No. 17-936

In the Supreme Court of the United States

GILEAD SCIENCES, INC., PETITIONER

v.

UNITED STATES EX REL. JEFFREY CAMPIE, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

NOEL J. FRANCISCO
Solicitor General
Counsel of Record
JOSEPH H. HUNT
Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
ALLON KEDEM
Assistant to the Solicitor General
MICHAEL S. RAAB
CHARLES W. SCARBOROUGH
WEILI J. SHAW
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether the government's continued payment for a product, after learning of allegations that the manufacturer had made misrepresentations to the government regarding that product, requires dismissal at the pleading stage of a suit under the False Claims Act, 31 U.S.C. 3729 *et seq.*, on the ground that any misrepresentations were not material as a matter of law.

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INTEREST OF THE UNITED STATES

This brief is submitted in response to this Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. The False Claims Act (FCA), 31 U.S.C. 3729 *et seq.*, imposes civil liability for a variety of deceptive practices involving government funds or property. Among other things, it renders liable any person who "knowingly presents, or causes to be presented" to the federal government "a false or fraudulent claim for payment or approval." 31 U.S.C. 3729(a)(1)(A). A person who violates the FCA is liable to the United States for civil penalties plus three times the amount of the government's damages. 31 U.S.C. 3729(a)(1).

The Attorney General may bring a civil action under the FCA. 31 U.S.C. 3730(a). The FCA also authorizes

private parties, known as relators, to file *qui tam* suits on behalf of the United States. 31 U.S.C. 3730(b)(1). When a relator brings a *qui tam* action, the government may intervene and proceed with the suit, 31 U.S.C. 3730(b)(2) and (c)(1), or it may decline to intervene and allow the relator to conduct the suit alone, 31 U.S.C. 3730(c)(3). In either event, if the suit is ultimately successful, the relator receives a portion of the recovery. 31 U.S.C. 3730(d). The FCA authorizes the Attorney General to move to dismiss suits filed under the Act. 31 U.S.C. 3730(c)(2)(A).

b. Under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, a manufacturer may not market a drug in the United States unless it first submits a new drug application to the Food and Drug Administration (FDA) and receives FDA approval. 21 U.S.C. 355(a). The FDA will approve an application only after determining, among other things, that the new drug is safe and effective for its intended use. See 21 U.S.C. 355 (2012 & Supp. V 2017). A manufacturer seeking approval must provide the FDA with a variety of information, including "a full list of the articles used as components of such drug," 21 U.S.C. 355(b)(1)(B), and "a full description of the methods used in, and the facilities and controls for, the manufacture, processing, and packing of such drug," 21 U.S.C. 355(b)(1)(D).

After a new drug has been approved, the manufacturer must submit a Prior Approval Supplement (PAS) in order to obtain FDA approval for any major manufacturing changes. 21 U.S.C. 356a(c)(1) and (2). The manufacturer must obtain FDA approval before distributing products made using the changed manufacturing practices. 21 C.F.R. 314.70(b). Foreign establishments

that manufacture drugs must register with the FDA before the drugs can be imported into the United States. 21 U.S.C. 360(i); 21 C.F.R. 207.21(b).

Adulterated or misbranded drugs may not be introduced into interstate commerce. 21 U.S.C. 331(a). A drug is adulterated if, among other things, "the methods used in, or the facilities or controls used for, its manufacture * * * do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that" the drug meets its stated quality and purity characteristics. 21 U.S.C. 351(a)(2)(B). A drug is misbranded if, among other things, "it was manufactured * * * in an establishment not duly registered" with the FDA. 21 U.S.C. 352(*o*).

