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

REPLY BRIEF FOR PETITIONER

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INTRODUCTION

The parties agree about the legal question at the heart of this case: When the Government declines to take action after learning of alleged infractions and the plaintiffs offer nothing to overcome the resulting inference of immateriality, does an action under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, fail? *See* Pet i; Opp. 2.[1] Gilead and six circuits say yes. Plaintiffs and the Ninth Circuit say no.

Plaintiffs attempt to shroud this clean legal question in factual disputes. The central premise of the Brief in Opposition is that "the offending conduct stopped in 2011, obviating the need for regulatory action." Opp. 4; *see also* Opp. 9, 16. But the operative complaint contradicts that premise, alleging that as of 2015, Gilead "*continues to incorporate Synthetics China-made [active pharmaceutical ingredients] into its finished drug products*." ER152 (emphasis added). Only by ignoring their own allegation can Plaintiffs avoid the obvious conclusion: If the alleged manufacturing infractions really were material, the Food and Drug Administration (FDA) would not have stood by for years, and the Government would not have continued paying for Gilead's products without objection. Yet that is precisely what happened. So it was incumbent on Plaintiffs to offer some overriding explanation

[1] Pet." refers to the Petition, "Opp." to the Brief in Opposition, "ER" to the Excerpts of Record in the Court of Appeals, "Pet. App." to the appendix to the Petition, and "C.A." to the Ninth Circuit's docket entries.

for why the alleged infractions were nevertheless material. Because Plaintiffs' complaint furnished no such explanation, their claims fail as a matter of law.

At base, Plaintiffs' core theory is that materiality inquiries are almost never fit for resolution on the pleadings. Their argument amounts to a demand for costly discovery as a matter of right. That would be a disastrous approach to the FCA, which is why this Court emphasized that materiality issues are *not* "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2004 n.6 (2016). If FCA plaintiffs could launch directly into discovery, a burgeoning industry of relator suits would be supercharged, imposing enormous costs and shifting regulatory authority from government agencies to profit-seeking individuals.

This Court should grant the petition.

ARGUMENT

I. The Government's Actual Behavior Is Critical To The Materiality Analysis Under The FCA.

Plaintiffs rest their position on the assertion that "Gilead cites no case holding that when the government continues to pay for a product despite knowledge of alleged infractions, that creates a strong inference of immateriality for the pleadings to somehow overcome." Opp. 20.

Here is our case: *Escobar*. In a unanimous opinion, this Court stated that "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." 136 S. Ct. at 2003. If Plaintiffs were correct that courts across the country have joined the Ninth Circuit in disregarding *Escobar*'s teaching, that would be independent cause for this Court's intervention. But as it stands, the Ninth Circuit is an outlier.

Courts outside the Ninth Circuit have accepted that the Government's continued payment after learning of allegations is powerful evidence of immateriality—and dispositive without some plausible explanation. *See, e.g., United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017) (citation omitted) (governmental inaction "in the wake of Relators' allegations … renders a claim of materiality implausible"); *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 8 (1st Cir. 2016) (pointing to the "FDA's failure actually to withdraw its approval of [a device] in the face of [plaintiff's] allegations"); *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1172-73 (10th Cir. 2016) ("The undisputed evidence instead confirms that [the relevant agency] did not withhold payment after learning of Relators' allegations."). Plaintiffs defend the Ninth Circuit's rejection of that rule, depicting materiality issues as fact-specific "matters of proof," Pet. App. 32a, that are almost impossible to dismiss on the pleadings. Opp. 19.

There is no doubt how this case would come out in other circuits. As the Ninth Circuit conceded, Plaintiffs' complaint "outline[s] a variety of facts that speak to the government's knowledge" of alleged infractions. Pet. App. 30a. All the while, no payments were refused, no refunds were sought, and no approvals were withdrawn. Absent some alternative explanation, that is proof that the allegations were immaterial to the Government. There may be circumstances in which the Government temporarily continues its payments in the face of material infractions. In six circuits, however, Plaintiffs would need to provide that explanation.

Not so in the Ninth. Plaintiffs survived a motion to dismiss despite having offered no plausible explanation for the Government's behavior. And their attempt to rehabilitate their position before this Court is a nonstarter. Plaintiffs' Brief in Opposition asserts that "Gilead stopped using [an active ingredient called] FTC from Synthetics China in 2011—obviating the need for regulatory action and explaining why the lack of FDA action does not imply immateriality."[2] Opp. 16; *see also* Opp. 4. But the operative complaint—filed in 2015—alleges that Gilead "continues to incorporate Synthetics China-made API"—an acronym for active pharmaceutical ingredients—"into its finished drug products." Pet. 9 (quoting ER152). There is no question that the Government knew about

[2] The Brief in Opposition also contradicts itself on this point: Despite its contrary account on pages 4 and 16, on page 9 the Brief in Opposition describes the allegation that "Gilead stopped sourcing" the relevant drug from Synthetics China but nevertheless "continued using stockpiles of contaminated product."

the alleged manufacturing violations by then, yet it neither withdrew its approval nor withheld payments even as (according to Plaintiffs' allegations) affected drugs continued to be sold.

