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 IN OPPOSITION

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QUESTION PRESENTED

In *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016), this Court "clarif[ied] how" the False Claims Act's "materiality requirement should be enforced" in implied false certification cases—cases in which a claim for payment is effectively false because of an underlying statutory, regulatory, or contractual violation. The Court explained that the proper inquiry is not whether the government would have the option to refuse payment, but whether the government likely would have refused payment had it known of the violation. The Court gave an illustrative example, stating 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." *Id*. at 2003.

Here, the court of appeals quoted *Escobar*'s discussion of materiality at length (Pet. App. 27a, 29a-30a) and concluded that the specific allegations in respondent relators' complaint—that petitioner Gilead Sciences unlawfully sought government payments for grossly nonconforming drugs—state a valid claim under the False Claims Act. *Id*. at 30a-32a. Gilead's materiality arguments, raised for the first time in Rule 28(j) letters, rest on the disputed factual premise that the government had actual knowledge of the violations when it paid for the drugs. The court of appeals explained that these arguments raised "matters of proof, not legal grounds to dismiss relators' complaint." *Id*. at 32a.

The Question Presented is whether the Ninth Circuit misapplied *Escobar* in this case.

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BRIEF IN OPPOSITION

For about five years, petitioner Gilead Sciences, Inc., a pharmaceutical manufacturer, sourced active drug ingredients from unapproved, substandard facilities and used those ingredients in drugs paid for by the government. Many of these ingredients were contaminated with glass, metal, arsenic, construction materials, dangerous microbes, and other adulterants. Gilead first concealed the source of the ingredients, passing off its unapproved drugs as the genuine article. It then falsified key test results, hiding the contamination to trick the Food and Drug Administration (FDA) into approving the illicit supplier. After the contamination became too severe to ignore, Gilead stopped using the unapproved facilities. Relators Jeffrey and Sherilyn Campie, then Gilead employees, learned of and investigated these frauds, ultimately telling Gilead that if it did not correct its behavior they would report the violations to the FDA. Gilead reacted by firing Mr. Campie, after which the Campies blew the whistle by filing a complaint under the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*.

The original complaint included allegations about many Gilead drugs and deceptions. The district court dismissed that complaint on two flawed rationales: that (1) because the FDA itself does not pay for drugs, a fraud on the FDA cannot give rise to an FCA claim, and (2) contamination is not actionable under the FCA unless it renders the drugs worthless. In the Second Amended Complaint, relators preserved their original claims but focused on the allegations about the unapproved facilities. The court dismissed those claims and Mr. Campie's retaliation claim.

The Ninth Circuit reversed, finding the district court's reasoning and conclusion erroneous. Gilead does not seek this Court's review of the core issues in that appeal: whether the district court correctly held that fraud on the FDA is not cognizable under the FCA; or whether companies may sell contaminated drugs to the government as long as those drugs are not worthless. Instead, seizing upon a single phrase from this Court's recent decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016)—decided after appellate briefing was completed and years after relators filed their most-recent complaint—Gilead now contends that its frauds were not material to the government's payment decisions. And Gilead urges this Court to adopt a new per se rule that any time the government continues to pay for a product after learning of a relator's allegations, the fraud is not material unless the pleadings "overcom[e] the strong inference of immateriality that arises from the Government's response." Pet. i.

Gilead's petition should be denied for three reasons.

First, the decision below is correct because the Ninth Circuit properly followed *Escobar*'s holistic approach to materiality, holding that continued government payments are important to, but not dispositive of, the inquiry. Under *Escobar*, when a complaint alleges that a manufacturer violates material specifications—like by contaminating its drugs with metal, glass, arsenic, and bacteria—but conceals those defects and charges the government full price, the complaint plausibly alleges a material fraud actionable under the FCA. The same is true when a manufacturer falsifies test results to obtain approval for a facility consistently churning out contaminated ingredients for medicines paid for by the

government. Gilead's attempt to reach the opposite result by transforming an illustrative example from *Escobar* into a new legal rule flatly contradicts this Court's decision.

Second, there is no circuit split. Gilead's attempt to characterize the Ninth Circuit as an outlier fails: defendants have won cases there on materiality grounds, and this Court has already denied a petition posing the same question but accusing the Ninth Circuit of applying the materiality requirement too harshly. *See* Petition for Writ of Certiorari, *McGrath v. Microsemi Corp.*, 138 S. Ct. 407 (2017) (No. 17-412), 2017 WL 4162297, at *i (asking: "Did the Ninth Circuit err in holding that materiality cannot be found in [an FCA] case if the government continues to pay after learning of the allegations of fraud, even where the fraudulent certifications go to the 'essence of the bargain'?"). More broadly, no circuit court has advanced Gilead's invented rule that when the government has continued paying for a product despite knowledge of alleged wrongdoing, the pleadings must allege some undefined extra thing to "overcom[e] the strong inference of immateriality" arising from that fact. Pet. i. Instead, all the circuits follow the same approach: they apply *Escobar*'s holistic standard to the facts before them, weighing continued government payments alongside other facts. Many of those courts have expressly reconciled the decision below with their own holdings—and it is evident that relators' complaint would have survived a motion to dismiss in every circuit.

Third, this case is a poor vehicle. Most important, the case presents facts that do not implicate the Question Presented. Gilead's question rests on two factual premises: (1) that the government continued to pay for products after learning of alleged violations; and (2) that

the complaint "offer[s] no basis" for overcoming a resulting inference of immateriality. Pet. i. Neither premise is true here. The complaint does not concede that anybody responsible for government payment decisions actually knew of Gilead's violations at the time of payment. Instead, it alleges facts undermining any potential inference of immateriality, *e.g.*, that the offending conduct stopped in 2011, obviating the need for regulatory action. Thus, even under the rule implied by Gilead's question, this complaint survives. There are other vehicle problems too: the issue is percolating, the case is interlocutory, and relators will likely seek to amend the very pleadings Gilead challenges. This also is not Gilead's last chance to contest materiality: if this Court denies review, the case will go to discovery. There, the parties will collect actual evidence about materiality, and Gilead can move for summary judgment, to be adjudicated under *Escobar*.

