No. 17-

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

When a plaintiff invokes the False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, to assert that a contractor has defrauded the Government in connection with a claim for payment, the plaintiff must plausibly allege that any misrepresentation was "material to the Government's payment decision." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). This Court has explained 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. Further, a plaintiff's failure to establish materiality is ripe for resolution "on a motion to dismiss or at summary judgment." *Id.* at 2004 n.6. In this case, the Ninth Circuit allowed an FCA suit to go forward without any allegations that could overcome the powerful inference of immateriality created by the Government's knowing decision to pay for the products at issue. That is in direct contrast to published decisions of six circuits over the past three years that have rejected lawsuits on the pleadings or at summary judgment in such circumstances.

The question presented is:

Whether an FCA allegation fails when the Government continued 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.

CORPORATE DISCLOSURE STATEMENT

Gilead Sciences, Inc. ("Gilead") is a publicly traded corporation. No publicly held company has a 10 percent or greater ownership interest in Gilead.

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INTRODUCTION[1]

The False Claims Act (FCA), 31 U.S.C. § 3729 *et seq.*, applies to those "who defraud the Government." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995 (2016). It creates a cause of action for the submission of false claims for payment, and it allows private individuals to share in the recovery by filing suits on the Government's behalf. *Id.* § 3730(b), (d).

This petition involves an increasingly common breed of FCA claim premised on allegations that a government contractor has falsely represented that it complied with regulatory requirements—here, regulations promulgated by the Food and Drug Administration (FDA). Such claims fail unless the false statements are "material to the Government's payment decision." *Escobar*, 136 S. Ct. at 2002.

In the last three years, six circuits in published opinions (plus one circuit in an unpublished opinion) have recognized that the Government's continued approval and acceptance of goods or services after learning of alleged regulatory violations is, as this Court explained in *Escobar*, "very strong evidence" of immateriality, 136 S. Ct. at 2003, which precludes an FCA claim absent countervailing evidence. Yet the Ninth Circuit stands apart, both from *Escobar* and from its sister circuits. The Ninth Circuit recognized that the complaint in this case "outline[s] a variety of facts

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[1] The Excerpts of Record in the Court of Appeals are cited as "ER__." The appendix to this petition is cited as "Pet. App. __." The Ninth Circuit's docket entries are cited as "C.A.__."

that speak to the government's knowledge" of alleged infractions. Pet. App. 30a-31a. It also acknowledged that the FDA has never altered its approval of the drugs at issue, and that "the government continues to make direct payments and provide reimbursements" for the drugs. Pet. App. 28a. Yet the court allowed the case to proceed, because Plaintiffs "allege *more than the mere possibility* that the government would be entitled to refuse payment if it were aware of the violations." Pet. App. 32a (emphasis added). This "more than mere possibility" standard is impossible to square with the rule that other circuits have applied.

The Ninth Circuit's approach threatens to turn every minor regulatory misstep into a potential FCA case with crushing liability. Consequently, it undermines the judgment of expert agencies in which Congress vested the power, expertise, and flexibility to police compliance with federal regulations and contracts. In the process, the Ninth Circuit's decision effectively transfers regulatory authority to private litigants motivated by the prospect of a financial bonanza.

This Court should grant the petition to resolve the split among the circuits, provide definitive guidance on a significant recurring issue, and ensure that *Escobar*'s rule operates uniformly throughout the country.

OPINIONS AND ORDERS BELOW

The opinion of the Court of Appeals is reported at 862 F.3d 890. Pet. App. 1a-37a. The Court of Appeals'

orders denying Gilead's petition for rehearing or rehearing en banc and granting Gilead's motion to stay the mandate are not reported. *See* Pet. App. 72a-73a; C.A.100. The district court's opinion dismissing the second amended complaint may be found at 2015 WL 3659765. Pet. App. 38a-71a.

JURISDICTION

The Court of Appeals denied Gilead's petition for panel rehearing or rehearing en banc on September 27, 2017. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

This petition involves provisions of the False Claims Act, 31 U.S.C. §§ 3729-30, and the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331, 355, 356a, as well as regulations involving the manufacture of and government payment for drug treatments, 21 C.F.R. § 211.1; 48 C.F.R. § 46.408. The relevant provisions are reproduced at Pet. App. 74a-84a.

STATEMENT OF THE CASE

The FCA is one of a "handful of extant laws creating a form of civil action known as *qui tam*," wherein "a private person (the relator) may bring a … civil action 'for the person and for the United States Government.'" *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 768-69 (2000) (quoting § 3730(b)(1)). A plaintiff suing under the FCA must alert the Department of Justice, which decides

whether to intervene. *See* 31 U.S.C. § 3730(b), (c); *Stevens*, 529 U.S. at 769.

