(a), (b). When a private party (a relator) brings a lawsuit in the name of the United States, the government may intervene and take over the action, allow the relator to proceed with the suit, or seek dismissal. *Id.* § 3730.

Wielded properly, the FCA is a "powerful tool" to uncover and deter fraud against the government and protect the public fisc. *United States v. Mackby*, 261 F.3d 821, 830 (9th Cir. 2001). FCA suits have produced substantial recoveries in cases where relators uncovered genuine fraud—such as cases where the government received worthless goods or services, or (worse yet) nothing at all. *See, e.g.*, *United States v. Bornstein*, 423 U.S. 303, 307–08 (1976); *see also Escobar*, 136 S. Ct. at 1996.

But experience has shown that the FCA is also subject to abuse. The statute's penalty provisions are severe: they provide for mandatory treble damages, mandatory attorneys' fees, and per-claim penalties between $11,000 and $22,000. 31 U.S.C. §§ 3729(a), 3730(d); 28 C.F.R. § 85.5. For that reason, this Court

has characterized the statute's remedial provisions as "essentially punitive in nature." *Escobar*, 136 S. Ct. at 1996 (quotations omitted).

To encourage private citizens to file *qui tam* suits, the FCA uses a bounty system—awarding relators up to 25 percent of the recovery in cases where the government intervenes and up to 30 percent in cases where it does not. 31 U.S.C. § 3730(d). Together, the FCA's penalty and bounty provisions create significant risk that private relators will roll the dice on lawsuits "motivated primarily by prospects of monetary reward rather than the public good." *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 949 (1997).

2. In recent years, the prospect of a lucrative recovery has caused an explosion in the number of FCA suits filed by private citizens. In fiscal year 1987 (the year after the FCA was enacted in its modern form), only 30 *qui tam* lawsuits were filed nationwide. *See* U.S. Dep't of Justice, *Fraud Statistics – Overview* 1 (Dec. 19, 2017) (*Fraud Statistics*).[2] By 2006, the number had increased exponentially, to 385. *Id.* By 2017, it had almost doubled again, to 674—an average of 13 *qui tam* lawsuits *per week*. *Id.* at 2.

Especially troubling is the dramatic increase in *qui tam* cases where the government declines to intervene, like this case. The FCA requires a relator to provide "all material evidence and information" to the government when he files an action. 31 U.S.C.

[2] https://www.justice.gov/opa/press-release/file/1020126/download.

§ 3730(b)(2). Once it is aware of the relevant allegations and evidence, the government is required to investigate the relator's claims and decide whether to take over prosecution of the case. *Id*. § 3730(a), (b)(4). But the government rarely exercises that option. As of 2011, the Department of Justice (DOJ) intervened in only about 20 percent of *qui tam* cases.[3] And while DOJ has the authority to seek dismissal of a case, 31 U.S.C. § 3730(c)(2)(A), it seldom does so.

Many of these non-intervened cases lack merit. Over the last 30 years, *qui tam* cases in which the government declined to intervene account for just 3 percent of all FCA recoveries. *See Fraud Statistics* 1–2. And one study found that between 1987 and 2004, 92 percent of declined *qui tam* cases were dismissed (either voluntarily or by court order). Christina Orsini Broderick, Note, Qui Tam *Provisions and the Public Interest: An Empirical Analysis*, 107 Colum. L. Rev. 949, 975 (2007). These statistics confirm the intuition that non-intervened FCA cases "presumably lack[] merit." *U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 331 (5th Cir. 2011).

3. Relators in *qui tam* cases often follow a common playbook. Under the "implied false certification" theory of FCA liability, a relator argues that each time a government contractor submits a claim for payment, "it impliedly certifies compliance" with every "mate-

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[3] Letter from Jim Esquea, Asst. Sec'y, U.S. Dep't of Health & Human Servs., and Ronald Weich, Asst. Att'y Gen., U.S. Dep't of Justice, to Hon. Charles E. Grassley, U.S. Senate 15 (Jan. 24, 2011), http://www.friedfrank.com/files/QTam/DOJ-HHS-joint-letter-to-Grassley%20Jan24_2011%20(2).pdf.

rial statutory, regulatory, or contractual requirement," so that a single violation of any of those requirements makes the claim false or fraudulent under the FCA. *Escobar*, 136 S. Ct. at 1995.

