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 U.S. Court of Appeals for the Ninth Circuit

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

Richard A. Samp
(Counsel of Record)
Cory L. Andrews
Washington Legal Foundation
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

Date: February 2, 2018

QUESTIONS PRESENTED

Whether a complaint filed by a Relator under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, adequately alleges the requisite materiality of an allegedly false claim when the Government continues to approve and pay for products after learning of alleged regulatory infractions and the pleadings offer no basis for overcoming the strong inference of immateriality that arises from the Government's response.

TABLE OF CONTENTS

Page

Page(s)

TABLE OF AUTHORITIES

Page(s)

Cases:

Page(s)

Statutes:

Miscellaneous:

INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public interest law firm and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

To that end, WLF has frequently appeared in this and other federal courts in cases concerning the appropriate scope and application of the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.* *See, e.g., Universal Health Services, Inc. v. United States ex rel. Escobar* ["*Escobar*"], 136 S. Ct. 1989 (2016); *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010); *Allison Engine Co. v. United States ex rel. Wilson*, 553 U.S. 662 (2008); *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007).

WLF does not condone fraud against the United States, however it may occur. WLF is concerned, however, that excessive FCA liability in recent years has spawned abusive litigation against businesses, both large and small, to the detriment of free enterprise, employees, shareholders, and consumers. WLF believes that the Court's *Escobar* decision

---

[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than 10 days prior to filing this brief, WLF notified counsel for Respondents of its intent to file. All parties have consented to the filing; blanket letters of consent are on file with the clerk.

properly balanced the need to prevent fraud against the Government with the need to ensure that private litigants do not use the FCA to extort unwarranted settlements from reputable government contractors. In particular, *Escobar* held that a relator's *qui tam* suit should not be permitted to pass beyond the pleadings stage unless the relator adequately pleads facts showing that any allegedly false claims were "material" to the Government's decision to pay the claim. *Escobar* emphasized that the materiality test is "demanding" and "rigorous" and is not met unless the relator's factual allegations demonstrate that the alleged misrepresentation "likely" induced the Government to pay the claim. *Escobar*, 136 S. St. at 2002-03.

The Ninth Circuit's decision fails to apply *Escobar*'s demanding materiality requirements. It reinstated the claims of Relators Jeffrey Campie, *et al.*, despite their failure to allege any facts demonstrating that the misrepresentations they allege likely caused the Government to pay claims that it would not otherwise have paid. The decision sharply conflicts with the decisions of other appeals courts that have faithfully adhered to *Escobar*. The mischief that will arise from the decision is far-ranging; WLF is concerned that the decision is likely to be applied to a broad range of industries that conduct business with the Government and to expose them to liability under the FCA for even inconsequential violations of federal regulatory requirements.

STATEMENT OF THE CASE

The facts of this case are set out in detail in the Petition. WLF wishes to highlight several facts of

particular relevance to the issues on which this brief focuses.

Gilead is the manufacturer of several highly effective anti-HIV drugs, including Atripla, Truvada, and Emtriva (collectively, "Atripla"). As the appeals court recognized, it is "undisputed" by the parties that "at all times relevant, the drugs at issue were FDA-approved" as safe and effective for their intended uses and that "the government continues to make direct payments and provide reimbursements for the sale of the three drugs." Pet. App. 28a. It is also undisputed that the various federal payment programs at issue state that the Government will reimburse the cost of prescription drugs administered to eligible patients if the Food and Drug Administration (FDA) has determined that the drugs are safe and effective for their intended uses and has approved an NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) for the drugs. *Id*. at 50a-52a.[2]

Relators allege that after FDA granted NDAs for Gilead's three drugs, Gilead began procuring FTC (the active ingredient in all three drugs) from a supplier (Synthetics China) that had not been approved by FDA—and did not become an FDA-approved supplier until 2009 or 2010. Pet. App. 7a-8a. Moreover, they allege, FDA would not have approved Synthetics China

---

[2] Gilead regularly receives payments (and/or causes others to receive reimbursement) under a wide variety of federal healthcare programs. The prerequisites for payment/reimbursement do not vary widely from program to program. *See, e.g.*, 42 U.S.C. § 1396r-8(a)(1) & 1396r-8(k)(2)(A)(i) (Medicaid reimbursement); 42 U.S.C. § 1395w-102(e) (Medicare reimbursement).

but for Gilead's fraudulent concealment of test results indicating that FTC produced by Synthetics China contained excessive levels of contaminants. *Ibid.* They further allege that FTC contamination problems continued and led Gilead to discontinue using Synthetics China as a supplier in 2011—and that those contamination issues were related to two 2014 product recalls. *Id.* at 8a.