For these reasons and those explained more fully below, this Court should deny certiorari.

STATEMENT OF THE CASE

I. Legal Background

The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). The term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id*. § 3729(b)(4). The FCA creates a qui tam cause of action allowing private whistleblowers to bring claims on behalf of the United States. *Id*. § 3730(b)(1).

The paradigmatic false claim is when a defendant seeks government payment for goods or services that were not delivered or did not conform to the government's specifications. But FCA liability is not limited to such "factually false" claims. Instead, "the Act was intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). It therefore covers cases where a defendant obtains a government contract or benefit by fraud, even if later individual claims for payment are not themselves false. It also applies when a defendant falsely certifies its compliance with a material legal condition of payment. These "certifications" can either be express (if, *e.g.*, the government requires them on an invoice) or implied (if a reasonable person would understand them to be implicit in the claim itself). The latter claim (implied false certification) arises when a defendant submitting a claim to the government impliedly certifies compliance with all conditions of payment but fails to disclose the violation of a material statutory, regulatory, or contractual requirement.

This Court recently considered implied certification claims in *Escobar*, which was decided after the parties here submitted their briefs to the Ninth Circuit. The questions there were whether and under what circumstances implied false certification claims are cognizable under the FCA. The defendant in *Escobar* argued that such claims are not cognizable or are cognizable only when a statute expressly designates the relevant legal requirement as a condition of payment. The defendant claimed that any other ruling would expose defendants to expansive liability for even trivial regulatory violations.

This Court rejected both of the defendant's arguments, holding that implied certification claims are cognizable (at least in some circumstances). *Escobar*, 136 S. Ct. at 1996. The Court determined that "liability for failing to disclose violations of legal requirements does not turn upon whether those requirements were expressly designated as conditions of payment." *Id.* Instead it turns on "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id*. The Court decided that enforcement of the materiality requirement adequately addressed FCA defendants' concern that implied false certification liability would become overbroad. *See id.* at 2002.

The Court also spent a few pages "clarify[ing] how that materiality requirement should be enforced." *Escobar*, 136 S. Ct. at 2002. It explained that this "demanding" requirement cannot be satisfied (1) "merely because the Government designates compliance with a particular . . . requirement as a condition of payment," (2) by showing "that the Government would have the option to decline to pay if it knew of the defendant's noncompliance," or (3) "where noncompliance is minor or insubstantial." *Id*. at 2003. Instead, the Court explained that, in an implied certification case, materiality turns on the likely effect of the defendant's noncompliance on the government's payment decision. Lower courts can evaluate this effect by considering either the likely response of a reasonable person or the government. *Id*. at 2002-03. The Court offered examples of the type of evidence that is probative, but not dispositive, of materiality:

> [P]roof of materiality can include, but is not necessarily limited to, evidence that the

> defendant knows 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. Conversely, 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.

Id. at 2003.

In *Escobar*, the complaint alleged that the defendant allowed inadequately trained, unqualified staff to provide mental health services, billing the government using codes corresponding to the use of qualified staff. 136 S. Ct. at 1997. The Court held that the claims were false because they were misleading. *Id*. at 1999-2001. Without deciding materiality, the Court acknowledged that the plaintiffs "may well have adequately pleaded a violation" because they had alleged that the defendant "misrepresented its compliance with mental health facility requirements that are so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations." *Id*. at 2004.

II. Factual Background

Gilead manufactures antiretroviral medications to treat human immunodeficiency virus (HIV). Three of these drugs—Emtriva, Truvada, and Atripla—contain the active ingredient emtricitabine (FTC). Pet. App. 5a-6a. The government pays for Gilead's FDA-approved antiretroviral medications through direct purchases (like buying drugs for government-run hospitals) and

reimbursement programs (like Medicare and Medicaid). E.R.113-14.

The FDA must approve a New Drug Application (NDA) before any drug can be marketed or sold in the United States. *See* 21 U.S.C. § 355(b)(1). An NDA details formulation, packaging, and manufacturing processes. *See id.*; 21 C.F.R. § 314.50(d)(1). Applicants must list the precise facility that will manufacture every active ingredient, so the government can ensure that facility meets crucial health and safety standards. *Id.*

Gilead did not keep to the terms of its NDAs. Unbeknownst to the FDA, Gilead started sourcing cheap FTC from a company called Synthetics China. E.R.139, 144. For about sixteen months (beginning in 2007), Gilead concealed the source of its FTC, passing off drugs containing FTC from Synthetics China as the real deal. E.R.144.

Unfortunately, these drugs were not just unapproved—they were contaminated. Of the three validation lots of FTC from Synthetics China, two failed Gilead's internal testing. E.R.144-45. The first lot contained residual solvents above established limits. *Id.* The second failed stability testing and contained mold; yeast; dangerous microbes; and heavy metals such as arsenic, chromium, and nickel. E.R.145.

Despite the contamination, Gilead tried to gain FDA approval to use Synthetics China. But instead of reporting the failed tests to the FDA, Gilead falsified its data to make its Synthetics China-sourced FTC appear as good as FTC from approved sources. E.R.140, 144-45. While Gilead waited for its fraudulent application to be approved, it continued using FTC from Synthetics China. E.R.147-49. Based on the falsified data, the FDA

approved amendments to the NDAs, E.R.140; it finally allowed Synthetics China to supply Gilead's FTC in 2010, E.R.146.