Apart from that counterfactual statement, Plaintiffs can manage only speculation: They merely imagine a hypothetical scenario in which the Government pays claims "under duress, relying on the FCA for a recovery." Opp. 17. But their complaint never suggests that is what happened here, much less provides specific facts to make such a theory plausible. That is fatal to their complaint, because this Court has explained that *plaintiffs*, not defendants, bear the cost of conjecture on a motion to dismiss. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("Factual allegations must be enough to raise a right to relief above the speculative level ….").

II. Numerous Cases Refute Plaintiffs' Argument That The Circuits Are Uniform In Their Approaches To Materiality.

Plaintiffs contend that every court in the country is evaluating materiality under the FCA in precisely the same way. This would come as news to the Ninth Circuit, which frankly acknowledged that "other courts have cautioned against allowing claims under the False Claims Act to wade into the FDA's regulatory regime." Pet. App. 28a-29a. And the First Circuit certainly did not think it was in sync with the Ninth when it criticized that court for failing to appreciate "the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted

at doing anything." *Nargol*, 865 F.3d at 36; *see also id.* (noting that the Ninth Circuit "decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solutions can be envisioned, even in theory"). Even beyond those stark statements of disagreement, the cases belie Plaintiffs' suggestion of uniformity in multiple ways.

For starters, the First and Third Circuits disagree with the Ninth about what weight to give the FDA's continued approval after it learns of alleged regulatory violations. *See* Pet. 13-16; *see also* Amicus Br. of Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization (PhRMA-BIO Br.) at 12-13. Plaintiffs fail to reconcile the Ninth Circuit's reasoning with the First Circuit's holding that the Government's failure to suspend its approval of a product in light of alleged violations "renders a claim of materiality implausible." *Nargol*, 865 F.3d at 34. Nor do Plaintiffs deny that in *D'Agostino*, the First Circuit concluded that the Government's payment of reimbursements "in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations" alleged. 845 F.3d at 7.

Plaintiffs seek to distinguish *Nargol* by noting that notwithstanding its skepticism of the Ninth Circuit's reasoning, the First Circuit accepted an alternative theory of liability based on "palming off" one product as another. Opp. 25; *see Nargol*, 865 F.3d at 40-41. But the First Circuit's decision depended on the allegation that the defendant sold "a defectively manufactured product that materially differed from

the device the FDA approved" to "unsuspecting government payors." *Nargol*, 865 F.3d at 37. Here, any claim that Gilead's products "materially differed" from those the FDA approved runs headlong into the Government's continued approval of and payment for Gilead's drugs even after learning of the alleged infractions. *See id.* at 35 (explaining that the already "very strong evidence" of immateriality arising from the Government's continued payment after acquiring knowledge of alleged violations "becomes compelling when an agency … is told what Relators have to say, yet sees no reason to change its position"). Nor can the specter of "unsuspecting government payors," *id.* at 37, be sustained in this case given what the Ninth Circuit itself recognized as a "variety of facts that speak to the government's knowledge." Pet. App. 30a.

Plaintiffs also cite the First Circuit's decision on remand in *Escobar*. *See* Opp. 24-25 (citing *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103 (1st Cir. 2016)). But there, the First Circuit found that the alleged violations—relating to a patient's adverse reaction to a medication that an attending nurse was not licensed to prescribe—went "to the very essence of the bargain." 842 F.3d at 108, 110 (quoting *Escobar*, 136 S. Ct. at 2003 n.5). That is certainly not the standard the Ninth Circuit applied here. Moreover, that case did not involve alleged fraud on the FDA and was decided before *Nargol* and *D'Agostino*; Plaintiffs' invocation of the earlier case does nothing to alleviate the conflict between the later cases and the Ninth Circuit's decision here.

The Ninth Circuit's rule is also at odds with the Third Circuit's finding of immateriality where the Government, after receiving evidence of the plaintiff's allegations, left its approval of the relevant drug intact and declined to initiate enforcement proceedings. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (2017). Plaintiffs respond that the Third Circuit "recognized that no single factor automatically disposes of materiality." Opp. 27. No one has argued otherwise. The point is that when the Government continues its approvals, payments, and reimbursements after learning of alleged infractions, it is up to FCA plaintiffs to explain why the allegations were nevertheless material to the Government's payment decision.

The Ninth Circuit's break from the First and Third—combined with the dissonance between its opinion and this Court's decision in *Escobar*—is more than enough to warrant this Court's review. But the disagreement runs deeper, as the petition explains. Pet. 16-20. In attempting to distinguish unfavorable cases, Plaintiffs argue that post-discovery rulings are somehow "less relevant." Opp. 28. Yet this Court allowed no such distinction in *Escobar*, stating instead that materiality can be resolved "on a motion to dismiss or at summary judgment." *Escobar*, 136 S. Ct. at 2004 n.6. That makes perfect sense: Courts that harness "the benefit of hindsight" rather than "ignor[ing] what actually occurred" on summary judgment must do so on the pleadings as well. *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017).