Relators allege that Gilead violated the FCA when it sought payment from the Government for Atripla containing FTC produced by Synthetics China, or caused others to seek reimbursement, and that those claims totaled many billions of dollars. They allege that the claims were false because Gilead falsely told the Government that it was supplying Atripla; according to Relators, the drugs actually supplied did not qualify as Atripla because they were produced in violation of FDA regulations and contained an active ingredient (FTC) of questionable pedigree. They allege that the false claims were "material" because the Government would not have paid the claims had it been aware of the violations. Relators do not allege, however, that Gilead made any *specific representations* about the drugs being supplied, other than that the drugs being supplied were, in fact, Atripla.

The district court dismissed the complaint with prejudice for failure to state a claim. Pet. App. 38a-71a. The court determined, among other findings, that Relators had failed to allege "implied false certification" because its submission of reimbursement claims merely implied (truthfully) that the drugs in question were approved by FDA as safe and effective for their intended uses. *Id.* at 48a-56a. It also

determined that Relators had failed to allege "factually false certification" because they failed "to adequately plead *no* medical value at all." *Id.* at 5a. In light of those rulings, the district court did not address Gilead's arguments that Relators also failed to adequately plead facts showing that Gilead's allegedly false claims were material to the Government's decision to make payments.

The Ninth Circuit reversed. Pet. App. 1a-37a. It concluded that Relators adequately pleaded not only falsity but also that the falsehoods were material to the Government's decision to pay the claims. *Id.* at 27a-32a. It did so despite recognizing that Relators "face an uphill battle" in establishing materiality in light of their acknowledgment that "the drugs at issue were FDA-approved and that the government continues to make direct payments and provide reimbursements for the sale of the three drugs." *Id.* at 28a.

In rejecting Gilead's no-materiality argument, the appeals court stated that it would be a "mistake" to "read too much" into FDA's continued regulatory approval of the three drugs and the Government's continued payments for them—even though the Government was aware of Relators' FCA claims and Gilead's use of Synthetics China as a supplier. Pet. App. 31a. The court explained:

> First, to do so would allow Gilead to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud. Second, as argued by Gilead itself, there are many reasons the FDA may choose to withdraw a drug approval,

> unrelated to the concern that the government paid out billions of dollars for nonconforming and adulterated drugs. Third, ... Gilead ultimately stopped using FTC from Synthetics China. Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance.

Ibid.

The appeals court concluded that "[t]he issues raised by the parties are matters of proof, not legal grounds to dismiss relators' complaint." *Id.* at 32a. While acknowledging that materiality could not be established if "the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated," the court stated that "such evidence is not before us." *Ibid.*

SUMMARY OF ARGUMENT

The Petition raises issues of exceptional importance. In the past two years, numerous federal appeals courts have to sought apply *Escobar*'s requirements for pleading materiality, with widely conflicting results. As the Petition demonstrates, review is warranted to resolve the sharp conflict between the decision below and the decisions of numerous other appeals courts—particularly the First

and Third Circuits—regarding materiality requirements for FCA claims asserted against drug or medical device companies.

Review is also warranted because the Ninth Circuit's holding that Relators have adequately alleged materiality is directly at odds with the "rigorous" and "demanding" materiality requirements established by this Court in *Escobar*. Relators have alleged no facts indicating that the federal government deems the alleged regulatory violations at issue here sufficiently serious that, when it becomes aware that a company has engaged in such practices, it routinely refuses to pay claims submitted by the company and/or seeks to recoup payments previously made. Indeed, Relators concede that the Government has not sought to revoke its approval of Gilead's New Drug Applications (NDAs) for the drugs in question and continues to pay billions of dollars for those drugs. Nor has the Department of Justice (DOJ) sought to intervene in this action in support of Relators. *Escobar* termed that state of affairs as "very strong evidence" that the alleged violations are not sufficiently material to support an FCA claim. *Escobar*, 136 S. Ct. at 2003.

The Ninth Circuit concluded that it was premature to evaluate materiality at the pleadings stage, stating that Gilead's challenges to materiality were "matters of proof, not legal grounds to dismiss relators' complaint." Pet. App. 32a. That statement directly contradicts *Escobar*'s conclusion that the "rigorous" materiality standard is not "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss" and that dismissal is warranted unless relators "plead[ ] facts to support

allegations of materiality" with "plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Escobar*, 136 S. Ct. at 2004 n.6.