In 2010, Gilead scaled up FTC production in a new Synthetics China facility without notifying the FDA or receiving its approval. E.R.149. This second facility was even more contaminated than the first: all three validation lots failed testing. E.R.150. The first two included shards of glass, cement, and fibrous building materials; the third contained brown paper strips and "unidentified organic material." *Id.* Gilead impermissibly tried to sieve out the contaminants and used the sieved FTC without disclosing that it had originated from the unapproved facility. E.R.151, 370-74. In 2011, Gilead stopped sourcing FTC from Synthetics China, but continued using stockpiles of contaminated product. E.R.152. To date, three lots of Atripla and one lot of Truvada have been recalled because of contamination from a "third-party manufacturer in China." *Id.*

Relator Jeffrey Campie, then the Senior Director of Global Quality Assurance at Gilead, E.R.112, discovered Gilead's frauds in December 2008. E.R.141-43. He began investigating together with his wife and co-relator Sherilyn Campie, also a Gilead employee. E.R.112. Mr. Campie voiced his alarm about the fraud in meetings with Gilead executives, who told him it was "none of his concern." E.R.162. He continued raising concerns internally but was consistently rebuffed. *Id.* Mr. Campie was eventually side-lined and told that he "was the major obstacle in getting material into commercial production." E.R.162-65. Mr. Campie resisted Gilead's fraud, saying he would report it to the government, so Gilead fired him. E.R.168.

III. Procedural History

1. On August 19, 2010, relators filed their original complaint, under seal, in the Eastern District of Pennsylvania. The government later declined to intervene. Pet. 7.

After the case was transferred to the Northern District of California, relators filed a First Amended Complaint. *See* E.R.308-498. Relators alleged that Gilead violated the FCA by obtaining government payments for approximately ten drugs that were adulterated, misbranded, and not manufactured in conformity with FDA-approved processes. E.R.314-15. The district court dismissed the complaint with leave to amend. E.R.52. It held that relators' false certification and promissory fraud theories could not survive a motion to dismiss because the alleged fraud was directed at the FDA, not at the payor agencies. E.R.35. The court held that it was irrelevant that the drugs were contaminated so long as they were not "truly 'worthless.'" E.R.46. The court also dismissed the retaliation claim. E.R.50.

Relators filed their Second Amended Complaint, addressing the district court's order by narrowing their complaint to the allegations related to Synthetics China. *See* E.R.106-205. They preserved an objection to the dismissal of their original claims. E.R.108 n.1. Relators allege four theories of FCA liability: First, Gilead's claims were factually false because it knowingly sought government payments for nonconforming knock-offs mimicking approved drugs. Second, Gilead committed promissory fraud by deceiving the FDA into approving amendments to the NDAs, knowing that that approval was necessary to continue receiving government payments. Third, Gilead implicitly certified that the drugs it sold were lawful to distribute in interstate

commerce, when they were not because they were adulterated and misbranded in ways material to the government's payment decision. And fourth, Gilead unlawfully retaliated against Mr. Campie.

The district court dismissed the Second Amended Complaint. E.R.21. The court held that relators failed to state a claim under the implied false certification theory because they failed to allege that Gilead committed fraud with respect to a condition of payment. E.R.10-11, 13. The court also held that relators failed to state a claim under the factually false certification theory, because (1) the FDA approved the drugs, so it did not matter that Gilead's pills did not conform to approved specifications, and (2) the complaint did not allege that the drugs had "*no* medical value at all." E.R.13-14. The court also dismissed the retaliation claim. E.R.16-18.

2. Relators appealed to the Ninth Circuit, arguing that the district court erroneously dismissed both complaints. The government filed a brief supporting relators, explaining that a claim may be false even if the product is not worthless. Gov't C.A. Br. 12. It also contended that "it is possible to articulate an FCA claim when the defendant lies to the FDA as part of the drug approval process." *Id.* at 13.

Because the briefing was complete when this Court decided *Escobar*, the parties addressed *Escobar* before the panel only in Fed. R. App. P. 28(j) letters and at oral argument. Relators pointed out that the allegations here (seeking government payments for substandard drugs) closely paralleled the allegations in *Escobar* (seeking government payments for substandard treatment). Gilead argued that its violations were not material because the FDA did not withdraw approval and the government did not refuse payment. Relators replied

that the complaint does not concede that the government paid any of Gilead's claims with actual knowledge of its violations.

The Ninth Circuit held that the Campies had stated a plausible claim under the FCA. Pet. App. 37a. It recognized that Gilead's "circumscribed view of [FCA] liability was expressly rejected by the Supreme Court in *Escobar*." *Id.* at 17a. The court also held that relators satisfied the FCA's falsity requirement under all three theories of liability. *Id.* at 21a-26a. It rejected the district court's conclusions that only claims made directly to a paying agency are actionable, as well as its holding that claims are actionable only if the products are worthless. *Id.* at 16a-18a, 23a.

The Ninth Circuit began its materiality discussion by quoting the FCA and *Escobar*, including that "[p]roof of materiality can include whether 'the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated.'" Pet. App. 27a (quoting *Escobar*, 136 S. Ct. at 2003). The court acknowledged that because the FDA had not withdrawn approval and the government had continued to pay, relators "face[d] an uphill battle in alleging materiality." *Id.* at 28a.

Relators won that battle at the pleading stage because, on the facts alleged, the government's continued approval and payments did not establish that Gilead's violations were immaterial. First, the complaint did not allege that when the government made any payments, it had "actual knowledge" of Gilead's fraud. Pet. App. 32a (noting that "the parties dispute exactly what the government knew and when, calling into question its 'actual knowledge'"). Second, Gilead stopped using FTC from Synthetics China, obviating the need for

prospective regulatory action or cessation of payments. *Id*. at 31a. Third, "it is not the FDA's purpose to prevent fraud on the government's fisc," and so "[m]ere FDA approval cannot preclude [FCA] liability, especially where, as here, the alleged false claims procured certain approvals." *Id*. at 29a.

The Ninth Circuit thus found that Gilead's materiality arguments raised "matters of proof, not legal grounds to dismiss relators' complaint." Pet. App. 32a. The court expressly distinguished Third Circuit precedent, noting that relators there inadequately pleaded materiality. *Id.* at 31a-32a. It also distinguished *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017), a prior Ninth Circuit decision applying *Escobar* to affirm dismissal of a complaint that failed to plead materiality. Pet. App. 32a.

Finally, the court held that the retaliation claim survived dismissal. Pet. App. 37a.

