No. 18-699

IN THE

Supreme Court of the United States

BROOKDALE SENIOR LIVING COMMUNITIES, INC., ET AL.,

Petitioners,

v.

UNITED STATES EX REL. MARJORIE PRATHER,

Respondent.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Sixth Circuit

BRIEF IN OPPOSITION

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BRIEF IN OPPOSITION

Respondent Marjorie Prather, relator for the United States, respectfully submits this brief in opposition to the Petition for a Writ of Certiorari.

STATEMENT OF THE CASE

This is a case under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, at the pleading stage. The operative Third Amended Complaint ("Complaint")[*] alleges that petitioners, which operate home health care businesses, defrauded Medicare by seeking payments from the program while knowingly violating its express conditions of payment with respect to *thousands* of claims.

A. The Applicable Medicare Requirements

The requirements at issue in this case require home health care providers to timely obtain a physician's certification that proposed services are medically necessary. That certification must be based on a face-to-face meeting with the patient. Compliance with these requirements is a condition of reimbursement from the Medicare program.

Specifically, 42 C.F.R. Part 424 is entitled "CONDITIONS FOR MEDICARE PAYMENT." As the regulations therein explain, it is a "[b]asic condition[]" for Medicare payment that, "the provider must obtain certification and recertification of the need for the

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[*] The Complaint is document number 98 on the district court docket for *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, No. 12-cv-00764 (M.D. Tenn.). Citations to the Complaint will be to the relevant paragraphs. Citations to other documents on the district court docket will be in the form "Doc. XX at YY," where "XX" is the document number, and "YY" the page number.

services [for which payment is sought] in accordance with subpart B of this part." 42 C.F.R. § 424.5.

Within subpart B, there is a specific regulation governing certification requirements for home health services. Intuitively named "Requirements for Home Health Services," it provides:

> (a) *Certification* -
>
> (1) *Content of certification.* As a condition for payment of home health services under Medicare Part A or Medicare Part B, a physician must certify the patient's eligibility for the home health benefit . . . .
>
> . . .
>
> (2) *Timing and signature.* The certification of need for home health services must be obtained at the time the plan of care is established or as soon thereafter as possible and must be signed and dated by the physician who establishes the plan.

42 C.F.R. § 424.22(a). In addition to certifying the need for home health services, the certification must include documentation describing a face-to-face encounter between the patient and a medical professional—which must occur "no more than 90 days prior to the home health start of care date or within 30 days of the start of the home health care." 42 C.F.R. § 424.22(a)(1)(v).

The certification requirements are crystal clear. In order to receive Medicare payments for home health care services, a medical professional must have a face to face encounter with the patient around the time that services begin, and a physician must certify the need for those services either when the plan of care is established or as soon thereafter as possible. In a prior appeal in this case,

the Sixth Circuit interpreted the regulatory requirement that a certification be obtained "as soon . . . as possible" by holding that any delay in obtaining a certification is permissible only to the extent justified by the reasons provided for the delay. Pet. App. 3; *United States ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 765 (6th Cir. 2016) ("*Prather I*"). Petitioners do not seek review of that holding.

The purpose of these requirements is straightforward, too. A certification of medical necessity is designed to ensure that public funds are spent only on necessary care. The timing of the certification promotes its accuracy. As the Sixth Circuit explained, "[a]bsent a deadline, a home-health agency might be able to provide unnecessary treatment absent a doctor's supervision and take the time to find doctors who are willing to validate that care retroactively." Pet. App. 23 (quoting *Prather I*, 838 F.3d at 764). Requiring a face-to-face meeting and a physician's certification at the outset thus makes it more likely that the care provided is actually medically necessary—as opposed to merely profitable for the home health agency.

Finally, these requirements are real, not optional. As the regulations explain, "[i]n order for home health services to qualify for payment under the Medicare program," the "physician certification and recertification requirements for home health services described in § 424.22" "*must be met*." 42 C.F.R. § 409.41 (emphasis added). Indeed, the regulations implement a statutory command, applicable to Medicare Parts A and B, conditioning payment for services on a physician's certification that the services are necessary. *See* 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A). The Complaint identifies numerous publications and reports stressing

that the government takes compliance with these requirements seriously. Complaint ¶¶ 47-52 (quoting from reports by the Department of Health and Human Services' Office of Inspector General, as well as a Medicare Administrative Contractor, and manuals issued by the Centers for Medicare and Medicaid Services (CMS)). And in a statement of interest filed in the district court, the United States explained that "[t]he statutory language is clear that the timing requirements are fundamental to the certification requirement, which in turn is a fundamental part of the bargain between a home health care provider and the Medicare program." Doc. 107 at 5.