Relators have not pleaded facts sufficient to overcome the presumption of non-materiality created by the Government's response to their allegations —its failure to revoke Gilead's NDAs, its decision to continue to pay billions of dollars for the drugs in question, and its decision not to seek the return of the billions of dollars previously paid. The fact that Gilead ultimately stopped using Synthetics China as a supplier cannot plausibly explain the Government's decision to continue payments. The Government became aware no later than 2009 that Gilead was using FTC supplied by Synthetics China, yet it continued to pay Gilead's invoices for the many years thereafter that Gilead continued to use Synthetics China as a supplier.

Nor are allegations that a drug company defrauded FDA sufficient to overcome the presumption. Relators allege that, following approval of the NDAs, Gilead needed to obtain FDA approval of a PAS (prior approval supplemental) before it began using a new supplier for its FTC (*i.e.*, Synthetics China). They further allege that Gilead obtained approval of a PAS by providing fraudulent data to FDA. But those allegations do not explain why, if FDA considered those allegations material, it did not revoke either the NDAs or the PAS after learning about those allegations. It would be highly unusual for a government agency, after learning that a regulated company that receives billions of dollars from the Government every year has obtained regulatory approvals through fraudulent

means, not to take significant disciplinary action against the company if it deemed the alleged fraudulent misconduct to be material. Moreover, this Court has strongly cautioned against permitting litigants to second-guess federal agency decision-making based on fraud-on-the-agency allegations. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Recognizing such claims creates a serious danger that federal regulatory officials will be haled into court to explain what they knew and why they acted as they did—thereby interfering with their ability to carry out their job functions.

REASONS FOR GRANTING THE PETITION

In its landmark *Escobar* decision, the Court stressed that the FCA's "rigorous" materiality requirement should be "strict[ly] enforce[d]" at the pleadings stage, as a means of ensuring that government contractors are not subject to "open-ended liability" for alleged violations of one or more of the "thousands of complex statutory and regulatory provisions" to which they are subject. *Escobar*, 136 S. Ct. at 2002.

The Petition ably demonstrates that review is warranted to resolve the conflict among the federal appeals court decisions that have sought to apply *Escobar*'s materiality standard. WLF writes separately to urge that review is also warranted because the decision below directly and sharply conflicts with *Escobar* itself.

I. THE DECISION BELOW CONFLICTS SHARPLY WITH *ESCOBAR*'S EXPLICATION OF THE FCA'S MATERIALITY REQUIREMENT

Relators contend that Gilead defrauded the Government of many billions of dollars it paid for medications in the increasingly successful fight against AIDS. The Government has been aware of those allegations since at least 2010, when Relators filed their FCA claims under seal. Given the magnitude of the alleged fraud, one would reasonably expect the Government—had it deemed the regulatory infractions alleged by Relators to be "material"—to have taken decisive action against Gilead. Decisive actions likely would have included ceasing the multi-billion-dollar annual payments to Gilead for the drugs, seeking to recoup some or all of the fraudulently obtained funds, and revoking approval for continued distribution of drugs by a company that obtained FDA approval through fraudulent means.

Yet, the Second Amended Complaint alleges no such government actions. Nor does it include any factual allegations that "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" that the FCA defendant is alleged to have violated. *Escobar*, 136 S. Ct. at 2003. The Ninth Circuit nonetheless reinstated Relator's complaint, ruling that the alleged deficiencies in the complaint "are matters of proof" and not subject to resolution at the pleadings stage.

A. *Escobar* Clarified That Payment of Claims Despite Government Knowledge of Regulatory Violations Is "Very Strong Evidence" that the Violation is Not Material

The FCA imposes significant penalties on those who defraud the Government. Those liable to the Government under the FCA include anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To establish liability, an FCA claimant must demonstrate: (1) falsity; (2) scienter; (3) materiality; and (4) payment by the Government. Pet. App. 13a.