Gilead petitioned for rehearing, raising the same arguments about a circuit split and practical consequences as it raises here. *See* C.A. Doc. 81. The Ninth Circuit denied rehearing without calling for a response. Pet. App. 73a. Gilead also moved to stay the mandate, but conceded that it did "not plan to challenge [the Ninth Circuit's] holding with respect to Mr. Campie's retaliation claim in its petition for certiorari." C.A. Doc. 99, at 3 n.1.

3. Gilead sought certiorari.

REASONS TO DENY THE WRIT

I. The decision below is correct.

At best, Gilead's petition asks this Court for error correction—but there is no error. Relators pleaded sufficient facts to state plausible FCA claims. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

1. Our first theory of liability is factual falsity—that Gilead sold knockoffs of its own drugs, substituting contaminated, unapproved drugs for FDA-approved antiretroviral medications. This intentional departure from the NDAs is plainly material to whether Gilead's drugs were reimbursable because—as the Ninth Circuit explained and Gilead does not dispute—"FDA approval is the *sine qua non* of federal funding." Pet. App. 27a (quotation marks omitted). By using inferior unapproved ingredients, Gilead misrepresented its products and fraudulently obtained government payment.

At the outset, it is unclear that *Escobar*'s materiality standard, which serves the particular function of limiting implied certification claims, applies to claims of factual falsity at all. The statutory text creates liability for a "false or fraudulent" claim. 31 U.S.C. § 3729(a)(1)(A). While the word "fraudulent" implies materiality, the word "false" may not.

Assuming *Escobar*'s materiality standard does apply (as the lower court did), relators' allegations meet the test because they mirror those in *Escobar* itself. Although this Court left materiality to the lower courts, it did note that the requirements the defendant violated were "so central to the provision of mental health counseling that the Medicaid program would not have paid these claims had it known of these violations." 136 S. Ct. at 2004. The fraud was apparent: "by submitting claims for payment

using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided [those services]." *Id.* at 2000. Universal Health further implicitly represented that the services were of approved quality and performed by licensed staff. *Id.* The services delivered, however, were substandard and unapproved. On remand, the First Circuit concluded that the complaint adequately pleaded materiality—even though Universal Health argued that the government knew about the alleged fraud when it made the payments. *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 110 (1st Cir. 2016).

Gilead's conduct is fundamentally indistinguishable: it provided substandard, unapproved healthcare and charged the government full price. Like the misconduct in *Escobar*, noncompliance with an NDA—especially affecting the composition of an active ingredient—is "so central" to the provision of pharmaceuticals that the government plausibly would not pay if it knew that a manufacturer flouted those requirements. 136 S. Ct. at 2004.

2. Our second theory of liability is that Gilead defrauded the FDA into approving the use of Synthetics China. The complaint alleges that out of three validation lots, two were hopelessly contaminated. E.R.144-45. There is no reasonable prospect that, had Gilead disclosed the actual test results, the FDA would have approved a facility so incapable of producing acceptable product. No allegation in the complaint suggests otherwise. Without this fraud, every pill containing FTC from Synthetics China would not have conformed to the NDA and thus would have been ineligible for reimbursement.

Gilead's own actions highlight the materiality of its fraud. By going to such great lengths to conceal its violations, Gilead showed its belief that those violations were material to the government's payment decisions. *See United States v. Triple Canopy, Inc.*, 857 F.3d 174, 178 (4th Cir.), *cert. dismissed*, 138 S. Ct. 370 (2017) (finding materiality based in part on "[defendant's] own actions in covering up the noncompliance"). Moreover, Gilead stopped using FTC from Synthetics China in 2011—obviating the need for regulatory action and explaining why the lack of FDA action does not imply immateriality.

3. Our third theory of liability is that it violates the FCA to knowingly claim government payment for drugs that are adulterated or misbranded in a way that fundamentally affects their quality. Gilead implies that allowing this claim would subject manufacturers to FCA liability "whenever a manufacturer departs, however trivially, from FDA regulations." Pet. 6. But unlike the "minor violations" Gilead alludes to, *id.*, the violations here—like the knowing distribution of drugs with contaminated active ingredients—lie at the heart of the FCA. *See, e.g.*, *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265-66 (9th Cir. 1996) ("The FCA was enacted . . . with the purpose of forfending widespread fraud by government contractors who . . . shipp[ed] faulty goods to the government."). While we acknowledge that adulteration and misbranding will not *always* be material, neither *Escobar* nor any other case suggests that they can *never* be. Here the complaint alleges that they were.

4. As Gilead conceded, its petition does not directly challenge the Ninth Circuit's retaliation decision. C.A. Doc. 99, at 3 n.1. Despite this concession, Gilead suggests

in a footnote that "[r]uling for Gilead on materiality would require reconsideration of that retaliation claim." Pet. 10 n.4. That makes no sense. A retaliation claim turns on whether the relator's investigation might reasonably lead to a viable FCA claim. *See, e.g.*, *Anton*, 91 F.3d at 1269. There is no way for a relator in Mr. Campie's situation to anticipate what the government may or may not do when it learns of facts he may or may not discover. Thus, the Question Presented does not affect the reasonableness of Mr. Campie's investigation, and his retaliation claim will move forward no matter the result here.

5. Gilead also overreads *Escobar*'s discussion of government knowledge. This Court referred to actual knowledge of violations as an example of evidence that could be relevant to materiality. *See* 136 S. Ct. at 2003. Gilead conflates this *example* of *actual* knowledge of *violations* with a *dispositive rule* that includes *constructive* knowledge of *allegations*. That is not what this Court said, and for good reason. To reject materiality whenever an allegation does not produce a draconian government response would be to ignore both that (1) the government does not have the ability or resources to investigate every alleged fraud, and (2) the government might pay under duress, relying on the FCA for a recovery. Healthcare cases vividly illustrate both phenomena. The government frequently reimburses for healthcare services, and then investigates frauds after the fact (or relies on FCA actions). That is because the government understands that to delay or deny reimbursement up front will harm patients. But the government's pro-reimbursement policy does not mean that pharmaceutical manufacturers have the right to

defraud the government, or that the government is content paying full price for substandard goods.