Further, Plaintiffs' depiction of the Fifth, Seventh, Tenth, and D.C. Circuits as applying the "same rule as the Ninth" is untenable. Opp. 28. In those courts, "continued payment by the federal government after it learns of the alleged fraud substantially increases the burden on the relator in establishing materiality." *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645, 663 (5th Cir. 2017); *see also* Pet. 16-19. Once again, things are different in the Ninth Circuit, which is willing to forge ahead into costly discovery and save materiality determinations for later.

III. This Case Is A Suitable Vehicle For Review.

Plaintiffs' argument that the question presented was not sufficiently vetted below is contradicted by their own assertion that the Ninth Circuit "quoted *Escobar*'s discussion of materiality at length." Opp. i. The arguments raised here were featured in Gilead's briefing before the Ninth Circuit. *See, e.g.*, C.A.41 at 45 (arguing that an "FCA claim cannot survive where the government learned of the alleged false statement and continued making payments for the product"). The issues were also debated in supplemental letters following *Escobar*'s issuance, *see* C.A.46-1, 47, 49, 50-1, 61, 65, 66, 69, 70, and at oral argument. And the Ninth Circuit made materiality a centerpiece of its opinion, acknowledging it was creating a split and teeing up a legal question for this Court to resolve. *See, e.g.*, *United States v. Williams*, 504 U.S. 36, 41 (1992) (noting that certiorari is appropriate "so long

as [an issue] has been passed upon" by the court below).[3]

In much the same way, Plaintiffs' urging of "further percolation" is undercut by their recognition—in the very same paragraph—that materiality cases have come in droves in recent years. Opp. 32 (acknowledging the "recent boom" in FCA cases raising materiality issues). There is no need to wait for more data points. Indeed, waiting would come at an extraordinary cost. As the amicus briefs demonstrate, whether the FCA's materiality requirement is applied in the "demanding" fashion that *Escobar* requires, 136 S. Ct. at 2003, has huge financial implications for companies across countless industries. *See, e.g.*, Amicus Br. of the Chamber of Commerce of the United States of America et al. (Chamber Br.) at 15-17. Private relators have recovered $911 million in the past two years alone.[4] Unless this Court intervenes, the

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[3] Plaintiffs incorrectly argue that they have "surviving sets of claims … for payments made before the government learned of Gilead's violations." Opp. 32. But the Government's decision to take no action upon learning of the alleged infractions shows that the infractions were immaterial throughout, absent some reason to believe that an infraction that is now *immaterial* previously was *material*. Plaintiffs also assert incorrectly that *Escobar*'s materiality standard applies only to fraudulent claims and not to "factually false claims." Opp. 32. In reality, *Escobar* referred to "§ 3729(a)(1)(A)'s materiality requirement"; it did not distinguish between "false" and "fraudulent" claims. 136 S. Ct. at 2002.

[4] *See DOJ, Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016* (Dec. 14, 2016), http://tinyurl.com/j3jobgb; *DOJ*, *Justice Department Recovers Over $3.7 Billion From False Claims Act Cases in Fiscal Year*

Ninth Circuit's approach threatens to trigger the next California Gold Rush: a westward stampede of plaintiffs (and attorneys) digging for nuggets of minor regulatory infractions in hopes of obtaining lucrative rewards.

The FCA actions that are invited and invigorated by the Ninth Circuit's lax standard will transfer power from expert regulators into the hands of private claimants seeking a financial bounty. *See* Amicus Br. of the Coalition for Government Procurement at 8-9, 14; Chamber Br. at 18-19. This is not what Congress intended. As this Court has explained, the FCA "is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 136 S. Ct. at 2003 (internal citation and quotation marks omitted); *see* PhRMA-BIO Br. at 3 (explaining that the Ninth Circuit's rule, which permits FCA plaintiffs "to proceed to trial on the question whether a manufacturer committed garden-variety breaches of the FDCA, even if FDA had conclusively determined that [there was] no violation warranting enforcement … defies Congressional intent" (internal quotation marks omitted)).

Finally, Plaintiffs argue that more details would be available on a "developed factual record." Opp. 34. Of course they would. That is true of every case that is dismissed on the pleadings. Yet it does not render every such dismissal inappropriate. The question is

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2017 (Dec. 21, 2017), https://tinyurl.com/ycx97lf7. As those sources reveal, in that same two-year period, the Government recovered $8.4 billion in FCA suits; $4.9 billion of that recovery came from the healthcare industry.

not whether we might know *more* after discovery. It is whether we know *enough* to establish the immateriality of Plaintiffs' claims as a matter of law. That is precisely why this Court made clear in *Escobar* that materiality can be resolved on a motion to dismiss.

By lowering the bar for materiality notwithstanding the Government's response to alleged infractions, the Ninth Circuit parted ways with its sister circuits, violated the logic of *Escobar*, and created a costly problem that this Court should resolve without delay.

CONCLUSION

The petition should be granted.

Respectfully submitted,

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