Escobar involved allegedly false claims submitted by a health-care provider. The Court described at length the FCA's "rigorous" requirement for pleading materiality, and then vacated and remanded because the appeals court had imposed an insufficiently rigorous materiality standard. 136 S. Ct. at 2002-04. The Court explained that the materiality requirement is derived from the FCA itself as well as from the common law. The Court stated, "Under any understanding of the concept, materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 2002 (citation omitted). When a claimant cannot allege facts demonstrating that the Government likely would not have paid a claim but for the fraud, *Escobar* stated that the pleadings cannot withstand a motion to dismiss. *Id.* at 2002-03. In particular, the Court stated:

> [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.

Id. at 2003 (emphasis added). Moreover, the Court emphasized that FCA cases are not too "fact intensive" to render them subject to dismissal on a Rule 12(b)(6) motion to dismiss. *Id.* at 2004 n.6. It stated that an FCA complaint is subject to dismissal on the pleadings for failure to meet this rigorous materiality standard if the plaintiffs fail to "plead their claims with plausibility and particularity" and to plead "facts to support materiality." *Ibid.*

B. The Decision Below Conflicts with *Escobar* by Discounting the Government's Response to the Alleged Fraud and Classifying No-Materiality Arguments as "Matters of Proof"

The Ninth Circuit gave no more than lip service to *Escobar*'s materiality standard. The court acknowledged that the Government became aware of Relators' allegations no later than 2010 (when they filed their FCA complaint) yet continued to pay billions of dollars of claims submitted by Gilead and took no action to revoke Gilead's NDAs. But in sharp contrast to *Escobar*, which held that Government action of that nature is "very strong evidence" that the regulatory requirements allegedly violated by the claimant "are not material to the payment decision," 136 S. Ct. at 2003, the appeals court expressly declined to attach significant weight to continued Government payments.

Pet. App. 31a.

The decision below also sharply conflicts with *Escobar* by ruling that a defendant's no-materiality arguments "are matters of proof" and thus are not appropriate for consideration in connection with a motion to dismiss on the pleadings. *Id.* at 32a. The appeals court held that an FCA relator's complaint sufficiently pleads materiality so long as he alleges "more than the mere possibility that the government *would be entitled to refuse payment* if it were aware of the violations." *Ibid* (emphasis added). In contrast, *Escobar* imposed a burden on FCA plaintiffs to plead "facts to support allegations of materiality," 136 S. Ct. at 2004 n.6, and explicitly *rejected* assertions that it is "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." *Id.* at 2003. *Escobar* made clear that when, as here, it is uncontested that the Government opted to continue making payment despite awareness of the alleged noncompliance, dismissal of the complaint is warranted unless the Relator pleads facts sufficient to overcome this "very strong evidence" that the noncompliance is not material. *Ibid.*

The Ninth Circuit listed several reasons why it thought that the record in this case (a record demonstrating continued Government payments and product-approval despite awareness of noncompliance claims) was less probative of non-materiality than it might be in other cases. Pet. App. 31a. The court recognized, however, that that record tended to undercut Relators' claims. *Id.* at 30a (stating that due to the record of continued Government payments and

product-approval, Relators "face an uphill battle in alleging materiality sufficient to maintain their claims"). Yet the court nonetheless reinstated Relators' claims despite that recognition and despite citing *no* factual allegations in the complaint that would overcome the normal non-materiality inferences that (according to *Escobar*) arise from a record of continued Government payments.[3] The court simply concluded that Gilead's no-materiality arguments "are matters of proof, not legal grounds to dismiss relators' complaint." *Id.* at 32a. That conclusion cannot be squared with *Escobar*'s holding that an FCA plaintiff bears the burden of "pleading facts to support allegations of materiality," 136 S. Ct. at 2004 n.6, including facts demonstrating that it is "likely" that the Government would have refused payment had it been aware of Gilead's regulatory violations at the time of payment.

Moreover, the three reasons proffered by the Ninth Circuit for discounting the continued-payment and continued-approval evidence are insubstantial. First, the court said that "reading too much into the FDA's continued approval ... would allow Gilead to use the allegedly fraudulently obtained FDA approval as a shield against liability for fraud." Pet. App. 31a. But it is uncontested that the Government was aware of Relators' fraud-on-the-FDA allegations by 2010 (when Relators filed their complaint) and fully investigated

---

[3] Such allegations might consist, for example, of factual claims that the Government, although continuing to make payments despite its awareness of noncompliance, imposed a large fine on the FCA defendant or initiated proceedings to debar the defendant (or its executives) from continued participation in federal health care programs. *See* 42 U.S.C. § 1320a-7(a).

those allegations—yet took no action against Gilead. Gilead is not using the continued-payment and continued-approval evidence as a "shield against liability for fraud"; it is simply using that evidence as a basis for drawing the inference mandated by *Escobar*: any false claims were not "material."