The FCA plaintiffs' bar has seized on this implied-false-certification theory. It regularly files *qui tam* suits alleging that a defendant failed to comply with some statutory, regulatory, or contractual requirement and therefore violated the FCA every time it submitted a claim for payment. *See* Michael Holt & Gregory Klass, *Implied Certification Under the False Claims Act*, 41 Pub. Cont. L.J. 1, 2 (2011) (concluding that "individual implied-certification cases have resulted in awards upwards of $99 million").

Before this Court's decision in *Escobar*, the implied certification theory of FCA liability was not universally recognized. *See Escobar*, 136 S. Ct. at 1998–99. *Escobar* held that "the implied certification theory can be a basis for liability" under the FCA when certain conditions are met. *Id.* at 2001. But the Court recognized an important limit on its holding—the FCA's materiality requirement. An implied certification FCA suit may proceed only when the defendant fails to "disclose noncompliance with *material* statutory, regulatory, or contractual requirements," so that the defendant's representations about goods and services provided in the claim for payment become "misleading half-truths," *i.e.*, fraud. *Id.* (emphasis added); *see also id.* at 2002.

Escobar's validation of the implied certification theory is "destined to increase the scope and complexity of FCA investigations and litigation." Jonathan Diesenhaus et al., *Is that Claim False?: Implied False Certification Liability After* Escobar, 2017 Health L. Handbook 1, 1 (2017). Indeed, in the two years since

the decision in *Escobar*, many *qui tam* relators have premised their FCA lawsuits on this theory. *See, e.g., U.S. ex rel. Ruckh v. Salus Rehab, LLC*, No. 8:11-cv-1303, 2018 WL 375720, at *1, 4–8 (M.D. Fla. Jan. 11, 2018) (setting aside a $350 million jury verdict on an implied-false-certification claim predicated on allegations of minor record-keeping noncompliance).

4. Companies that operate in heavily regulated industries or sell critical products to government agencies face an especially high risk of baseless *qui tam* suits. That is because those companies "are often subject to thousands of complex statutory and regulatory provisions." *Escobar*, 136 S. Ct. at 2002. "[T]he sheer volume of [applicable] laws and regulations" means, as a practical matter, that "total compliance" is "unrealistic." Joan H. Krause, *"Promises to Keep": Health Care Providers and the Civil False Claims Act*, 23 Cardozo L. Rev. 1363, 1398–99 (2002). Most of the time, a relator can find at least one instance of alleged noncompliance—or manufacture an allegation of noncompliance through an after-the-fact reinterpretation of one of the many applicable requirements.

As an industry's regulatory requirements increase, so does the likelihood that a relator will find a way to allege some *post hoc* example of regulatory noncompliance. And the communications industry—in which CTIA's members operate—is "governed by a complicated and, at times, less than clear set of rules and regulations," *United States v. Green*, 592 F.3d 1057, 1061 (9th Cir. 2010), including an entire title of both the United States Code and the Code of Federal Regulations.

B. Meritless FCA Suits Impose Significant Costs On Taxpayers, Government Contractors, And The Economy

1. The negative industry impact from non-meritorious FCA suits is significant and growing. As these suits proliferate, companies are forced to expend their limited resources to defend against even the flimsiest FCA suits, and the cost of doing business with the government goes up.

Defending an FCA suit is expensive. When a suit is filed, a defendant typically will undertake an internal investigation into the history of the relationship between the defendant and the agency, reviewing performance under the contract or program, payment and billing practices, and any allegations of noncompliance with applicable requirements. Because *qui tam* suits often challenge payments made under contracts or programs that have been in place for years (or even decades), these internal investigations can consume significant time and resources. And these investigations typically take place before discovery, so their costs are frontloaded into every case.