Whether or not the Department of Justice participates in the lawsuit, the private plaintiff stands to reap massive rewards from a successful FCA action. The Act provides for treble damages and civil penalties for knowingly presenting "a false or fraudulent claim for payment or approval" or making "a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). Bounties for FCA plaintiffs "generally rang[e] from 15 to 25 percent if the Government intervenes …, and from 25 to 30 percent if it does not … plus attorney's fees and costs." *Stevens*, 529 U.S. at 769-70 (citing 31 U.S.C. § 3730(d)(1)-(2)).

Government purchasers pay for medicines that are FDA-approved

This case involves three life-saving HIV treatments that Gilead markets: Atripla, Truvada, and Emtriva. Pet. App. 5a. Agencies like the Department of Defense, the Department of Veterans Affairs, and the Bureau of Prisons buy these medicines directly from Gilead. The Government also reimburses purchases of the drugs through programs such as Medicare, Medicaid, TRICARE, and the Federal Employee Health Benefits Program. Pet. App. 9a. The Federal Government spent over $5 billion on the medicines in 2008 and 2009 alone. Pet. App. 5a.

Government purchasers rely on the FDA to determine whether a treatment is eligible for payment and

reimbursement. As long as the treatment is FDA-approved, the Government may pay for it. ER116-29. With respect to reimbursement programs, for example, Medicaid covers drugs that are "approved for safety and effectiveness as a prescription drug under" the Federal Food, Drug, and Cosmetic Act. 42 U.S.C. § 1396r-8(k)(2). With respect to direct payment programs, a Federal Acquisition Regulation assigns to the FDA "Government-wide responsibility for quality assurance support for acquisitions of … drugs, biologics, and other medical supplies." 48 C.F.R. § 46.408(a).

The FDA administers a "detailed regulatory regime," *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001), to ensure that medical products are effective and safe and to address any concerns about their production or marketing. The agency has discretion to pursue "difficult (and often competing) objectives." *Id.* at 349 (discussing the statutory and regulatory framework with respect to medical devices).

When a pharmaceutical company wants to release a new drug, it submits a "new drug application" (NDA) describing the drug's ingredients, manufacturing processes, and uses. Approval of an NDA authorizes the company to sell the product in the United States. *See* 21 U.S.C. § 355; *United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 701 (4th Cir. 2014).[2] The FDA "may refuse an application or with-

[2] *See also* FDA, *New Drug Application (NDA)* (last updated Mar. 29, 2016), http://tinyurl.com/y9zau36r.

draw a previously approved application if the[] methods or facilities" used to manufacture a drug "are inadequate to preserve [the drug's] identity, strength, quality, and purity." *Omnicare*, 745 F.3d at 701 (quoting 21 U.S.C. § 355(d), (e)). The FDA also must "withdraw approval" upon learning that "the application contains any untrue statement of a material fact." 21 U.S.C. § 355(e). If the manufacturer wants to change the method by which it produces a drug, it may not proceed unless the FDA approves a "prior approval supplement" (PAS). *See id.* § 356a.

A related federal law prohibits marketing "adulterated or misbranded" drugs. 21 U.S.C. § 331(a), (c). The definition of "adulterated" is broad; it can apply whenever a manufacturer departs, however trivially, from FDA regulations specifying "the minimum current good manufacturing practice for preparation of drug products." 21 C.F.R. § 211.1(a); *see* 21 U.S.C. § 351(a)(2)(B) (defining "adulterated"). When a drug is deemed to be adulterated, "it does not mean that there is necessarily something wrong with the drug." FDA, *Facts About the Current Good Manufacturing Practices (CGMPs)* (last updated Oct. 6, 2017), http://tinyurl.com/muq4rs. To the contrary, the drug "may still meet its labeled specifications, and the risk that the drug is unsafe or ineffective could be minimal." *Id; see also Omnicare, Inc.*, 745 F.3d at 702 n.7 ("[A]dulterated drugs are subject to reimbursement by Medicare and Medicaid."). Likewise, "misbranded" can include minor violations such as failing to list an inactive ingredient on the drug label, 21 U.S.C. § 352(e)(1)(A)(ii), or failing to display information prominently enough, *id.* § 352(c).

Precisely because these sorts of infractions can be minor, federal laws covering the Government's payment for drugs "do not expressly prohibit reimbursement for drugs that have been adulterated." *Omnicare*, 745 F.3d at 701. Nor do they treat compliance with specific manufacturing processes or FDA regulations "as a precondition to reimbursement." *Id.* The FDA may continue its approval of a drug even if there have been minor departures from manufacturing guidelines. *Cf.* C.A.20 (Br. of Amicus Curiae United States) at 26 (indicating that not all "problems … are so serious that FDA would have … withheld or withdrawn its approval of the drug application for all indications"). Equally important, the Government may continue to purchase that drug notwithstanding the lack of perfect compliance with every FDA regulation and procedure. *See id.* at 25-26 (noting that "[p]ayment under the government health programs is not generally conditioned on a manufacturer's compliance with various FDA procedures, or its compliance with the Food, Drug, and Cosmetic Act").