The FDA is authorized or required to withdraw an existing drug approval under specified circumstances, which generally require findings that the benefits of the drug no longer exceed the risks. See 21 U.S.C. 355(e). If the FDA proposes to withdraw approval, the drug's sponsor has substantial procedural rights, including a right to judicial review. See *ibid.*; 21 U.S.C. 355(h); 21 C.F.R. 314.200(g). Given the rigors of this process, and the FDA's public-health obligation to avoid unnecessarily limiting patient access to safe and effective drugs, see generally 21 U.S.C. 355(d), 355-1, 393(b), the agency very rarely undertakes this process. Rather, when the FDA becomes aware of a problem with an approved drug, it typically seeks to address the problem through less disruptive mechanisms. See 21 U.S.C. 355(e), 355(*o*)(3)-(4), 355-1; 21 C.F.R. 201.57, 314.80(j).

c. FDA approval is relevant to payments made under many government healthcare programs. Some government agencies purchase pharmaceutical products directly. In those circumstances, FDA approval may be

a prerequisite for the agencies' purchases. See 48 C.F.R. 46.408.

Other government programs operate under a reimbursement model, in which program beneficiaries receive goods or services directly from a private entity, which then seeks reimbursement from the federal government. FDA approval generally is a precondition for coverage and payment under Medicaid and under Medicare Part D's prescription-drug benefit for self-administered drugs. See 42 U.S.C. 1396r-8(k)(2)(A); 42 U.S.C. 1395w-102(e)(1). FDA approval is also typically required for drug reimbursement under Medicare Part B. See Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., *Medicare Benefit Policy Manual*, Ch. 15, § 50.4 (Rev. 241, Feb. 2018), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

2. Petitioner manufactures several drugs used in treating HIV. Pet. App. 5a. When petitioner obtained FDA approval for three of its drugs, it represented that it would source the drugs' active ingredient, emtricitabine (known as FTC), from specified registered facilities in the United States, Canada, Germany, and South Korea. *Id.* at 6a-7a. Respondents are former employees of petitioner who allege that, after obtaining FDA approval, petitioner covertly contracted to produce FTC with a Chinese manufacturer, Synthetics China, using an unregistered facility that was not approved for that purpose. *Id.* at 7a. Petitioner allegedly imported FTC from Synthetics China into the United States beginning in December 2007, falsely telling the FDA that the FTC came from its approved manufacturer in South Korea. *Ibid.*

In October 2008, petitioner sought approval to use Synthetics China to manufacture FTC. Pet. App. 7a.

Respondents allege that petitioner falsified or concealed data in order to obtain that approval. *Id.* at 7a-8a. The FDA approved petitioner's amended PAS in May 2009, and the Synthetics China facility was registered in 2010. *Id.* at 8a. Petitioner stopped using Synthetics China in 2011 because of contamination issues, which petitioner had allegedly concealed. *Id.* at 8a.

3. Respondents filed suit against petitioner under the FCA. Respondents alleged that the FDA "would not have approved the use of the Synthetics China manufacturing facility" if it had not been misled as to the relevant facts. Pet. App. 8a. Respondents further alleged that, "because the drugs paid for by the government contained FTC sourced at unregistered facilities, they were not FDA approved and therefore not eligible for payment under the government programs." *Id.* at 9a. Respondents also alleged that the contaminated drugs were "adulterated" or "misbranded" and therefore could not lawfully be introduced into or received in interstate commerce. *Ibid.* (quoting 21 U.S.C. 331(a) and (c)); see *id.* at 9a-10a.

a. The district court dismissed respondents' second amended complaint for failure to state a claim. Pet. App. 38a-71a. The court held that respondents could not establish that petitioner had submitted a false claim for payment because (in the court's view) petitioner's alleged misrepresentations were made only to the FDA, not directly to the agencies that had paid the relevant claims (such as the Centers for Medicare and Medicaid Services (CMS)). *Id.* at 48a-57a. The court also rejected what it characterized as respondents' argument that petitioner had unlawfully sought reimbursement for "worthless" drugs, concluding that respondents had

failed to plead that the drugs had "*no* medical value at all." *Id.* at 58a; see *id.* at 58a-59a.

b. The court of appeals reversed. Pet. App. 1a-37a. The court held that a claimant who seeks payment for nonconforming goods may face FCA liability even if the goods are not totally worthless. *Id.* at 15a-18a, 21a-22a.