In addition, defendants in FCA suits often "incur significant attorneys' fees." James R. Murray et al., *False Claims Act Notice Issues: To Disclose, or Not to Disclose*, 22 Westlaw J. Ins. Coverage 1, 5 (2012). Twenty years ago, in FCA suits "that involve[d] complex theories of liability," these costs "reach[ed] $10 million or more." William E. Kovacic, *The Civil False Claims Act as a Deterrent to Participation in Government Procurement Markets*, 6 Sup. Ct. Econ. Rev. 201, 225 (1998). That figure is surely higher today.

The financial risk created by the FCA's severe penalty provisions also "places great pressure on defendants to settle even meritless suits." John T. Boese

& Beth C. McClain, *Why* Thompson *Is Wrong: Misuse of the False Claims Act to Enforce the Anti-Kickback Act*, 51 Ala. L. Rev. 1, 18 (1999). Relators magnify this potential risk by treating each request for payment as a "claim" under the FCA, so that they can allege that the defendant made hundreds or even thousands of claims under a single contract. *See Bornstein*, 423 U.S. at 309 n.4 (relying on "the number of individual false payment demands"); *see also, e.g.*, *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 651 (5th Cir. 2017) ($664 million judgment based on "16,771 false claims"). By dramatically increasing the number of claims at issue in FCA suits, relators expose defendants to "the risk, however small, of potentially ruinous liability," thereby placing "inordinate or hydraulic pressure on defendants to settle." *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001).

Baseless FCA suits drive up compliance costs, particularly in highly regulated industries. Because FCA liability is "essentially punitive in nature," companies "anticipate and prioritize compliance obligations" to minimize the risk of FCA litigation. *Escobar*, 136 S. Ct. at 1996, 2002 (quotations omitted). As that risk increases, companies that receive federal funds must commit more money, personnel, and resources to policing compliance. Kovacic, 6 Sup. Ct. Econ. Rev. at 225.

2. These defense costs ultimately reduce investment, innovation, employment, and other productive economic activity. Litigation expenses are a sunk cost. And increased spending on extreme compliance measures to avoid even the most minor breach or regulatory violation does nothing to advance the FCA's purpose of protecting the government from fraud.

Given the enormous volume of government contracting, these costs affect businesses across nearly every sector of the American economy. The economic impact of government spending (through contracts and other programs) is outsized and ever-expanding. In 2015 alone, the federal government awarded contracts worth more than $430 billion.[4] As government spending increases, so do the number of businesses that receive federal funds through contracts and government programs. Every one of those businesses is at risk of relator-driven FCA litigation, regardless of its efforts to comply with applicable contractual or regulatory requirements.

Ultimately, taxpayers bear the burden of these increased costs. As then-Chief Judge Breyer explained, the result of "significantly increasing competitive firms' cost of doing federal government business[]" is "the government's being charged higher [prices]." *United States v. Data Translation, Inc.*, 984 F.2d 1256, 1262 (1st Cir. 1992). When the government pays more to procure goods and services, taxpayers do too.

II. THE MATERIALITY ELEMENT IS A CRITICAL MECHANISM FOR DISMISSING MERITLESS FCA SUITS

A. Courts Must Be Able To Dismiss Meritless FCA Suits At The Pleading Stage

Where DOJ does not intervene nor seek dismissal of meritless cases, companies need to be able to obtain dismissal of those suits on the pleadings.

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[4] U.S. Gov't Accountability Office, GAO-17-244SP, *Contracting Data Analysis: Assessment of Government-wide Trends* 1 (2017), https://www.gao.gov/assets/690/683273.pdf.

An FCA suit can be dismissed on the pleadings if the complaint does not properly allege fraud. In an implied certification case, the plaintiff contends that the defendant's claims for payment are fraudulent because the claims implied that the defendant complied with all applicable federal requirements, when in fact (the relator alleges) the defendant did not. *Escobar*, 136 S. Ct. at 1999–2000. Recognizing that companies are subject to a multitude of statutory, regulatory, and contractual requirements, the Court has "emphasize[d]" that the FCA does not encompass "insignificant regulatory or contractual violations." *Id.* at 2004. Correcting "regulatory problems is a worthy goal," but regulatory infractions are only actionable under the FCA when there is "*actual fraudulent conduct*." *U.S. ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (quotations omitted).