Plaintiffs sue despite uninterrupted approval of, and payment for, Gilead's medicines

Plaintiffs filed their initial FCA complaint in 2010. They filed their second amended complaint, which is the one relevant to this petition, in 2015. ER609. The Department of Justice declined to intervene in the case, though it submitted a statement of interest in the district court, ER604, and an amicus brief in the Ninth Circuit, Pet. App. 12a.

Plaintiffs concede that the FDA has never suspended or rescinded its approval of Gilead's medicines. Pet. App. 28a. Yet, they contend that alleged manufacturing problems and related misrepresentations justify recovery in a private lawsuit under the FCA. Specifically, Plaintiffs allege that Gilead represented in its NDA that it would obtain the medicines' active ingredient (emtricitabine, or "FTC") from certain registered facilities, but that Gilead acquired a portion of that ingredient from a then-unregistered (though later-approved) facility operated by a company named Synthetics China. ER139. Plaintiffs also allege that Gilead concealed the role of Synthetics China through record manipulation, faulty certificates, and misleading labeling, and that Gilead did not reveal other manufacturing issues affecting the FTC it obtained. ER139-40.

The core of Plaintiffs' theory is that some batches of FTC were produced by an unregistered source. Plaintiffs contend that the medicines containing unauthorized FTC were not eligible for payment or reimbursement by the Government because Gilead allegedly "represented to the FDA that its active ingredients had been manufactured in approved facilities" and allegedly "requested payment for drugs that fell outside of [FDA] approval and omitted critical information regarding compliance with FDA standards." Pet. App. 22a-23a; *see* ER141. Plaintiffs also argue that Gilead's prior approval supplement regarding FTC from Synthetics China contained misstatements about product testing. ER140. On

Plaintiffs' rationale, these statements, too, are actionable under the FCA. ER170-71.[3]

Plaintiffs' own filings demonstrate that the Government has known about Gilead's relationship with Synthetics China for years. To start, the Government had iterations of Plaintiffs' complaint dating back to 2010. Moreover, Gilead submitted a prior approval supplement seeking approval of Synthetics China in 2008, and then amended that PAS before it was approved. ER140. And, when necessary, Gilead initiated product recalls of drugs containing FTC produced by Synthetics China. ER152. In addition, the complaint alleges that the FDA was monitoring Gilead's production of ingredients for its HIV medications in other ways, as reflected in a 2010 warning letter, a June 2012 inspection, and a July 2012 letter—prompted by a "field alert filed by Gilead" itself—in which the FDA outlined possible deviations from federal regulations. ER375-76, 382; *see* ER152.

The FDA, however, never rescinded its approval of Gilead's medicines. Moreover, federal purchasers continued to pay for those medicines without seeking refunds or lodging complaints. Pet. App. 28a. That is despite Plaintiffs' allegation in 2015 that Gilead "continues to incorporate Synthetics-China-made [ingredients] into its finished drug products." ER152.

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[3] Plaintiffs' lengthy complaint contains various other allegations, but the allegations discussed above comprise the core of Plaintiffs' theory and the focal point of the Ninth Circuit's decision. *See* Pet. App. 22a-26a.

The Ninth Circuit refuses to dismiss the FCA allegations as immaterial

The district court dismissed Plaintiffs' second amended complaint in 2015. Pet. App. 38a-71a. The Ninth Circuit (Judges Reinhardt, Tashima, and Molloy (D. Mont., by designation)) reversed. The court concluded that Plaintiffs' allegations satisfied the FCA's falsity and scienter requirements. Pet. App. 21a-27a. It held that whether the alleged misrepresentations were material raised "matters of proof" that could not be resolved on the pleadings. Pet. App. 32a.[4]

The Ninth Circuit acknowledged that "FDA approval is the 'the *sine qua non*'" of the Government's payment decisions. Pet. App. 27a. It also noted that "at all times relevant, the drugs at issue were FDA-approved." Pet. App. 28a. It even recognized "that other courts"—namely, the First, Third, and Fourth Circuits—have "cautioned against allowing claims

[4] The complaint also alleges false claims under analogous state laws, as well as federal and state whistleblower-retaliation claims on behalf of plaintiff Jeffrey Campie. Pet. App. 10a. The district court dismissed the federal retaliation claim and declined to exercise supplemental jurisdiction over the state-law claims. Pet. App. 69a-70a. The panel reversed the district court's decision with respect to the federal retaliation claim. Pet. App. 33a-34a. Ruling for Gilead on materiality would require reconsideration of that retaliation claim as well: The absence of an FCA violation would be relevant to determining whether it was reasonable for Campie to believe Gilead was "possibly committing fraud against the government" and whether Gilead knew Campie was engaged in a protected activity. Pet. App. 34a.

under the False Claims Act to wade into the FDA's regulatory regime." Pet. App. 28a-29a.