The court of appeals also rejected the district court's conclusion that respondents' FCA claims were deficient "because the alleged fraud was directed at the FDA, not the payor agency." Pet. App. 23a. The court stated that, if a defendant's false statements were an essential part of a causal chain leading to payments of federal funds, the fact that the misstatements were made to persons other than the payor agency would not preclude FCA liability. See *id.* at 23a-24a. The court also noted respondents' allegation that, "in addition to making a number of false and fraudulent statements to the FDA, [petitioner's] submission of alleged unapproved and noncompliant drugs to the payor agencies was itself an alleged false certification." *Id.* at 24a.

The court of appeals further held that respondents had adequately alleged materiality. Pet. App. 27a-33a. The court explained that, under this Court's decision in *Universal Health Services, Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (*Escobar*), the materiality inquiry "turns on a number of factors" bearing on the likelihood that the misstatement affected the government's payment decision. Pet. App. 29a. Emphasizing one such factor identified in *Escobar*, petitioner argued that any misstatements in this case could not have been material because "the government continued to pay for the medications after it knew of the FDA violations." *Id.* at 30a.

The court of appeals agreed that, given the government's continued payments, respondents "face[d] an uphill battle in alleging materiality." Pet. App. 28a. The court explained, however, that petitioner had "ultimately stopped using FTC from Synthetics China," and that "[o]nce the unapproved and contaminated drugs were no longer being used, the government's decision to keep paying for compliant drugs does not have the same significance." *Id.* at 31a. The court further explained that "the parties dispute exactly what the government knew and when, calling into question its actual knowledge." *Id.* at 32a (internal quotation marks omitted). The court remanded for further proceedings, explaining that, because the district court had not addressed whether respondents' complaint satisfies the heightened-pleading standard of Federal Rule of Civil Procedure 9(b), the court of appeals would not decide that question in the first instance. *Id.* at 33a, 37a.

DISCUSSION

The courts of appeals recognize that the government's continued payment for a product, after learning that the manufacturer has made misrepresentations to the government regarding that product, can be strong evidence that the misrepresentations were not material to the government's payment decisions. The court below agreed with that proposition. It nevertheless concluded, under the circumstances of this case, that the fact of continued government payments did not by itself require dismissal of respondents' claims at the pleading stage. That conclusion was correct and was consistent with decisions issued by other circuits in comparable circumstances. Further review is not warranted.

A. The Government's Continued Payment For Petitioner's Drugs, Despite Knowledge Of Allegations That Petitioner Had Made Misstatements Concerning Those Drugs, Did Not Render The Alleged Misstatements Immaterial As A Matter Of Law

1. Under the FCA, "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." *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 136 S. Ct. 1989, 2002 (2016). The FCA defines the term "material" to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. 3729(b)(4). Whether a misrepresentation is material turns on its "effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Escobar*, 136 S. Ct. at 2002 (quoting 26 R. Lord, *Williston on Contracts* § 69:12, at 549 (4th ed. 2003)).

The Court in *Escobar* stated that the FCA's "materiality standard is demanding," and that a variety of factors are "relevant" to the inquiry. 136 S. Ct. at 2003. A party's misstatement about its compliance with a legal or contractual requirement is more likely to be material when the requirement goes to the "essence of the bargain," and when the party's noncompliance has been significant rather than "minor or insubstantial." *Id.* at 2003 & n.5 (internal quotation marks omitted). The Court explained that, when assessing materiality, no one factor is "automatically dispositive." *Id.* at 2003.

Of particular relevance here, the Court in *Escobar* discussed the significance to the materiality inquiry of the government's actual payment decisions. The Court

stated that it is not "sufficient for a finding of materiality that the Government would have the *option* to decline to pay if it knew of the defendant's noncompliance." 136 S. Ct. at 2003 (emphasis added). Rather, the Court explained, the inquiry should focus on the likely effect of accurate information on the government's payment decision:

> [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. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003-2004.

2. In this case, the court of appeals correctly stated and applied the relevant principles for determining materiality under *Escobar*. The court recognized that the determination whether a misstatement is material "turns on a number of factors," including the government's payment decisions. Pet. App. 29a. The court explained that, because federal agencies had continued to pay for petitioner's drugs after being made aware of some of the allegations of petitioner's misconduct, respondents "face[d] an uphill battle in alleging materiality sufficient to maintain their claims." *Id.* at 28a.