The materiality requirement distinguishes actual fraudulent conduct from "garden-variety" "regulatory violations" that fall outside the FCA's reach. *Escobar*, 136 S. Ct. at 2002–03. Materiality requires proof that a misrepresentation would or did matter to the payment decision. *See id.* at 2002 (materiality depends on the "effect on the likely or actual behavior of the recipient of an alleged misrepresentation"). A misrepresentation is not material merely because the government "designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment" or because the government "would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* at 2003. And noncompliance with a requirement is not "material" if it is "minor or unsubstantial." *Id.*

B. *Escobar* Provides Important Guidance On Materiality In FCA Cases, But More Is Needed

1. In *Escobar*, the Court took an important step toward facilitating early dismissal of meritless FCA suits on materiality grounds. But there is more work to be done.

Escobar instructed lower courts to "dismiss False Claims Act cases on a motion to dismiss" when relators fail to plead facts that satisfy the FCA's "rigorous" and "demanding" materiality requirement. 136 S. Ct. at 2003, 2004 n.6. The Court specifically rejected the view that "materiality is too fact intensive to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." *Id.* at 2004 n.6. Dismissal on the pleadings is especially appropriate because FCA plaintiffs "must plead their claims"—including "facts to support allegations of materiality"—"with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Id.* If a complaint fails to sufficiently plead materiality, it must be dismissed. *Id.*

The Court provided specific examples of cases where noncompliance with a requirement is immaterial—examples that often arise in real cases. In many non-intervened *qui tam* suits, two things are true: (1) the government had knowledge of the defendant's alleged statutory, regulatory, or contractual violation, and (2) the government nonetheless continued to pay the claims the defendant submitted. *E.g.*, *Harman*, 872 F.3d at 667–68; *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017); *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447–48 (7th Cir. 2016); *U.S. ex rel. Thomas v.*

Black & Veatch Special Projects Corp., 820 F.3d 1162, 1172–73 (10th Cir. 2016).

The Court recognized that when both of those facts are present, a relator must overcome the strong inference of immateriality that necessarily arises—even at the pleading stage. "[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." *Escobar*, 136 S. Ct. at 2003. Similarly, "if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position," that also is "strong evidence" of immateriality. *Id.* at 2003–04. In short, where the government has learned of the alleged fraud, its decision to continue paying claims gives rise to a "strong presumption against materiality." *Harman*, 872 F.3d at 652.

2. Although the Court in *Escobar* instructed that failure to plead materiality can be a basis for dismissal at the pleading stage, the Court did not apply the materiality standard in that case. That is because the question before the Court was whether the implied-false-certification theory could *ever* be a basis for liability. 136 S. Ct. at 1998–99. For the lower courts to heed *Escobar*'s instruction and grant early dismissal of meritless FCA suits, they need further guidance from this Court on how to evaluate whether an FCA complaint provides adequate factual support for its allegation of materiality.

III. THE COURT SHOULD GRANT CERTIORARI TO ENSURE THAT THE LOWER COURTS CORRECTLY APPLY THE MATERIALITY REQUIREMENT AT THE PLEADING STAGE

A. The Courts Of Appeals Have Disagreed On The Question Presented

In the two years since *Escobar*, the courts of appeals already have divided on the question whether an FCA suit must be dismissed when the complaint (1) alleges that the government has learned of the defendant's alleged fraud and nonetheless continued to pay the defendant's claims and (2) contains no factual allegations that rebut the presumption of immateriality that arises from those two facts. The First, Second, and Third Circuits have dismissed such suits, and the Ninth Circuit (in the decision below) has allowed them to proceed. *Compare U.S. ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 35–36 (1st Cir. 2017); *Coyne v. Amgen, Inc.*, No. 17-1522, 2017 WL 6459267, at *3 (2d Cir. Dec. 18, 2017); *and U.S. ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017), *with* Pet. App. 30a–32a. *See generally* Pet. 13–20.[5]

Embedded in those decisions are differences about exactly how to assess materiality at the pleading stage. For example, the lower courts have struggled to determine what level of government knowledge is necessary—whether the government must have

[5] In addition to these decisions, petitioner also cites decisions of the Fifth, Seventh, Tenth, and D.C. Circuits granting summary judgment (as opposed to motions to dismiss) on materiality grounds. Pet. 17–20.

knowledge of the *allegations* of noncompliance,[6] or knowledge of *actual* noncompliance.[7] The split among the circuits on the motion-to-dismiss standard, combined with confusion about what type of government knowledge is necessary, shows that this Court's guidance is needed.