For similar reasons, the fact that the FDA does not withdraw approval for medications altogether cannot categorically foreclose FCA liability. It would be irresponsible to ban all treatments just because a manufacturer flouts the rules for a subset of its drugs. But that does not excuse the violations, nor insulate them from liability. As the Ninth Circuit correctly recognized, "it is not the FDA's purpose to prevent fraud on the government's fisc," so "[m]ere FDA approval cannot preclude [FCA] liability, especially where, as here, the alleged false claims procured certain approvals." Pet. App. 29a. If it did, Gilead would be able "to use the allegedly fraudulently-obtained FDA approval as a shield against liability for fraud." *Id.* at 31a. That result would conflict with *Escobar*, which specifically endorsed the implied certification theory of liability.

Here especially, any inference of immateriality following from continued government payment does not exist. Although Gilead correctly asserts that the "Government never suspended or withdrew its approval of the medicines at issue," Pet. 21, it ignores the complaint's allegation that Gilead's wrongdoing stopped shortly after the complaint was filed (and likely before the conclusion of any government investigation). As the Ninth Circuit observed, "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. And while the FDA has not suspended approval, two recalls were initiated because of contamination from what Gilead identified as a "third-party manufacturer in China." E.R.152.

Gilead similarly fails to contend with relators' allegation that it intentionally hid its noncompliance from the government. Gilead claims that the government "kn[ew] about the purported infractions for years," Pet. 21, because it knew about "Gilead's relationship with Synthetics China," *id.* at 9. However, this does not amount to "actual knowledge that certain requirements were violated," *Escobar*, 136 S. Ct. at 2003. Merely knowing that Gilead had some relationship with Synthetics China does not suggest that the government knew of Gilead's lies about ongoing contamination and prior use of Synthetics China.

In sum, the Ninth Circuit correctly concluded that the contested issues "are matters of proof, not legal grounds to dismiss relators' complaint." Pet. App. 32a. It would contravene the purposes of the FCA—which empowers private plaintiffs to investigate and prosecute fraud on the government—to require relators to prove materiality before being allowed discovery into the government's knowledge and payment decisions. *Cf. Escobar*, 842 F.3d at 112 (reversing dismissal on remand and questioning relators' ability to access key materiality evidence before discovery). Relators here adequately pleaded sufficient facts to state facially plausible FCA claims, including on materiality. Federal Rule of Civil Procedure 12(b)(6) requires nothing more.

6. Finally, contrary to the arguments made by Gilead and its *amici*, this suit does not undermine the FDA's regulatory authority. The FCA includes an important safety valve allowing the government to dismiss a qui tam suit even over a relator's objections. 31 U.S.C. § 3730(c)(2)(A). The government considers exercising this authority when a suit interferes with an agency's policies or the administration of its programs.

See Memorandum from Michael Granston, Dir., Commercial Litig. Branch, Fraud Section, Dep't of Justice, to Section Attorneys & Assistant U.S. Attorneys Handling False Claims Act Cases 4-5 (Jan. 10, 2018), http://goo.gl/rjeGk7. Gilead is thus wrong to worry that the decision below moves regulatory authority from the federal government to private litigants. When that risk materializes, the government can end the lawsuit. But when, as here, a suit advances the government's interests, it can file a brief supporting the relators.

II. There is no circuit split.

Gilead seeks to manufacture a split where none exists. No court has formulated a legal rule resembling the Question Presented—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. *See* Pet. i. Instead, every court of appeals to consider materiality has applied the same legal rule to different facts.

Escobar's rule is simple: materiality is a holistic inquiry that looks to the likely effect of defendants' misconduct on government payment decisions. This Court made clear that "materiality cannot rest on 'a single fact or occurrence as always determinative.'" *Escobar*, 136 S. Ct. at 2001 (quoting *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 39 (2011)). Courts should consider whether:

- "the Government designates compliance with a particular statutory, regulatory or contractual requirement as a condition of payment," *id.* at 2003;

- the government acts when it has actual knowledge of similar violations, *id.* at 2003-04;
- the violation goes to the "essence of the bargain," *id.* at 2003 n.5 (quotation marks omitted); and,
- the violation is significant or "minor or insubstantial," *id.* at 2003.

To aid in this analysis, the Court provided an example: "[P]roof of materiality can include . . . if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated" *Escobar*, 136 S. Ct. at 2003. That actual knowledge would be "very strong evidence" that particular requirements "are not material." *Id*. Put otherwise, government payment despite *actual* knowledge of fraud is strong, though not *dispositive*, evidence of immateriality.

Factbound application of this rule has not created a circuit split. The Ninth and First Circuits, each of which have applied *Escobar* multiple times, make this point particularly clear. Each of these circuits has decided materiality both in favor of and against FCA plaintiffs, depending on the facts. The remaining courts of appeals follow the same approach. The Second, Third, and Fourth Circuits have ruled on materiality at the motion-to-dismiss stage. And the Fifth, Seventh, Tenth, and D.C. Circuits have resolved materiality after discovery. In all these circuits, case-specific factors drive the analysis.

A. The Ninth and First Circuits undertake a holistic materiality review.

The Ninth and First Circuits have each found that some frauds were material while others were not. This is

no split in authority; actually, it shows that these courts both apply *Escobar*'s fact-intensive rule.

Ninth Circuit. Consistent with this Court's guidance, courts within the Ninth Circuit have conducted an inclusive, contextual materiality analysis.

1. This case is a prime example. The Ninth Circuit quoted *Escobar* at length and applied its rule to this case's facts. The court noted that the "standard is demanding," and stressed that materiality "cannot be found where noncompliance is minor or insubstantial." Pet. App. 27a (quoting *Escobar*, 136 S. Ct. at 2003). It considered *Escobar*'s government knowledge example, cautioning that "Relators thus face an uphill battle in alleging materiality." *Id.* at 28a. Relators' complaint survived because of the strength of the facts alleged, not because the Ninth Circuit adopted an unduly lax legal rule.