Second, the appeals court observed that "there are many reasons the FDA may choose not to withdraw a drug approval, unrelated to the concern that the government paid out billions of dollars for nonconforming drugs." *Ibid.* But that observation cuts strongly in *Gilead's* favor. When the Government determines that quality-assurance concerns regarding a drug's manufacturing process are insufficient grounds to stop payments, withdraw marketing authority, or undertake some other significant regulatory response, *Escobar* holds that that is "very strong evidence" that the quality-assurance concerns are not material. 136 U.S. at 2003.

Third, noting that "Gilead ultimately stopped using FTC from Synthetics China," the appeals court stated, "Once the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance as if the government continued to pay despite continued noncompliance." Pet. App. 31a. That statement is based on a factually incorrect premise: Gilead continued selling Atripla containing FTC supplied by Synthetics China for many years after the Government became aware that Synthetics China was a major supplier and many years after it became aware of Relators' false-claims allegations. Thus, even under the Ninth Circuit's analysis, the Government

had every incentive to take action against Gilead if it believed that the products being supplied by Gilead were *materially* deficient.

More importantly, the court's statements regarding the "significance" of continued payment and continued product-approval conflict with *Escobar* and defy common sense. Relators allege that a major government contractor has intentionally deceived the Government, with the result that the Government purchased billions of dollars worth of substandard products that the Government never would have purchased had it known the true facts. If those materiality allegations were deemed accurate by the Government, it is not plausible that if a contractor then said, "We have mended our ways and promise that all future products shipments will be up to snuff," the Government would merely respond, "Never mind your past transgressions. We will take no remedial actions and will continue to pay you billions of dollars every year." Instead, any competent government administrator who believed that the allegations against Gilead were truthful and material would have had serious reservations about continuing to purchase massive amounts of anti-HIV drugs from Gilead, without regard to whom Gilead planned to use as its future FTC suppliers. That the Government continues to purchase billions of dollars worth of the three drugs each year is thus strong evidence that the Government does not deem Gilead's alleged false claims to have been material.

C.. The Decision Below Conflicts with *Escobar*'s Definition of an "Implied False Certification" Claim

Much of the *Escobar* decision focused on defining FCA falsity; in particular, it addressed the circumstances under which requests for payment submitted to the Government should be deemed false certifications of compliance with statutory, regulatory, or contractual requirements. *Escobar* held that such submissions can be actionable under the FCA if they impliedly (even though not expressly) certify compliance. 136 S. Ct. at 1999-2002. Review is also warranted because the appeals court's faulty materiality analysis was colored by its misunderstanding of *Escobar*'s holding regarding what constitutes an implied false certification.

Escobar held that implied certification theory can be a basis for FCA liability where two conditions are satisfied:

> [F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

136 S. Ct. at 2001.

The Ninth Circuit's conclusion that "Relators

have adequately satisfied the falsity requirement under a theory of implied false certification," Pet. App. 22a, cannot be squared with the above-quoted definition of an implied false certification. The appeals court pointed to no "specific representation[s]" included within Gilead's requests for payments for its three drugs—other than representations that the drugs being supplied really were Atripla, Truvada, or Emtriva. In the absence of any specific representations regarding compliance with statutory, regulatory, or contractual requirements, Gilead cannot be deemed to have uttered "half-truths" that were rendered misleading because unaccompanied by disclosure of noncompliances. The court asserted that references in Gilead's payment requests to the names of the drugs being supplied "fall squarely within the rule that half-truths ... can be actionable misrepresentations" if, as alleged by Relators, the drugs were not produced in compliance with FDA regulations yet the invoices failed to disclose the noncompliances. *Id*. at 22a-26a. That assertion conflicts with *Escobar*'s definition of an implied false certification, as well as this Court's statement that the FCA is not "a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003.

Relators' allegations regarding the content of Gilead's payment requests can only plausibly establish falsity under a "factually false certification" theory, not under an "implied false certification" theory. An FCA plaintiff claiming "factually false certification" alleges that the government contractor provides a product that is not the one he claims to have supplied. In the context of Civil War frauds, that was the contractor who claimed that his shipment contained guns but

instead contained straw, or contained guns that could not shoot. In the context of prescription drugs, a "factually false certification" claim asserts that the drug supplied was meaningfully different from the drug approved for marketing by FDA.