B. The Ninth Circuit Seriously Erred In Evaluating Materiality In This Case

This case follows the typical pattern for an implied-false-certification case. Petitioner is a large pharmaceutical manufacturer that has supplied prescription drugs to the federal government for many years. Pet. App. 5a–6a. Those drugs have been approved by the FDA. *Id.* at 6a–7a. Respondent brought this FCA suit, contending that petitioner committed fraud because it did not fully comply with all requirements for FDA approval. *Id.* at 22a–23a. The complaint alleges two facts key to materiality: (1) the government had knowledge of petitioner's alleged regulatory violations, and (2) the government nonetheless continued to pay the claims petitioner submitted. *Id.* at 28a (continued payment), 30a–31a (knowledge).

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[6] *See, e.g.*, *DePuy*, 865 F.3d at 34–35; *D'Agostino* v. *ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016); *City of Chicago v. Purdue Pharma L.P.*, 211 F. Supp. 3d 1058, 1079 (N.D. Ill. 2016); *U.S. ex rel. Kolchinsky v. Moody's Corp.*, No. 12cv1399, 2017 WL 3841866, at *2 (S.D.N.Y. Sept. 1, 2017).

[7] *See, e.g.*, *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 111–12 (1st Cir. 2016); *U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1050 (C.D. Cal. 2016); *Smith v. Carolina Med. Ctr.*, No. 11-2756, 2017 WL 3310694, at *12 (E.D. Penn. Aug. 2, 2017); *U.S. ex. rel. Williams v. City of Brockton*, No. 12-cv-12193-IT, 2016 WL 7429176, at *6 (D. Mass. Dec. 23, 2016).

The Ninth Circuit, however, refused to dismiss this suit on materiality grounds. *Id.* at 32a.

That decision is erroneous in several respects. First, and most fundamentally, the Ninth Circuit took a speculative, counterfactual approach to assessing the significance of continued government payments in the face of knowledge of the alleged infractions. After acknowledging that the FDA "continued" to "approv[e] of the drugs even after the agency became aware of certain noncompliance"—which meant that other federal agencies would continue to purchase the drugs—the Ninth Circuit decided that it "would be a mistake" to "read too much into the FDA's continued approval." Pet. App. 9a, 31a. But *Escobar* tells us exactly what to "read . . . into" that decision: "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." 136 S. Ct. at 2003 (emphasis added).

Second, the Ninth Circuit refused to dismiss the case because it viewed materiality issues as "matters of proof, not legal grounds to dismiss." Pet. App. 32a. But *Escobar* expressly rejected the view that "materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss." 136 S. Ct. at 2004 n.6.

Third, the Ninth Circuit used the wrong materiality standard. It said a relator can "sufficiently plead[] materiality" by "alleg[ing] *more than the mere possibility* that the government would be entitled to refuse payment if it were aware of the violations." Pet. App. 32a (emphasis added); see *id.* at 31a (speculating that "there are many reasons the FDA may choose not to withdraw a drug approval"). But *Escobar* confirmed

that it is *not* "sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." 136 S. Ct. at 2003. The question is not whether the government *could* refuse payment if it knew the truth, but whether it likely *would* or actually *did*. *Id.* at 2002. And the government's payment decisions "may be (and often are) the best available evidence of whether alleged misrepresentations had an objective, natural tendency to affect a reasonable government decision-maker." *U.S. ex rel. Am. Sys. Consulting, Inc. v. ManTech Advanced Sys. Int'l*, 600 F. App'x 969, 976 (6th Cir. 2015) (unpublished).