Nevertheless, the Ninth Circuit refused to decide materiality on a motion to dismiss. In the court's view, "to read too much into the FDA's continued approval—and its effect on the government's payment decision—would be a mistake." Pet. App. 31a. Because Plaintiffs "allege[d] more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations," the court found that they "sufficiently [pled] materiality at this stage of the case." Pet. App. 32a.

Gilead filed a petition for panel rehearing or rehearing en banc. C.A.81. The Ninth Circuit declined to rehear the case, Pet. App. 72a-73a, but it granted Gilead's motion to stay the mandate pending a decision on this petition, C.A.100.

REASONS FOR GRANTING THE WRIT

I. The Ninth Circuit's Approach To Materiality Conflicts With Published Decisions Of Six Circuits That Have Faithfully Applied Or Anticipated *Escobar*.

FCA plaintiffs must demonstrate that the misrepresentations they allege were "material to a false or fraudulent claim" for government payment. 31 U.S.C. § 3729(a)(1)(B); *see Escobar*, 136 S. Ct. at 2002 (explaining that § 3729(a)(1)(A) also requires the relator to prove materiality). This Court addressed the materiality requirement—a crucial safeguard against frivolous FCA suits—directly and unequivocally in

Escobar. The Court left no doubt that "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable." *Id.* at 2002.

Escobar also underscored that "[t]he materiality standard is demanding" and "rigorous." *Id.* at 2002-03. It is not enough "that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* at 2003. Nor is it enough to allege an infraction that "is minor or insubstantial." *Id.* This principle inheres in "any understanding of the concept" of materiality—which is to say, in both the statutory definition, *see* 31 U.S.C. § 3729(b)(4), and the common law background. *Escobar*, 136 S. Ct. at 2002. The materiality requirement plays a pivotal role by preventing plaintiffs from transforming the FCA into an "all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* at 2003 (citation and quotation marks omitted).

Of course, a statutory safeguard means little without effective ways to invoke it. Recognizing this, *Escobar* expressly rejected any suggestion that materiality is "too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss or at summary judgment." *Id.* at 2004 n.6. What this Court did not decide expressly in *Escobar* is how an FCA complaint should be resolved when the allegations demonstrate that the Government knows about the alleged misrepresentations and yet continues to pay claims fully. The Court strongly indicated that such a claim cannot survive, but the question was not before it. This case now

asks the Court to finish the task and recognize what the vast majority of circuits do: namely that, in this situation, the FCA complaint should be dismissed.

Circuits across the country recognize that the Government's continued payment of claims after learning of alleged infractions is "very strong evidence" that requires dismissing a case absent compelling countervailing allegations that demonstrate materiality. *Id.* at 2003. The Ninth Circuit, on the other hand, allows a plaintiff to plow ahead even when the complaint establishes that the Government was on notice of the alleged violations but continued to pay claims anyway. This Court should resolve the split and provide definitive guidance on how *Escobar*'s materiality standard should be applied when the complaint itself demonstrates Government knowledge.

A. Six circuits require rigorous scrutiny of materiality in light of the Government's actual response.

On one side of the ledger are six circuits that require a rigorous materiality analysis and focus on the Government's actual behavior when it was aware of alleged misrepresentations. Some of those decisions properly read *Escobar* to compel that result, while others pre-dated *Escobar*, anticipating its animating principles.

1. Two circuits have addressed questions of materiality at the pleadings stage in precedential opinions involving drugs or medical devices, reflecting the

same principles of FDA regulatory authority and discretion that apply here. A third has done so in a summary order.

In *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), the plaintiff charged the defendant with making fraudulent representations to the FDA in seeking approval to market and sell a medical device. The plaintiff argued that "as long as [the defendant's] representations at issue 'could have' influenced the FDA to grant approval, the representations were material." *Id.* at 7.

The First Circuit disagreed, concluding that "the FCA requires that the fraudulent representation be material to the government's payment decision" and ruling that the plaintiff failed to state a claim for relief. *Id.* The court explained that the Government's choice to continue reimbursing purchases "in the wake of [the plaintiff's] allegations casts serious doubt on the materiality of the fraudulent representations" being alleged. *Id.* Moreover, the FDA's refusal to withdraw its approval based on the alleged infractions "preclude[d]" the plaintiff "from resting his claims on a contention that the FDA's approval was fraudulently obtained." *Id.* at 8.