Based on a number of case-specific circumstances, however, the court concluded that the fact of continued government payments did not dictate dismissal of respondents' complaint at the pleading stage. *Id.* at 31a-32a.

Most significantly, the court of appeals recognized that, under *Escobar*, the relevance of a government payment decision turns on whether the government had "actual knowledge" of violations at the time of payment. Pet. App. 32a; see *Escobar*, 136 S. Ct. at 2003 (noting that, when "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," that payment decision is "very strong evidence" of immateriality). The court emphasized that in this case, "the parties dispute exactly what the government knew and when, calling into question its 'actual knowledge'" with respect to petitioner's misconduct. Pet. App. 32a. Respondents' complaint includes detailed allegations that petitioner falsified documents and engaged in other behavior designed to conceal its wrongdoing from the government. See pp. 4-5, *supra*. The pleadings also provide no basis for concluding "that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated." Pet. App. 32a; see C.A. E.R. 138, ¶ 142 (allegation in second amended complaint that the government has previously sought recovery under the FCA against defendants engaged in similar misconduct).

The court of appeals also correctly recognized that, even when the government has actual knowledge of *past* legal or contractual violations, continued payments do not always show that the violations were immaterial. Pet. App. 31a. The government sometimes learns of prior violations only after a contractor's noncompliance

has been rectified. If the government continues to buy the relevant goods thereafter, its "decision to keep paying for compliant [goods] does not have the same significance as if the government continued to pay despite continued noncompliance." *Ibid.*

3. Petitioner contends (Pet. 21) that any alleged misstatements it made about its compliance with FDA requirements were immaterial as a matter of law because the government "has known about the purported infractions for years," yet has not stopped paying for petitioner's drugs. Petitioner argues (*ibid.*) that the government was on notice of any misconduct at least since 2010, when respondents' FCA complaint was filed. Petitioner also points (*ibid.*) to its 2009 amended PAS, which "incorporate[d] new test results regarding batches of FTC produced at a Synthetics China facility"; and to an FDA warning letter issued to petitioner in 2012, which was followed by inspections of petitioner's facilities in 2012 and 2013. Petitioner argues (Pet. 21-22) that the government's continued payment for petitioner's drugs under those circumstances creates a strong presumption of immateriality that respondents have failed to overcome.

a. Most of the circumstances on which petitioner relies do not necessarily show relevant government knowledge. Petitioner does not claim, and the current record does not reflect, that its disclosures in the 2009 amended PAS were accurate and complete; indeed, respondents allege otherwise. See Pet. App. 7a-8a (describing allegation that petitioner failed to disclose two contaminated drug batches in its amended PAS). It is also not clear whether the 2012 warning letter concerned precisely the same subject-matter as respondents' allegations, or what the government's subsequent

inspections revealed. The extent and timing of the government's "actual knowledge" of wrongdoing is accordingly unsettled at this stage of the litigation. See *id.* at 32a (factual disputes "call[] into question" what the government knew at the time of payments).

b. More fundamentally, petitioner's argument conflates the government's knowledge of *allegations* that contractual or legal requirements have been violated, which the government may potentially obtain through a *qui tam* complaint or other sources, with government knowledge that violations have *actually occurred*. The Court in *Escobar* identified government payments made with "actual knowledge that certain requirements were violated" as a circumstance tending to disprove materiality, 136 S. Ct. at 2003, but it did not suggest that knowledge of allegations has the same significance. As the First Circuit observed on remand from this Court's decision in *Escobar*, "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *United States ex rel. Escobar* v. *Universal Health Servs., Inc.*, 842 F.3d 103, 112 (2016).