It is questionable whether Relators have adequately alleged facts demonstrating that the drugs supplied by Gilead were (because of alleged regulatory violations) meaningfully different from the drugs described in the three NDAs approved by FDA. But even if Relators have adequately alleged falsity under a "factually false certification" theory, the Ninth Circuit's ruling that Relators have adequately pleaded materiality under that theory conflicts sharply with *Escobar*. The uncontested evidence regarding the Government's response to Relator's allegations that Gilead supplied something other than the three FDA-approved drugs—the Government continued its approval of the drugs, it continued to pay all claims, and it took no action to seek refund of claims that were paid before its receipt of Relators' allegations—is "very strong evidence" that the Government did deem "material" any falsity in Gilead's claims that the drugs it delivered were the ones described in the FDA-approved NDAs.[4]

---

[4] Relators repeatedly argued below that no significance should be attached to the Government's failure to seek recoupment of allegedly false claims—whether by filing its own FCA suit, intervening in Relator's suit, or simply writing a letter demanding a total or partial refund. In federal court filings, the Government has repeatedly disagreed with that argument. *See, e.g., United States ex rel. Badr v. Triple Canopy, Inc.*, Fourth Cir. No. 13-2190, Supplemental Brief for the United States at 15 (Dkt. 78, Aug. 19,

II. REVIEW IS WARRANTED BECAUSE THE NINTH CIRCUIT'S MATERIALITY HOLDING SHARPLY CONFLICTS WITH OTHER CIRCUITS' INTERPRETATION OF *ESCOBAR*

The *Escobar* decision led numerous federal appeals courts to re-examine the FCA's materiality requirement. As the Petition explains more fully, the decision below sharply conflicts with post-*Escobar* decisions from every other federal appeals court to address the materiality issue. Indeed, the First Circuit last summer expressly criticized the Ninth Circuit's decision to permit Relators to proceed with their FCA claim, observing that the Ninth Circuit "offers no

---

2016) ("The Army did not renew its contracts with Triple Canopy [following receipt of the relator's false-claims allegations], and the United States intervened in the relator's *qui tam* action. These actions confirm the significance of the violations and the importance the government attaches to them."). Both the Third and Fourth Circuit's agree that DOJ's decision regarding intervention is an important determinant of materiality in FCA litigation. *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017); *United States ex rel. Badr v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017) (DOJ's decision to "immediately intervene in the litigation" is evidence that the FCA defendant's falsehood was material and "affected the Government's decision to pay.").

The Ninth Circuit misstated the nature of the Government's involvement in this litigation. It asserted that the Justice Department "submitted a brief as amicus curiae supporting reversal of the district court." Pet. App. 12a. That assertion is incorrect. DOJ's brief took issue with several of the district court's legal conclusions regarding what constitutes a false statement under the FCA, but it expressly declined to take a position regarding whether Relators' Second Amended Complaint should be dismissed for failure to state a claim. DOJ Ninth Cir. Br. 1-2.

solution to the problems of proving that the FDA would have made a different approval decision in a situation in which a fully informed FDA has not itself even hinted at doing anything." *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 36 (1st Cir. 2017). Review is warranted to resolve that conflict

WLF confines its discussion to conflicting rulings from the First and Third Circuits, the courts with whose rulings the decision below most strikingly conflicts. In a ruling that preceded the decision below, the First Circuit relied on *Escobar* to affirm dismissal on the pleadings of an FCA claim against a medical-device manufacturer. *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). The manufacturer allegedly obtained FDA approval for its device by making fraudulent representations to the agency. The court held that "FDA's failure to actually withdraw its approval of [the device] in the face of [the relator's] allegations" precluded the relator from asserting a promissory fraud claim against the manufacturer because "[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval and effectively require that a product largely be withdrawn from the market even when the FDA itself sees no reason to do so." *Id.* at 6. The Ninth Circuit cited but made no effort to distinguish *D'Agostino*, merely responding that "FDA approval cannot preclude False Claims Act liability, especially where, as here, the allegedly false claims procured certain approvals in the first instance." Pet. App. 29a.