The First Circuit adhered to this view in *United States ex rel. Nargol v. DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), another case decided on the pleadings. The plaintiffs in *Nargol* alleged that the defendant "made a series of false statements to the FDA and doctors, but for which the FDA would not have approved [devices] for hip replacements or would have withdrawn that approval, and doctors

would not have certified the devices for government reimbursement." *Id.* at 32. Plaintiffs sought to recover under the FCA, but the First Circuit rejected their theory. The FDA's decision not to suspend or withdraw its approval after learning of the alleged violations "render[ed] a claim of materiality implausible." *Id.* at 34. Even after the Government "heard what Relators had to say," it continued to pay claims. *Id.* at 36. On the issue of immateriality, this fact was "compelling." *Id.* at 35.

Punctuating the point, the First Circuit challenged the Ninth Circuit's logic in this very case. It observed that the Ninth Circuit "offers no rebuttal at all to [the] observation that six jurors should not be able to overrule the FDA." *Nargol*, 865 F.3d at 36. The Ninth Circuit does not "deem these problems fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solutions can be envisioned, even in theory." *Id.* But the First Circuit does.

The Third Circuit does, too. That court recently affirmed the dismissal of an FCA claim alleging misrepresentations related to the use and labeling of a drug—in another case, like this one, in which FDA approval was critical to government payment. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017). The problem with the plaintiff's theory was that the Government "would *consistently reimburse*" purchases of the drug "with full knowledge of the purported noncompliance." *Id.* at 490. Even after the plaintiff relayed the alleged false statements to the Government, the FDA neither initiated enforcement proceedings nor required changes to the drug's label. The Department of Justice followed

suit, taking no action against the defendant and declining to intervene in the FCA action. Given the Government's reaction, the allegations at most showed "'minor or insubstantial' noncompliance." *Id.*[5]

The Second Circuit similarly pointed to the Government's "operation in practice" after learning about alleged misrepresentations, holding (in a non-precedential opinion) that an FCA complaint failed to allege materiality. *Coyne v. Amgen, Inc.*, No. 17-1522-cv, 2017 WL 6459267, at *3 (2d Cir. Dec. 18, 2017) (Jacobs, Calabresi, Chin, JJ.). The court summarily affirmed the dismissal of an FCA complaint that alleged misrepresentations on the packaging of an anemia treatment. Crucial to that conclusion was that the complaint established the Government learned about the alleged misrepresentations when the defendant changed its labels. *Id.* at *2-*3. "Yet armed with this information, [the Government] did not alter its reimbursement practices … or exercise any independent discretion from the presumption of FDA approval." *Id.*

2. While FCA cases continue to arise in the context of pharmaceuticals and medical devices, cases

[5] The Ninth Circuit attempted to distinguish *Petratos* on the ground that the case included a concession that the Government would continue reimbursing claims even with knowledge of the alleged infractions. Pet. App. 31a. Such concessions are unnecessary if the complaint demonstrates that the Government's payment decisions were not affected by the alleged misrepresentations. *See Escobar*, 136 S. Ct. at 2003-04 & n.6.

from other industries follow the same practice of rejecting FCA claims on materiality grounds based on the Government's actual response.

The Seventh Circuit, for example, addressed a claim that a college falsely implied compliance with Title VI regulations in order to obtain federal funding. *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016). The plaintiff could not establish materiality because "the subsidizing agency and other federal agencies" already had investigated the college "multiple times over and concluded that neither administrative penalties nor termination was warranted." *Id.* at 447. Similarly, in a recent case involving aircraft parts, the Seventh Circuit deemed alleged false statements to be immaterial because the Government continued paying for the product at issue after investigating the plaintiff's concerns. *United States ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 563 (7th Cir. 2015).

The Fifth Circuit has also explained how governmental inaction undermines the assertion of materiality. In the context of regulatory requirements for oil producers, the court recognized "strong evidence" of immateriality in the Government's failure to take disciplinary action or terminate a contract following inquiries into alleged infractions. *Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 388 (5th Cir. 2017) (quoting *Escobar*, 136 S. Ct. at 2003-04). The Fifth Circuit followed the same logic in another recent case, holding that "continued payment by the federal government after it learns of the alleged fraud substantially in-

creases 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).[6]

The Tenth Circuit is in accord. In a recent case, the plaintiffs alleged that the defendant altered documents related to visas and work permits. *United States ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1165-66, 1168 (10th Cir. 2016). After learning of the alleged violations, the Government never withheld payment. Instead, it paid invoices "without objection or reservation." *Id.* at 1172. The plaintiffs' contentions thus were "simply incapable" of showing materiality. *Id.* at 1174.