Other post-*Escobar* decisions in the Ninth Circuit also belie Gilead's characterization. In *Kelly*, the court found that the relator inadequately pleaded materiality. 846 F.3d at 334. There, the relator alleged that a defense contractor had failed to record its costs as required by Department of Defense guidelines. *Id.* at 332. But the court found no evidence that the defendant had to comply with those guidelines at all, much less that compliance was material to the government's payment decision. *Id.* at 334. The court rejected the relator's argument that the government could have refused payment if the defendant had disclosed its substandard procedures, noting that, after *Escobar*, evidence that the government could refuse payment does not by itself establish materiality. *Id.* at 333-34. The government had also accepted the disputed reports despite knowledge of non-compliance. *Id.* at 334.

Thus, the court held that no reasonable jury could find for the relator on his implied false certification claim. *Id.*

In *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir.), *cert. denied*, 138 S. Ct. 407 (2017), the Ninth Circuit cited *Escobar*'s discussion of materiality in ruling against the relator. The relator sought certiorari, claiming that the court's harsh application of the materiality standard rendered the FCA "toothless." Petition for Writ of Certiorari, *McGrath*, 138 S. Ct. 407 (No. 17-412), 2017 WL 4162297, at *26. That decision also demonstrates that the Ninth Circuit does not apply a pro-plaintiff rule in FCA cases.

2. District courts applying Ninth Circuit precedent have not hesitated to rule in defendants' favor on materiality. For example, in granting a motion to dismiss, one court observed that the case before it was "a far cry from *Campie*" because its relator's "allegations d[id] not come close to [the Campies'] level of specificity." *United States ex rel. Mateski v. Raytheon Co.*, 2017 WL 3326452, at *6-7 (C.D. Cal. Aug. 3, 2017), *appeal pending*, No. 17-56320 (docketed 9th Cir. Aug. 31, 2017); *see also United States ex rel. Durkin v. County of San Diego*, 2017 WL 3315784, at *12-14 (S.D. Cal. Aug. 3, 2017). These opinions disprove Gilead's claim that district courts in the Ninth Circuit have turned the FCA into an "all-purpose antifraud statute." Pet. 26 (quotation marks omitted).

In support of its alarmism about rogue district courts, Gilead musters only a single, misleading citation—*United States ex rel. Ferris v. Afognak Native Corp.*, No. 3:15-cv-150, Doc. 295 (D. Alaska Aug. 11, 2017). In *Ferris*, the district court denied a motion to dismiss despite the defendants' protestation that the government knew of the allegations and took no action. But that court

specifically concluded that actual government knowledge had not been established: "there is nothing in what is currently before the court that shows that the Department of Justice shared the information in relator's complaint with the [payor agency]." *Id.* at 15. Instead of acknowledging this narrow finding, Gilead merely parroted the *Ferris* defendants' conclusory assertion that "the government has been aware of relator's allegations for almost four years." *Id.* at 14.

3. Gilead seizes upon a sentence fragment from the decision below to suggest that a complaint would survive in the Ninth Circuit whenever a relator pleads "more than the mere possibility" of materiality. Pet. 19 (emphasis omitted). But the "mere possibility" language was not an articulation of the Ninth Circuit's rule; it merely distinguished this case from *Kelly*. *See* Pet. App. 32a (citing *Kelly*, 846 F.3d at 334). In *Kelly*, the complaint alleged only that "the government would be entitled to refuse payment if it were aware of [defendant's] alleged violations," which the court held was "insufficient by itself to support a finding of materiality." 846 F.3d at 334. Gilead's suggestion that the Ninth Circuit adopted a "more than a mere possibility" rule is further refuted by the district court cases discussed above (none of which relied on this language) and by the Ninth Circuit's actual articulation of the rule, which quoted, at length, the materiality discussion from *Escobar*, Pet. App. 27a, 30a.

First Circuit. The First Circuit joins the Ninth in applying an all-inclusive materiality standard.

1. On remand in *Escobar*, the First Circuit applied "the holistic approach to determining materiality laid out by the Supreme Court," finding the complaint sufficient. 842 F.3d at 110. First, the alleged misrepresentation violated a condition of payment. *Id.* Second, the

misrepresentations cut "to the 'very essence of the bargain'" with the relevant agency. *Id.* (citation omitted). And third, there was "no evidence in the record that [the agency] paid [the fraudulent] claims" with actual knowledge of violations. *Id.* at 111. The court held that "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance," and found that there was "no evidence in the complaint" that the paying agency "had actual knowledge of any of these allegations (much less their veracity) as it paid [the] claims." *Id*. at 112. The court thus had "little difficulty in concluding" that the relators had sufficiently alleged materiality. *Id.* at 110.

2. Other First Circuit cases demonstrate the same, searching approach. In *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, the First Circuit upheld dismissal of the relators' claims that the defendant made false statements to secure FDA approval for a hip replacement device. 865 F.3d 29, 31 (1st Cir. 2017), *petition for cert. pending*, No. 17-1108 (filed Feb. 5, 2018). There, the complaint admitted that the government had taken no action despite having actual knowledge of the alleged noncompliance. *Id.* at 35. But the court did allow the relators to pursue their claim that the defendants sold a device that deviated materially from its approved specifications (a claim fundamentally similar to respondents' first and third theories of liability). *See id.* at 41. *Nargol* distinguished this case: "the record in *Campie* lacked what we have here," meaning "a situation in which the FDA . . . acquired *full knowledge* of Relators' claims." *Id.* at 36 (emphasis added).

Gilead (at 14, 24) also leans on *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016). But the holding in *D'Agostino*

was on causation, not materiality. The court discussed materiality only to reject the relator's argument that the alleged misrepresentations were actionable because they "'could have' influenced the FDA to grant approval." *Id.* at 7. *D'Agostino* therefore does not conflict with this case. In fact, the First Circuit later noted that "[t]he example of a valid claim given in *Campie* would be a valid claim under *D'Agostino* too, since it rests not on lying to the FDA but rather on palming off one product as another," *Nargol*, 865 F.3d at 36 (footnote and internal citation omitted).[1]

B. All circuits to grant motions to dismiss have applied the same standard, and granted such motions only in particularly clear cases.