When it has received allegations that a particular contracting partner has violated legal or contractual requirements, the government may have a variety of reasons for continuing to pay that entity for goods or services. At least initially, the government may pay claims in order to keep federal programs operating, and to ensure compliance with the government's own legal and contractual obligations, while it investigates the allegations. At a later date, the government may have investigated the allegations but concluded (perhaps incorrectly) that no violation has occurred. The government

may have investigated and found past violations but believe (perhaps incorrectly) that the defendant will comply going forward. Or the government may have determined that the alleged violation is not sufficiently serious to warrant a refusal to pay. Of the possible motivations included in this non-exhaustive list, only the last implies that the requirements alleged to have been violated were not material to the government's payment decision.

c. Petitioner acknowledges (Reply Br. 4) that "[t]here may be circumstances" in which the government continues payment despite violations that are material. Petitioner nevertheless argues (*ibid.*) that an FCA relator has the burden, at the pleading stage, to establish the government's motivations for doing so. Petitioner contends that, unless the relator can satisfy that requirement, the government's continued payments must be treated as "dispositive" of materiality, requiring dismissal of the complaint. *Id.* at 3.

Petitioner's proposed rule is inconsistent both with *Escobar* and with background pleading rules. Requiring dismissal whenever a complaint fails to identify the government's motivation for continued payments would render a single factor "automatically dispositive" in precisely the manner that *Escobar* rejected. 136 S. Ct. at 2003. Petitioner's approach would thus negate the relevance of other factors, such as whether the alleged violation goes to the essence of the government's bargain, and whether the defendant's alleged infractions are minor or substantial. See *id.* at 2003-2004. Where several reasonable inferences from alleged facts are possible, drawing *only* the inference least favorable to the nonmoving party "improperly inver[t]s the pleading standard." *United States ex rel. Prather* v. *Brookdale*

Senior Living Cmtys., Inc., 892 F.3d 822, 834 (6th Cir. 2018); see *Ashcroft* v. *Iqbal*, 556 U.S. 662, 678 (2009) (plaintiff must allege enough facts to allow the court to "draw the reasonable inference that the defendant is liable for the misconduct alleged").

Petitioner correctly emphasizes (Reply Br. 5) that, even at the pleading stage, an FCA relator cannot rest solely on "conjecture" or "speculation." A relator's burden is to plead with particularity facts from which a factfinder might plausibly infer that the relevant misstatements were material. And given *Escobar*'s holding that not every violation of a federal payment condition is material, see 136 S. Ct. at 2003, a complaint may be inadequate as to materiality even though it adequately alleges a violation. That distinction has particular salience in this case. Because the FDA rarely withdraws an existing drug approval even when it finds a violation, see p. 3, *supra*, an FCA plaintiff must ordinarily allege substantially more than a violation simpliciter in order to raise a reasonable inference that the agency would have withdrawn a drug approval if it had known of the defendant's breach.

Nothing in the decision below, however, is inconsistent with those principles. A number of facts may be "relevant to but not dispositive of" the materiality inquiry. *Escobar*, 136 S. Ct. at 2001. In circumstances where the relator has pleaded facts other than the government's payment decision that support an inference of materiality, a relator need not *also* plead facts establishing the government's motivations for its payment decision.

d. Petitioner argues (Pet. 23-24) that the Ninth Circuit's decision would allow juries to second-guess the expert judgments of agencies like the FDA, and thus to

interfere with important regulatory objectives. Under the FCA, however, the United States is authorized to dismiss *qui tam* suits over a relator's objection. 31 U.S.C. 3730(c)(2)(A). The United States has exercised that authority in many cases where continuation of the litigation would have interfered with the work of the affected federal agency. See, *e.g.*, *United States ex rel. Mateski* v. *Mateski*, 634 Fed. Appx. 192 (9th Cir. 2015); *Ridenour* v. *Kaiser-Hill Co., LLC*, 397 F.3d 925 (10th Cir.), cert. denied, 546 U.S. 816 (2005); *Swift* v. *United States*, 318 F.3d 250 (D.C. Cir.), cert. denied, 539 U.S. 944 (2003). The government's authority to dismiss *qui tam* suits is not limited to circumstances where the defendant is *entitled* to dismissal on legal or factual grounds, but may be exercised whenever the government concludes that continued prosecution of the suit is not in the public interest.