Finally, the D.C. Circuit also appreciates "the benefit of hindsight" in resolving questions of materiality based on "what actually occurred." *United States ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027, 1034 (D.C. Cir. 2017). The court recently decided a case involving alleged misrepresentations about support services for American troops. The Government conducted an investigation after learning of the alleged misstatements and "did not disallow any charged costs." *Id.* To the contrary, it continued to pay "an award fee for exceptional performance." *Id.* That

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[6] In *Harman*, the Fifth Circuit did its best to distinguish the Ninth Circuit's decision in this case. But the distinction fails. The Fifth Circuit noted that "the record [in *Harman*] leaves no question about 'what the government knew and when.'" 872 F.3d at 668. The relevant question, though, is not exactly what the Government knew in one case or another. It is whether the plaintiff pled enough to overcome the clear inference to be drawn from the fact that the Government knew about the alleged misrepresentations and kept paying anyway.

amounted to "very strong evidence" of immateriality. *Id.* (quoting *Escobar*, 136 S. Ct. at 2003). Like its sister circuits, the D.C. Circuit recognized the powerful inference of immateriality that arises from the Government's failure to change its approval and payment behavior after learning of alleged infractions.

B. The Ninth Circuit's approach to materiality conflicts with that of its sister circuits.

The Ninth Circuit's decision is irreconcilable with all of these cases. In the Ninth Circuit, a plaintiff adequately pleads materiality by "alleg[ing] *more than the mere possibility* that the government would be entitled to refuse payment if it were aware of the violations." Pet. App. 32a (emphasis added). That court allows a plaintiff to overcome a motion to dismiss on materiality grounds simply by saying that it will dispute "exactly what the government knew and when." *Id.* The Ninth Circuit acknowledged here, for example, that "it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated." *Id.* Yet it refused to dismiss the case, because "such evidence is not before us." *Id.* In the Ninth Circuit, then, it is up to the *defendant* to show *immateriality*, even where the Government continued making purchases after it learned of the alleged violations. That is an impossible task on a motion to dismiss, where the court must accept the facts as alleged in the complaint.

In the six circuits with precedential opinions discussed above, the complaint would have been dismissed. Whenever a complaint is dismissed, there will be the possibility that discovery would later uncover facts that *could* reveal more about "exactly what the government knew and when." And in countless cases, the Government *could* "be entitled to refuse payment if it were aware of the violations." But as the cases from other circuits confirm, when the Government is aware of alleged infractions, the key question is how it responds. *Supra* I.A.

C. The Ninth Circuit's approach misinterprets *Escobar*.

The other circuits have the better of the argument with respect to the interpretation and application of *Escobar*. For one thing, the Ninth Circuit's logic has the rule exactly backwards: FCA plaintiffs must "plead their claims with plausibility." *Escobar*, 136 S. Ct. at 2004 n.6. And *Escobar* teaches that what is plausible to allege depends in large part on what actually occurred. 136 S. Ct. at 2003.

Moreover, "more than merely possible" is not the standard; the Government's mere "option to decline to pay" is not enough. 136 S. Ct. at 2003. Reliance on hypotheticals to demonstrate materiality does violence to *Escobar*, as the Fourth Circuit recently noted in reconciling its own previous approach to materiality with *Escobar*. *See United States v. Palin*, 874 F.3d 418, 422-23 (4th Cir. 2017) (recognizing that *Escobar* teaches that courts must look to "the likely or actual

behavior of the recipient of the alleged misrepresentation").[7]

This case illustrates the flaws in the Ninth Circuit's approach. The Government has known about the purported infractions for years—obviously since the initial complaint was filed in 2010, and even before: Gilead put the Government on notice of its intention to use Synthetics China as a supplier as early as 2008 and amended its prior approval supplement in 2009 to incorporate new test results regarding batches of FTC produced at a Synthetics China facility. Pet. App. 7a-8a. Indeed, Plaintiffs *themselves* "outline a variety of facts that speak to the government's knowledge," including an "inspection and noncompliance letter" from 2012 and inspections of facilities in 2012 and 2013. Pet. App. 30a-31a.

Despite this knowledge, the Government never suspended or withdrew its approval of the medicines at issue. It chose not to intervene in this suit. *Compare Petratos*, 855 F.3d at 490 (noting Department of

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[7] *See also United States v. Triple Canopy, Inc.*, 857 F.3d 174, 179 (4th Cir. 2017), *cert. dismissed*, No. 17-247, 2017 WL 3536480 (U.S. Oct. 20, 2017) (looking to actual conduct in reasoning that the Government's refusal to renew a contract and its intervention in an FCA lawsuit were "evidence that [the] falsehood affected the Government's decision to pay"). The Sixth Circuit followed the Fourth Circuit's prior rule emphasizing hypotheticals over actual results. *United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp.*, 400 F.3d 428, 445-46 (6th Cir. 2005), *superseded by statute on other grounds,* Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, 123 Stat. 1617 (2009). While the Fourth Circuit has since acknowledged *Escobar*'s focus on what actually occurred, the Sixth Circuit has not yet revisited the issue in light of *Escobar*.