Three other circuits have considered *Escobar*'s materiality standard on motions to dismiss. In each case, the allegations were clear enough to warrant judgment without further factual development.

Second Circuit. In *Coyne v. Amgen, Inc.*, 2017 WL 6459267 (2d Cir. Dec. 18, 2017), the relator alleged that the defendant omitted data from a drug label disclosing health risks and limitations of the drug. But the complaint included only a "conclusory assertion" of materiality, made implausible because the section of the

[1] 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." *Nargol*, 865 F.3d at 36. But nobody suggests that a relator should prevail by arguing that the FDA would have withdrawn approval if the FDA states it would not have done so. Here, the complaint alleges that the FDA would not have approved Gilead's application to use FTC from Synthetics China had it known the truth about the quality of FTC from that facility. That allegation is plausible; the pleading stage requires nothing more.

label at issue was irrelevant to the FDA's approval decision. *Id*. at *2. The manufacturer subsequently added the language the relator argued was required, and the government did not limit reimbursements for the drug despite knowing of the increased risks. *Id.* at *3. This sequence of events also undermined the suggestion that the misrepresentation was material. Here, the complaint has the "concrete allegations" lacking in *Coyne*, *id*. at *2—there is no conflict.

Third Circuit. The Third Circuit recently recognized that no single factor automatically disposes of materiality, even when the payor agency has actual knowledge that a defendant has violated express conditions of payment. *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017). Even though the relator "essentially concede[d] that [the agency] would *consistently reimburse* [the challenged] claims with full knowledge of the purported noncompliance," the court conducted a rigorous analysis. *Id.* It discussed most of the materiality factors mentioned in *Escobar*, *see id.* at 489, concluding that "Petratos's allegations do not meet this high standard," *id.* at 490. This opinion is not the source of a circuit split. In fact, the Ninth Circuit explicitly distinguished *Petratos* in its materiality discussion. *See* Pet. App. 31a-32a.

Fourth Circuit. The Fourth Circuit applied both *Escobar* and "common sense" to find materiality in *Triple Canopy*. 857 F.3d at 178. There, a military base security contractor hired "guards that [could not] shoot straight." *Id.* at 179. The government "immediately intervened in the litigation" after hearing of this fraud. *Id.* But even with this clear government response, the court still considered all the allegations. For instance, it found compelling the defendant's "own actions in covering up

the noncompliance." *Id.* at 178. Like a guard that cannot shoot straight, contaminated medicine is material to the government. The Fourth Circuit would not decide this case any differently.

C. All circuits that have determined materiality with the aid of a factual record have also engaged in a holistic analysis.

At its core, materiality is a factual question, and development of the record will often give a clear picture of the materiality of an alleged fraud. Thus, several circuits have resolved materiality after discovery. The different procedural posture of these cases renders them less relevant here. But they still apply the same rule as the Ninth Circuit.

Fifth Circuit. In *United States ex rel. Harman v. Trinity Industries Inc.*, the court found no materiality in reviewing the denial of a post-trial motion for judgment as a matter of law. 872 F.3d 645, 647 (5th Cir. 2017), *petition for cert. pending*, No. 17-1149 (filed Feb. 12, 2018). There, the relator made a full presentation to the government, alerting it to defects in highway guardrails. *Id.* at 649. But on the eve of trial, the government issued a memorandum explaining that despite the presentation, the guardrails remained eligible for reimbursement. *Id*. at 650. The Fifth Circuit surveyed precedents from the First, Third, Seventh, Ninth, and D.C. Circuits—including this case. Describing the uniform rule from those cases, the court held that "continued payment by the federal government after it learns of the alleged fraud" is "not dispositive." *Id.* at 663. But the "gravity and clarity of the government's decision" settled the issue there. *Id*. Just as important, the Fifth Circuit distinguished *this case*, explaining that "there are and

must be boundaries to government tolerance of a supplier's failure to abide by its rules." *Id*. at 664.

Similarly, in *Abbott v. BP Exploration & Production, Inc.*, the Fifth Circuit affirmed summary judgment against a relator. 851 F.3d 384, 389 (5th Cir. 2017). The relator alleged that engineers had not approved various stages of construction on the Atlantis, a floating oil production facility, in violation of applicable regulations. These allegations "led to Congressional hearings, an investigation by a federal agency, and [an agency report which] considered many of the same arguments advanced" by the plaintiffs. *Id.* at 388. After this investigation came up clean, the government agency "allow[ed] the Atlantis to continue drilling." *Id.*

Seventh Circuit. In *United States v. Sanford-Brown, Ltd.*, the Seventh Circuit affirmed summary judgment against the relator where the payor agency had "already examined [the enterprise] multiple times over and concluded that neither administrative penalties nor termination was warranted." 840 F.3d 445, 447 (7th Cir. 2016) (quotation marks omitted).[2]

D.C. Circuit. The D.C. Circuit conducted a rigorous materiality analysis despite the government's apparent actual knowledge of fraud. *See United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017). There, the relator accused the defendant of inflating data relevant to payment, but government witnesses testified that this data "had no bearing on costs billed to the Government, and that there was no

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[2] Gilead (at 17, 27) also cites *United States ex rel. Marshall v. Woodward, Inc.*, a pre-*Escobar* decision with facts much like those in *Sanford-Brown*. 812 F.3d 556, 563 (7th Cir. 2015), *cert. denied*, 136 S. Ct. 2510 (2016).

indication the data affected award fee decisions." *Id.* at 1033. Only after an extended discussion of the other facts did the court turn to government knowledge, observing that the agency conducted an investigation after learning of the alleged misstatements and "did not disallow any charged costs." *Id.* at 1034. In fact, the summary judgment record showed that, despite the government's actual knowledge of violations, it awarded a "fee for exceptional performance." *Id.*