Pursuant to that authority, the Department of Justice has determined that, if this case is remanded to the district court, the government will move to dismiss respondents' suit under Section 3730(c)(2)(A). That determination is based in part on the government's thorough investigation of respondents' allegations and the merits thereof. In addition, if this suit proceeded past the pleading stage, both parties might file burdensome discovery and *Touhy* requests for FDA documents and FDA employee discovery (and potentially trial testimony), in order to establish "exactly what the government knew and when," which would distract from the agency's public-health responsibilities. Pet. App. 32a; see *United States ex rel. Sequoia Orange Co.* v. *Baird-Neece Packing Corp.*, 151 F.3d 1139, 1146 (9th Cir. 1998) (holding that goal of minimizing expenses and burdens on government resources is a legitimate ground

for exercising the government's dismissal authority under Section 3730(c)(2)(A)), cert. denied, 525 U.S. 1067 (1999). Based on all those considerations, the government has concluded that allowing this suit to proceed to discovery (and potentially a trial) would impinge on agency decisionmaking and discretion and would disserve the interests of the United States.*

4. In concluding that respondents had adequately alleged facts from which the materiality of petitioner's misrepresentations could reasonably be inferred at the pleading stage, the court of appeals stated that respondents "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 (citing *United States ex rel. Kelly* v. *Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017). Petitioner repeatedly asserts (Pet. 2, 11, 19, 28) that the court thereby established "more than mere possibility" as the governing legal test. That is incorrect.

In *Kelly*, the Ninth Circuit noted this Court's holding in *Escobar* that the government's *legal authority* to re-

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* The government also has means short of dismissal for making clear that the relevant agency does not view adherence to particular restrictions as material to its payment decisions. See Br. in Opp. 26 n.1 ("[N]o one suggests that a relator should prevail by arguing that the FDA would have withdrawn approval if the FDA states that it would not have done so."); *United States ex rel. Harman* v. *Trinity Indus. Inc.*, 872 F.3d 645, 650, 652, 663-664 (5th Cir. 2017) (holding that the evidence at trial did not permit a finding of materiality, and that the defendant therefore was entitled to judgment as a matter of law, based on a Federal Highway Administration memorandum stating the agency's view that allegedly noncompliant guardrails remained eligible for reimbursement at all times), petition for cert. pending, No. 17-1149 (filed Feb. 12, 2018).

fuse payment based on a particular breach is insufficient, standing alone, to establish that the breach is material. See *Kelly*, 846 F.3d at 334 (citing *Escobar*, 136 S. Ct. at 2004). The *Kelly* court then stated: "Likewise, here, the possibility that the government would be entitled to refuse payment if it were aware of Serco's alleged violations is insufficient by itself to support a finding of materiality." *Ibid.* The language in the opinion below that petitioner highlights did not articulate a legal test, but simply distinguished this case from *Kelly*. See Br. in Opp. 24. That language is best understood to mean that respondents have alleged more than a mere legal entitlement for the government to withhold payment; they have alleged facts from which one reasonable inference is that the government would have taken that course if it had known all the relevant facts when the payment decisions were made.

B. The Decision Below Does Not Conflict With Decisions Of Other Courts Of Appeals

The courts of appeals that have considered the question broadly agree that materiality is a holistic inquiry and that continued payment by the government, despite actual knowledge of violations, can constitute important but not necessarily dispositive evidence that the violations were not material.

1. Several of the decisions on which petitioner relies are distinguishable because they arose at summary judgment or after trial, rather than at the pleading stage. See *Harman*, *supra* (after trial); *Abbott* v. *BP Exploration & Prod., Inc.*, 851 F.3d 384 (5th Cir. 2017) (summary judgment); *United States ex rel. McBride* v. *Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (summary judgment); *United States* v. *Sanford-Brown, Ltd.*, 840 F.3d 445 (7th Cir. 2016) (summary judgment); see

also *United States ex rel. Thomas* v. *Black & Veatch Special Projects Corp.*, 820 F.3d 1162 (10th Cir. 2016) (summary judgment; prior to *Escobar*); *United States ex rel. Marshall* v. *Woodward, Inc.*, 812 F.3d 556 (7th Cir. 2015) (summary judgment; prior to *Escobar*), cert. denied, 136 S. Ct. 2510 (2016). At those later stages of a case, the plaintiff cannot rest on the pleadings, but must identify record evidence that creates a genuine factual dispute.