Justice's failure to take action against the defendant and its decision not to intervene in the FCA lawsuit). It never denied payments or sought refunds for payments previously made. It even approved the very manufacturing facility that Plaintiffs complain about. Pet. App. 8a. Even on Plaintiffs' version of the facts, the implication could hardly be clearer: The only ones who think there is an issue worth pursuing are the private individuals who stand to reap an enormous personal windfall. As far as the experts at the FDA are concerned, the allegedly false claims do not warrant any changes in drug approval or government payment behavior. And Plaintiffs offer nothing to overcome this "very strong evidence" of immateriality. *Escobar*, 136 S. Ct. at 2003.

Contrary to the Ninth Circuit's rationale, reflexively treating materiality issues as "matters of proof" to be saved for later is exactly what courts are *not* supposed to do; that is the entire point of *Escobar*'s instruction that materiality can be resolved on a motion to dismiss or on summary judgment. *See id.* at 2004 n.6. When the Government's payments were not affected by the alleged misrepresentations, that is powerful evidence of immateriality, which the plaintiff must overcome if the case is to proceed. Plaintiffs here did not make any such showing. That should spell the end of their claim—as it does in six circuits.

II. The Question Presented Is Important, Recurring, And Warrants This Court's Immediate Resolution.

The disagreement among the circuits over how to apply *Escobar* highlights the need for clarification

from this Court. In the last two years, the adjudication of materiality at the pleading stage in the FCA context alone has yielded five cases in four circuits. In the past three years, four more circuits have addressed the relevance of government knowledge to materiality in other contexts. The sheer frequency with which these cases have been reaching the courts of appeals is proof that now is the time for this Court to provide further guidance.

1. The Ninth Circuit's decision dangerously transfers regulatory authority from expert agencies to private litigants. That approach could affect the availability of drugs and other valued products and services. These are serious consequences for lawsuits "motivated primarily by prospects of monetary reward rather than the public good." *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997); *cf. United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 765 (3d Cir. 2017) ("[A]t base, this case appears to be nothing more than an effort to convert an unprofitable private audit … into a successful recovery of funds under the guise of a qui tam action.").

The consequences are particularly stark in the FDA context presented here. The FDA is the expert agency charged with regulating highly complex, research-and-development-intensive products that can be distributed globally and used across a range of government programs, as was the case with the drugs at issue here. Moreover, "the federal statutory scheme amply empowers the FDA to punish and deter fraud." *Buckman*, 531 U.S. at 348. The FDA "possesses a full array of tools" for combating fraud during the drug

and device approval process and is "armed with robust investigatory powers to protect public health and safety." *Nargol*, 865 F.3d at 34-35. "[T]his authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Buckman*, 531 U.S. at 348. That is why the FDA's expert judgment is so important, why FCA lawsuits by private individuals are so problematic when the agency has chosen not to act, and why the FDA's response to alleged infractions is such powerful evidence of immateriality. *See Nargol*, 865 F.3d at 35.

Ultimately, the FDA is best equipped to decide how to respond to alleged infractions. *See id.* at 36. Congress did not intend for "a jury of six people" to be able to "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." *D'Agostino*, 845 F.3d at 8. And even if the FCA litigation does not succeed (or settles), a lawsuit second-guessing the FDA's decisions forces regulated companies to navigate an additional, costly layer of oversight.

The need for consistency across jurisdictions is all the more important because manufacturers of pharmaceutical products and medical devices are not all based in the same jurisdiction. If the complaint in this case had been filed in Massachusetts or New Jersey, this litigation would be at an end. It cannot be that the outcomes of federal causes of action turn on the whim of geography. So long as they do, plaintiffs will seek a way to bring their cases to the Ninth Circuit, citing the nationwide distribution of products and the multiple locations of many manufacturers.

Medical suppliers and their customers have much to lose if the Ninth Circuit's approach is allowed to stand. There will be transfers of money—and corresponding increases in prices—from producers to private plaintiffs in FCA suits, even when the FDA never withdrew its approval and the Government was content to keep paying for the products in question because it received the full value of what it purchased.

And that is the best-case scenario if review is denied. The amount of money at stake is dizzying—"essentially punitive in nature," in this Court's own words. *Stevens*, 529 U.S. at 784. Civil penalties for FCA violations now range from a minimum of $10,957 to a maximum of $21,916 *per claim*, 28 C.F.R. § 85.5; *see Stevens*, 529 U.S. at 769, before factoring in treble damages for the Government's losses, 31 U.S.C. § 3729(a). Last year alone, the Department of Justice "obtained more than $4.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government." *DOJ, Justice Department Recovers Over $4.7 Billion From False Claims Act Cases in Fiscal Year 2016* (Dec. 14, 2016), http://tinyurl.com/j3jobgb. The amount paid out to private individuals in that time was also staggering: $519 million. *Id.* The bleaker possibility is therefore that the specter of massive FCA recoveries will lead some producers to restrict or discontinue products that people need and that the FDA wants them to have.