Finally, the Ninth Circuit mistakenly relied on a "dispute" over "exactly what the government knew and when." Pet. App. 32a. But there was no dispute that the government knew of petitioner's alleged noncompliance with FDA regulations. Petitioner sought dismissal based on the complaint, and the complaint "outline[d] a variety of facts that speak to the government's knowledge." *Id.* at 30a–31a (warning letter, noncompliance letter, three inspections, and two recalls). The Ninth Circuit should have realized that the FDA's knowledge of the alleged infractions—combined with the "undisputed" fact that "the government continue[d]" to pay for the drugs, *id.* at 28a—gives rise to a strong presumption of immateriality that, if unrebutted, warrants dismissal. *Cf. Harman*, 872 F.3d at 652. The only remaining question is whether the complaint pleaded any facts to rebut that strong presumption (a question the Ninth Circuit did not attempt to answer).

The Ninth Circuit's errors make it nearly impossible for district courts in that circuit to dismiss FCA

complaints on materiality grounds. As a result, meritless cases will proceed to burdensome and expensive discovery, where defendants face enormous (and unwarranted) settlement pressures. The burden of this approach will be borne by companies that do business with the federal government and, ultimately, by taxpayers. The Ninth Circuit's decision thus threatens to transform the FCA from a statute intended to protect taxpayers into one that financially harms them.

C. This Court's Review Is Warranted Now

This Court should weigh in now, rather than waiting for further developments in the lower courts. The question presented is an important, frequently recurring issue in *qui tam* FCA suits brought by private relators—especially those, like this one, where the government has declined to intervene. The circuit split, combined with the large number of pending FCA suits, the enormous amounts of money involved in these suits, and the federal government's aggressive position on materiality in the lower courts, makes further guidance critically important.

Hundreds of FCA suits are filed every year, and the number keeps increasing. *Fraud Statistics* 2. Since *Escobar*, dozens of district courts have issued

decisions addressing materiality at the motion-to-dismiss[8] and summary-judgment[9] stages. And each of these lawsuits has the potential to expose the company that does business with the government to "extraordinarily expansive . . . liability." *Escobar*, 136 S. Ct. at 2004.

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[8] *See, e.g.*, *U.S. ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 817–18 (S.D.N.Y. 2017); *U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 265 F. Supp. 3d 782, 794–801 (M.D. Tenn. 2017); *U.S ex rel. Lee. v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 295–96 (E.D.N.Y. 2016); *Purdue Pharma*, 211 F. Supp. 3d at 1078–79; *U.S. ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 220 F. Supp. 3d 676, 681–82 (E.D. Va. 2016); *U.S. ex rel. Lott v. Not-For-Profit Hosp. Corp.*, No. 16-cv-1546, 2017 WL 5186344, at *6 (D.D.C. Nov. 8, 2017); *U.S. ex rel. Mateski v. Raytheon Co.*, No. 2:06-cv-03614, 2017 WL 3326452, at *7 (C.D. Cal. Aug. 3, 2017); *U.S. ex rel. Curtin v. Barton Malow Co.*, No. 14-2584, 2017 WL 2453032, at *5–7 (W.D. La. June 6, 2017); *U.S. ex rel. Schimelpfenig v. Dr. Reddy's Labs., Ltd.*, No. 11-4607, 2017 WL 1133956, at *6–7 (E.D. Penn. Mar. 27, 2017); *U.S. ex rel. Se. Carpenters Reg'l Council v. Fulton Cty., Ga.*, No. 1:14-cv-4071, 2016 WL 4158392, at *8 (N.D. Ga. Aug. 5, 2016).