In *Abbott*, for example, the summary-judgment record included a detailed report of the government's "full investigation" of the defendant's wrongdoing—conducted after congressional hearings into the matter—which explained at length the government's decision not to take action. 851 F.3d at 386. Given such evidence of the government's "substantial investigation into [the] Plaintiffs' allegations," the government's explanation of its reasons for not acting, and the plaintiffs' failure to introduce contrary evidence, the court concluded that the plaintiffs had "failed to create a genuine dispute of material fact as to materiality." *Id.* at 388; see *Sanford-Brown*, 840 F.3d at 447 (relying on evidence of "multiple" investigations by several federal agencies) (citation omitted); *Marshall*, 812 F.3d at 563-564 (relying on results of government investigation, including deposition testimony from investigator). The circumstances of this case, in which respondents' complaint does not indicate that the government had actual knowledge of violations at the time of payment, are not comparable.

2. The pleading-stage decisions that petitioner cites (Pet. 14-16) likewise do not conflict with the ruling below.

On remand from this Court's decision in *Escobar*, the defendant argued that, in light of the government's continued payment of claims, the misrepresentations alleged in the relator's complaint (regarding a mental health facility's compliance with licensing and supervision requirements) should be deemed immaterial as a matter of law. 842 F.3d at 110-112. In rejecting that argument, the court explained that *Escobar* requires a "holistic approach to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive." *Id.* at 109. The court further observed that "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance." *Id.* at 112.

Contrary to petitioner's contention (Pet. 14-15), subsequent First Circuit decisions have not retreated from this analysis. *D'Agostino* v. *ev3, Inc.*, 845 F.3d 1 (2016), did not involve a dispute about materiality. Instead, the court concluded that the relator had not alleged a sufficient "causal link between the representations made to the FDA and the payments made by CMS." *Id.* at 7. The court explained that, although the relator had "trie[d] to rebut th[at] conclusion by relying on the FCA's materiality standard," the relator had "misconstrue[d]" that standard. *Ibid.* The court then made the statement, on which petitioner relies (Pet. 14), that "[t]he fact that CMS has not denied reimbursement for [the defendant's product] in the wake of [the relator's] allegations casts serious doubt on the materiality of the fraudulent representations that [the relator] alleges." 845 F.3d at 7. But the court did not rule that the misstatements were immaterial as a matter of law. Rather, it held only that the relator would be unable to prove

causation "even if the alleged fraudulent representations were material." *Ibid.*

Petitioner's reliance on *United States ex rel. Nargol* v. *DePuy Orthopaedics, Inc.*, 865 F.3d 29 (1st Cir. 2017), cert. denied, 138 S. Ct. 1551 (2018), is similarly misplaced. Materiality was at issue in *Nargol*, but the circumstances of that case differed significantly from those involved here. In *Nargol*, the First Circuit found, based on the relators' own allegations, that the "Relators told the FDA about every aspect of the design" that was alleged to be defective. *Id.* at 35; see *id.* at 36 (relators "fully informed [the] FDA" about the defects). In this case, by contrast, the court of appeals noted the existence of a "dispute" about "exactly what the government knew and when." Pet. App. 32a. Although portions of the First Circuit's opinion in *Nargol* elide the distinction between the government's knowledge of *allegations* and its knowledge of *actual violations*, there is no reason to believe that the decision represents an abandonment of the principles articulated on remand in *Escobar*.

In *Coyne* v. *Amgen, Inc.*, 717 Fed. Appx. 26 (2017), the Second Circuit found the defendant's alleged misrepresentations about its drug to be immaterial based on multiple factors, including the complaint's failure to "present concrete allegations from which the court may draw the reasonable inference that the misrepresentations on [the defendant's] packaging and marketing materials caused the Government to make the reimbursement decision." *Id.* at 29; see *ibid.* ("The amended complaint relies on a conclusory assertion."). After concluding that the alleged misrepresentations were "unlikely to impact CMS reimbursement," the court explained that the government's inaction upon discovering the

truth "confirms the lack of materiality." *Ibid.* The court thus treated the government's continued payment as one of several factors bearing on materiality.