The First Circuit's later *Nargol* decision reaffirmed *D'Agostino* and severely criticized the Ninth

Circuit's interpretation of the materiality requirement set forth in *Escobar*. Affirming dismissal of an FCA claim against a medical device manufacturer, the First Circuit held that FDA's decision not to "withdraw or even suspend" its product approval "in the wake of Relators' [fraud] allegations ... renders a claim of materiality implausible." *Nargol*, 865 F.3d at 34. The First Circuit noted that "*Campie* offers no rebuttal at all to *D'Agostino*'s observation that six jurors should not be able to overrule the FDA" and that *Campie* "decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solution can be envisioned, even in theory." *Id.* at 36.

The Ninth Circuit's understanding of *Escobar* also conflicts sharply with that of the Third Circuit in *Petratos*. Citing failure to adequately plead materiality, the Third Circuit affirmed dismissal of a relator's FCA claims against a drug manufacturer who allegedly caused doctors to submit false Medicare claims by providing false information regarding the health risks of its drug. *Petratos*, 855 F.3d at 489-93. Noting that the Government, following receipt of the relator's allegations, continued to reimburse all claims submitted for payment, the court concluded that the relator had failed to establish that the defendant's false statements were material to the payment of claims. *Ibid.* The Third Circuit observed, "In holding that Petratos did not sufficiently plead materiality, we now join the many other federal courts that have recognized the heightened materiality standard after [*Escobar*]." *Id.* at 492 (citing cases).

III. THE DECISION BELOW IS LIKELY TO HAVE A SIGNIFICANT IMPACT ON A BROAD RANGE OF INDUSTRIES AND REGULATORY AGENCIES

Review is also warranted because the decision below is likely to serve as a magnet for FCA filings within the Ninth Circuit and to expose a broad array of government contractors to FCA claims for even inconsequential violations of federal regulatory requirements. Despite *Escobar*'s admonitions that the FCA is not a vehicle for punishing "garden-variety" regulatory violations and that the statute's "rigorous" materiality requirement should ensure that insubstantial claims are subject to dismissal on the pleadings, it is difficult to see how, under the Ninth Circuit's materiality standard, a defendant could *ever* win a Rule 12(b)(6) motion to dismiss an FCA claim that is based on a contractor's alleged noncompliance with regulatory requirements.

According to the Ninth Circuit, disputes regarding the materiality of alleged regulatory violations are "matters of proof, not legal grounds to dismiss" an FCA claim. Pet. App. 32a. The appeals court applies that lenient materiality pleading standard even when, as here, the response of the Government—when informed of the alleged regulatory infractions—indicates that it does not deem the infractions to be particularly serious. The pharmaceutical industry is but one of numerous industries that are subject to thousands of federal regulatory requirements. Given the huge financial incentives provided to *qui tam* filers, the Ninth Circuit's materiality standard ensures that each of those industries will be subject to burdensome FCA

suits whenever they can plausibly be alleged to have violated some regulatory requirement.

In *Escobar*, many industry groups expressed fears that if the Court endorsed the implied false certification theory as a basis for establishing falsity in an FCA claim, the business community would be exposed to virtually unlimited FCA liability. *Id.* at 2002. The Court sought "to allay [those] concerns," even as it held that the implied false certification theory can be a basis for liability, by stating that "other parts of the False Claims Act" properly cabin potential FCA liability. *Ibid.* It explained:

> [I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements.

Ibid (citations omitted). The decision below undercuts those assurances.

The decision below also burdens regulatory agencies by significantly increasing the likelihood that agency personnel will be required to testify in FCA proceedings regarding materiality issues. Relators argue that FDA approval of Gilead's NDAs and PAS are suspect because Gilead deceived FDA during the approval process. But this Court has repeatedly cautioned against permitting litigants to second-guess agency decisionmaking based on fraud-on-the-agency allegations. In *Buckman*, the Court barred private

litigants from challenging a manufacturer's right to market a medical device by asserting that the manufacturer had fraudulently obtained FDA marketing authority, concluding that such suits would undercut FDA's efforts to balance competing objectives. *Buckman*, 531 U.S. at 348. For similar reasons, the Court held that federal law did not permit certain private health-care facilities to sue drug companies that allegedly defrauded the federal government in connection with their pricing structures; the Court concluded that such suits would interfere with the ability of government officials to administer federal health-care programs. *Astra USA Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011). Review is warranted to determine whether, based on similar considerations, the decision below imposes unwarranted burdens on regulatory agencies.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

Richard A. Samp
(Counsel of Record)
Cory L. Andrews
Washington Legal
Foundation
2009 Mass. Ave., NW
Washington, DC 20036
(202) 588-0302
rsamp@wlf.org

Dated: February 2, 2018