Tenth Circuit. Gilead cites *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1164 (10th Cir. 2016), in which the Tenth Circuit affirmed summary judgment for the defendant because the alleged contractual violations were not material to USAID's payment decisions. Pet. 18. To begin, *Thomas* cannot be about the meaning of *Escobar*, because it is a pre-*Escobar* case. In any event, *Thomas* does not conflict with this case. The court there explained that "an FCA plaintiff may establish materiality by demonstrating that the defendant violated a contractual or regulatory provision that undercut the purpose of the contract." 820 F.3d at 1171 (quotation marks and alteration omitted). Even if a defendant violated "only a tangential or minor contractual provision, the plaintiff may establish materiality by coming forward with evidence indicating that, despite the tangential nature of the violation, it may have persuaded the government not to pay the defendant." *Id*. In *Thomas*, the alleged violations were immaterial because they were minor and unrelated to the core purpose of the contract. *See id.* Here, by contrast, the violations were anything but minor, and nothing in the complaint suggests otherwise.

* * *

In sum, Gilead has identified no outcome-determinative difference in the circuits' legal rules. The courts of appeals have uniformly determined that continued government payment, while an important factor, forms only one part of the materiality analysis. Many courts have expressly considered this case, but none has disagreed with the Ninth Circuit's decision. Gilead does not like how that analysis turned out—but, at most, this amounts to a claim that the lower court misapplied a generally accepted, properly stated legal rule. Gilead's disagreement with that factbound conclusion does not warrant this Court's review.

III. This case is a poor vehicle to decide the Question Presented.

Even if the decision below were wrong and the circuits were split, certiorari should be denied because this case is a poor vehicle. Materiality was not the focus of litigation below; the case could not be fully resolved by this Court; and the case's idiosyncratic facts do not directly raise the Question Presented. If Gilead is correct that "these cases will continue to come in droves," Pet. 27, there will be many better opportunities to take up the question. At minimum, this Court should not grant this case before the facts have been developed—the Question Presented turns on the government's knowledge, which a relator can usually only speculate about at the pleading stage.

1. The litigation below did not focus on materiality. The district court paid almost no attention to it. *Escobar* was not decided until after briefing in the Ninth Circuit, and materiality was a subsidiary issue in the appeal. If this Court wishes to revisit the standard for materiality

so soon after *Escobar*, it would be better served by doing so in a case where the issue was fully aired below.

Moreover, the Question Presented would benefit from further percolation in the courts of appeals. In the two years since *Escobar*, several circuits have considered materiality, but few cases have posed a close factual question. The recent boom in these cases will be short-lived, because it is merely a symptom of *Escobar*'s novelty. Defendants have a new tool—*Escobar*'s "demanding" materiality standard—and they have sought judgment in many pending cases. Once more of these cases have been resolved, the issue will be litigated less often. Further percolation will allow the circuits to consider different factual patterns and iron out any potential wrinkles.

2. Answering the question now will not resolve this case. Regardless of the answer to the Question Presented, relators have at least three surviving sets of claims: (1) for retaliation, which Gilead does not challenge here, (2) for payments made before the government learned of Gilead's violations, and (3) for factually false claims, which do not necessarily implicate *Escobar*'s discussion of materiality in implied certification cases because they do not raise the Court's concern that minor regulatory violations could lead to unpredictable liability. If there is sufficient evidence to go to trial, this Court will have another opportunity to determine the appropriate standard for materiality and to resolve all these claims together.

Relators also may amend their complaint to incorporate at least some allegations from the First Amended Complaint. It would be all but impossible for this Court to evaluate the materiality of those claims until relators have amended the complaint, making review now premature.

3. The facts here do not implicate Gilead's Question Presented. That question is premised on the fact that the government continued to approve and pay for products after learning of alleged violations. Pet. i. But the complaint never concedes that the government knew of the conduct giving rise to our claim: distribution of non-conforming drugs and deliberate concealment of contamination. The complaint especially never concedes that any *paying agency* knew of this fact, and Gilead cites no authority saying that the government should be treated as a monolith, such that Department of Justice or FDA knowledge should be imputed to the Center for Medicare and Medicaid Services or the other paying agencies.

The Question Presented also assumes that the pleadings "offer no basis" to overcome an inference of immateriality. Pet. i. But the complaint alleges facts explaining the government's continued approval and reimbursement of those drugs, including that by the time the First Amended Complaint was filed, Gilead had not been using FTC from Synthetics China for years. Thus, even if this Court agrees with Gilead's answer to its Question Presented, this case would survive.

The facts alleged also do not implicate Gilead's assertion that applying the Ninth Circuit's opinion would turn "every minor regulatory misstep into a potential FCA" violation. Pet. 2. This case is not about minor violations. The complaint alleges sustained fraud: that Gilead falsified test results to hide severe contamination of an active ingredient and repeatedly lied to the government. E.R.140, 144-45. This behavior is so far beyond a "minor regulatory misstep," Pet. 2, that this case would not aid this Court in considering the effect of any materiality rule on truly minor violations. More

broadly, because this is not a boundary-line case, it presents a poor vehicle for identifying the precise boundary between material and immaterial lies.

4. Given the centrality of government knowledge to this Question Presented—and the difficulty of alleging details about that knowledge at the pleadings stage—it would be better to take this issue up in a case with a developed factual record. When the government continues to pay despite "actual knowledge" of noncompliance, that is "strong evidence" against materiality. *Escobar*, 136 S. Ct. at 2003. But without further factual development here, there is no way to know whether the government had "actual knowledge" of Gilead's misconduct. Nor does "strong evidence" mean "dispositive as a matter of law"—especially in a pretrial posture, where courts must draw all inferences in favor of the non-moving party. Although materiality issues are not necessarily "too fact intensive" to be determined "on a motion to dismiss or at summary judgment," *id.* at 2004 n.6, that does not mean courts should always prefer the former. Discovery would allow the parties here to litigate this question based on evidence, rather than speculation. For now, this Court need not intervene merely to save a multibillion dollar company the cost of discovery into its misconduct.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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