The Third Circuit in *United States ex rel. Petratos* v. *Genentech Inc.*, 855 F.3d 481 (2017), similarly relied on multiple factors, including the "minor or insubstantial noncompliance" alleged by the relator. *Id.* at 490 (citation and internal quotation marks omitted). In discussing the government's continued payment for the defendant's drug, moreover, the court noted that the relator had "essentially concede[d] that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance." *Ibid.* And the relator in that case failed even to "plead that knowledge of the violation could influence the Government's decision to pay." *Ibid.*

Finally, the decision below is consistent with the Sixth Circuit's decision in *Prather*, *supra*. There, the court applied a "holistic" materiality analysis to conclude that the relator's complaint should not have been dismissed. 892 F.3d at 831 (citation omitted). Among other things, the court rejected the defendants' reliance on the government's continued payment for the defendants' services because the relator alleged "that the government did not know that the claims the defendants submitted were false." *Id.* at 834; see *ibid.* ("Without actual knowledge of the alleged non-compliance, the government's response to the claims submitted by the defendants * * * has no bearing on the materiality analysis."). The court also rejected, as "illogical" and inconsistent with the normal "pleading standard," the defendant's assertion that "a relator (or the United States) [must] plead allegations about past government action in order to survive a motion to dismiss." *Ibid.*

C. This Case Would Be A Poor Vehicle For Considering The Question Presented

The pleadings in this case do not contain many of the facts that would be relevant to the materiality inquiry, such as the contents of the FDA's 2010 warning letter or the results of the FDA's 2012 and 2013 facility inspections. See Pet. App. 30a-31a. As this case comes to the Court, it therefore is unclear "exactly what the government knew and when." *Id.* at 32a. And because this Court decided *Escobar* after briefing had concluded in the Ninth Circuit, the facts and arguments relevant to the materiality analysis were less developed than they would be in a case pleaded and litigated after that decision.

The materiality inquiry in this case, moreover, requires analysis of the likely effect of accurate information on the behavior of multiple federal agencies. FDA approval of petitioner's drugs was a prerequisite to payment by other government agencies, and respondents have alleged in part that petitioner misled the FDA into granting and maintaining that approval. See Pet. App. 15a. The materiality inquiry therefore turns in part on what regulatory actions the FDA would have taken if it had known of particular violations at particular points in time. See *id.* at 31a; Pet. 24.

Respondents have also alleged, however, that petitioner failed to disclose alleged contamination problems that (if known) might have affected the payment decisions of federal payor agencies. See, *e.g.*, Pet. App. 14a, 24a. With respect to those allegations, the materiality inquiry turns on whether the payor agencies would have refused payment for particular deliveries if they had been aware of all relevant facts. The need to consider the likely effect of alleged violations on both the FDA

and federal payor agencies adds a layer of complexity to the materiality inquiry here.

Finally, the court of appeals specifically declined to decide whether respondents' allegations satisfy the heightened-pleading requirements of Federal Rule of Civil Procedure 9(b), since the district court had not resolved that question. Pet. App. 33a, 37a. Thus, neither of the courts below has definitively ruled on whether respondents' allegations of materiality are sufficient to survive a motion to dismiss. This case therefore would be an unsuitable vehicle for deciding whether respondents' complaint alleged with adequate specificity that the FDA would have withdrawn its drug approval, or that federal payor agencies would have withheld payment, if either had known the true circumstances at an earlier date. Rather, the only question squarely presented here is whether the fact of continued government payments is an independent ground for dismissal, even assuming that respondents' allegations of materiality were otherwise sufficient. For the reasons stated above, that question does not warrant this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

NOEL J. FRANCISCO
Solicitor General
JOSEPH H. HUNT
Assistant Attorney General
MALCOLM L. STEWART
Deputy Solicitor General
ALLON KEDEM
Assistant to the Solicitor General
MICHAEL S. RAAB
CHARLES W. SCARBOROUGH
WEILI J. SHAW
Attorneys

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