[9] *See, e.g.*, *U.S. ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 430–32 (W.D. Penn. 2017); *Celgene Corp.*, 226 F. Supp. 3d at 1049–51; *U.S. ex rel. Bahnsen v. Boston Scientific*, No. 11-1210, 2017 WL 6403864, at *7–15 (D.N.J. Dec. 15, 2017); *U.S. ex rel. Lutz v. Berkeley HeartLab, Inc.*, No. 9:14-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017); *A1 Procurement, LLC v. Thermcor, Inc.*, No. 2:15cv15, 2017 WL 2881350, at *5–7 (E.D. Va. July 5, 2017); *U.S. ex rel. Hall v. LearnKey, Inc.*, No. 2:14-cv-379, 2017 WL 1592472, at *6–7 (D. Utah Apr. 28, 2017); *U.S. ex rel. Scutellaro v. Capitol Supply, Inc.*, No. 10-1094, 2017 WL 1422364, at *20–21 (D.D.C. Apr. 19, 2017); *Rose v. Stephens Inst.*, No. 09-cv-05966, 2016 WL 5076214, at *5–7 (N.D. Cal. Sept. 20, 2016).

The uncertainty created by the Ninth Circuit's decision creates immediate, tangible risks for CTIA's members. The FCA's broad venue provision allows *qui tam* suits to be brought in any district where the defendant "can be found, resides, transacts business," or did an act proscribed by the FCA. 31 U.S.C. § 3732(a). The Ninth Circuit is an important place of business for CTIA's members; wireless carriers employ over 15,000 people in California alone. A would-be relator anywhere in the country wishing to bring an FCA suit against a wireless communications company is likely to try to go to a district in the Ninth Circuit to take advantage of the circuit's permissive standard for pleading materiality.

The government's litigating position in non-intervened FCA cases further underscores the need for the Court to promptly revisit materiality. In *Escobar*, this Court rejected the government's proposed materiality standard. 136 S. Ct. at 2004. The government's response has been to try to change the materiality standard at the pleading stage by filing statements of interest in FCA cases where it has declined to intervene. *See* Daniel Wilson, Escobar *Prompts Increased DOJ Interest in FCA Cases*, Law360 (Sept. 13, 2016); *see generally* 28 U.S.C. § 517. The government's statements of interest consistently take a view of materiality that is contrary to *Escobar*, arguing that "even where the government has actual knowledge of a defendant's wrongful conduct and continues to pay claims, such action does not necessarily undermine a materiality finding because there are many good reasons . . . why the government might continue to pay claims in such circumstances." United States' Statement of Interest at 7, *U.S. ex rel. Beauchamp v.*

Academi Training Ctr., 220 F. Supp. 3d 676 (E.D. Va. 2016) (No. 1:11-cv-371), 2016 WL 6936604, at *1.[10]

In light of the substantial respect the federal courts ordinarily afford to the federal government's views, DOJ's statements of interest are likely to exert significant influence over the lower courts' resolution of materiality questions at the pleading stage. Daniel Wilson, *Gov't Statements Show Expansive View of* Escobar *Liability*, Law360 (June 16, 2017) ("a number of courts have shown their willingness to at least partially adopt the government's views"). Indeed, the Ninth Circuit adopted the government's preferred view of materiality in the decision below. *See* Pet. App. 31a. The government's aggressive attempts to relitigate *Escobar* in the lower courts lend further urgency to the need for this Court's intervention. Accordingly, there are very good reasons for the Court to grant review now.

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[10] *Accord* Statement of Interest of the United States at 6–8, *U.S. ex rel. Kolchinsky v. Moody's Corp.*, No. 1:12-cv-1399 (S.D.N.Y. May 8, 2017); United States' Statement of Interest at 5, *U.S. ex rel. Zaya v. AstraZeneca Biopharmaceuticals*, No. 1:14-cv-1718 (E.D.N.Y. Aug. 8, 2016); United States' Statement of Interest at 7, *U.S. ex rel. LaPorte v. Premier Educ. Grp., L.P.*, No. 1:11-cv-3523 (D.N.J. July 13, 2016); *see also* Brief for the United States as Amicus Curiae at 24, *U.S. ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103 (1st Cir. 2016) (No. 14-1423), 2016 WL 4506190, at *24; Brief for the United States as Amicus Curiae at 24–25, *U.S. ex rel. Chickoiyah Miller v. Heritage College*, 840 F.3d 494 (8th Cir. 2016) (No. 14-1760), 2016 WL 4975250, at *24.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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