These concerns are heightened by the reality that, given the scope and complexity of FDA regulations, infractions are inevitable. In a recent one-year period, the FDA issued over 4,500 notifications of possible

statutory violations, 691 for drug products.[8] Yet not all violations rise to the same level of severity. Where the FDA sees a minor mistake unlikely to reduce the efficacy of an important treatment, it can continue approving and the Government can continue paying for the drug while using other tools to improve compliance going forward. By contrast, FCA lawsuits are a blunt instrument, yielding the prospect of huge damages for any misstep. That is why such suits are limited to the domain of material misrepresentations.

The Government spent over $117 billion on prescription drugs in 2016 through Medicare and Medicaid alone. Centers for Medicare & Medicaid Services, *National Health Expenditures by Type of Service and Source of Funds, CY 1960-2015* (last updated Dec. 7, 2017), http://tinyurl.com/cm5jfk4. That is 117 billion reasons to scour the Code of Federal Regulations and scrutinize pharmaceutical companies' every move, looking for any hint of a violation that might lead to a reward. The materiality requirement exists to push back against this financial pressure for an ever-expanding FCA.

2. Of course, the FCA covers far more than medical products, so similar concerns apply to industry after industry. Already, district courts in the Ninth Circuit are turning the FCA into "an all-purpose antifraud statute," *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine Co. v. United States ex rel. Sanders*,

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[8] FDA, *FDA Form 483 Frequently Asked Questions* (last updated July 24, 2017), http://tinyurl.com/y6udmwox; FDA, *FY 2016 Inspectional Observation Summaries* (last updated Dec. 14, 2016), https://tinyurl.com/y9usftmq.

553 U.S. 662, 672 (2008)), far beyond the medical context. One court, for example, applied the Ninth Circuit's decision in this case in the Small Business Administration context, to reject an argument that alleged false claims by an Alaskan company were immaterial because "the government has been aware of relator's allegations for almost four years" without changing its behavior. *United States ex rel. Ferris v. Afognak Native Corp.*, No. 3:15-cv-00150-HRH, Dkt. No. 295, at 14-17 (D. Alaska Aug. 11, 2017). Next up could be military contractors, *Kellogg Brown & Root Servs. v. United States ex rel. Carter*, 135 S. Ct. 1970 (2015); *McBride*, 848 F.3d 1027; *Marshall*, 812 F.3d 556; healthcare providers, *see Escobar*, 136 S. Ct. 1989; energy companies, *Abbott*, 851 F.3d 384; institutions of higher education, *Sanford-Brown*, 840 F.3d 445; or insurance companies, *see State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 137 S. Ct. 436 (2016).

Permitting cases to proceed past a motion to dismiss even when the complaint fails to plausibly allege materiality will subject companies that already spend a fortune on regulatory compliance to burdensome discovery. The Government will feel the sting as well. A complaint that survives the Ninth Circuit's watered-down materiality analysis will mire agencies like the FDA in years of onerous fact-gathering concerning the degree of their knowledge, even when the complaint already establishes that the Government knew enough to decide whether to act.

As long as the Ninth Circuit's rule stands, these cases will continue to come in droves. That makes it all the more urgent for this Court to act now, both to

resolve the existing circuit split and to make clear that *Escobar* cannot be circumvented by implausible allegations that clash with how the Government actually reacted.

III. This Case Presents An Ideal Vehicle For The Court's Review.

This case is an excellent vehicle for resolving the circuit split over the interplay between materiality and the Government's response to alleged misrepresentations. Gilead argued below that Plaintiffs' theory is "too implausible to survive … because the government, despite knowing about these allegations for at least five years, has never taken any steps to withdraw approval for these medicines." C.A.41, at 34. Following this Court's decision in *Escobar*, Gilead notified the Ninth Circuit of the "numerous courts" that had "dismissed False Claims Act claims for lack of materiality where the government knew of the alleged violations and nevertheless continued to make payments to the defendant." C.A.49 (28(j) Ltr. from Gilead). The Ninth Circuit set forth its contrary interpretation of the FCA in plain terms: A plaintiff can "sufficiently plead[] materiality" by "alleg[ing] more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations." Pet. App. 32a. Granting certiorari would allow this Court to provide guidance on a significant and recurring issue by clarifying how the Government's response upon learning of alleged infractions affects the viability of an FCA complaint.

Finally, the case's procedural posture—arising on a motion to dismiss—confirms its desirability as a vehicle for review. The First and Third Circuit cases that halted FCA claims in the FDA context did so at the pleadings stage. *See Nargol*, 865 F.3d at 31; *Petratos*, 855 F.3d at 485; *D'Agostino*, 845 F.3d at 3. Such cases now have new life in the Ninth Circuit, notwithstanding *Escobar*'s teaching that materiality is not "too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment." 136 S. Ct. at 2004 n.6. This case is an opportunity to put that principle into action.

CONCLUSION

For the foregoing reasons, this Court should grant the petition.

Respectfully submitted,

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