B. Petitioners' Violations

The Complaint alleges that petitioners systematically failed to comply with these and other conditions on Medicare payments in thousands of claims.

Petitioners operate a nationwide network of businesses, including senior communities, assisted living facilities and home health agencies. Starting around 2011, petitioners implemented an extremely aggressive solicitation strategy for their home health business, *i.e.*, a concerted, nationwide effort to bill as much to Medicare as possible. Complaint ¶ 3; Pet. App. 7. Thus, petitioners' home health care businesses began performing more and more services on the residents of petitioners' senior communities and assisted living facilities. Petitioners encouraged their employees at the residential facilities to find patients for the home health services, and they also sought to bill services to Medicare that otherwise would have been provided by their own businesses (for example, services that ordinarily would be provided by an assisted living facility at no cost to Medicare were instead performed by home health care staff and billed to

Medicare). Complaint ¶¶ 66-74. In this frenzy of selling services, petitioners frequently did not obtain the proper certifications of medical necessity, including the required documentation of a face-to-face meeting. Pet. App. 7-9; Complaint ¶¶ 77, 115-20.

Nevertheless, petitioners billed Medicare for these services. Medicare payments for home health services are made for 60-day "episodes of care." Pet. App. 5. Petitioners billed Medicare in two phases. First, they submitted "Requests for Anticipated Payment," or "RAPs," which are initial percentage payment requests to Medicare. Then, they were required to submit final claims to receive the balance owed, and to prevent the government from recouping the RAPs. *Id*.

The lack of required certifications was a major problem for petitioners: they knew that their claims were not be eligible for payment, and any audit would reveal as much. Nevertheless, petitioners submitted many RAPs without the required certifications. Then, when the time to submit final claims came and went (so that the RAPs were canceled), petitioners often resubmitted them in order to retain the payments—again without the required certifications. Complaint ¶¶ 99-100.

Meanwhile, petitioners "held" the claims while attempting to backfill the missing certifications. Eventually, however, this backlog of held claims became acute: more than 7,000 claims, representing $35 million in billings, were held up—representing a "looming financial crisis" for the company if the government sought to recoup the RAPs. Pet. App. 7; Complaint ¶ 97. Petitioners thus hired additional utilization review nurses at its headquarters to review claims and solicit the missing certifications as part of a "Held Claims

Project." Respondent was one of these nurses. Pet. App. 8; Complaint ¶ 75-76.

As part of the project, respondent and the other staff reviewed patient charts and claims for missing pieces, created a checklist of compliance problems, and then sought to fill in the blanks, including by soliciting the belated certifications from petitioners' affiliates across the country. Once the utilization review nurses and other reviewing staff verified that the checklists were complete, claims were immediately billed to Medicare. Pet. App. 8; Complaint ¶¶ 80, 82.

The point of the Held Claims Project was to prepare claims, as quickly as possible, for billing, *i.e.*, to do as little as petitioners thought they could get away with. Thus, supervisors repeatedly told respondent that "charts were being reviewed too closely," and to "ignore any compliance issues regarding the information in the records." Complaint ¶¶ 87-91, 93-95. Basically, staff were instructed to review claims for completeness—not correctness or actual compliance. Even when reviewers raised concerns, they were told to do nothing. *Id*. ¶ 92, 96. Instead, they were told, "[o]n more than one occasion," that "[w]e can just argue in our favor if we get audited." *Id*. ¶ 114; *see* Pet. App. 9.

Eventually, petitioners began compensating physicians for the time spent retroactively certifying held claims. But petitioners knew what they were doing was questionable: they told their staff that if physicians did not want to sign a document, then staff "can not force this process." Complaint ¶ 98. Petitioners also began offering incentive compensation to their own employees based on the number of claims submitted for billing. *Id*. ¶¶ 103. Again, the emphasis was on speed—not accuracy.

Many of the claims submitted raised real compliance concerns. The Complaint includes illustrative examples where the care billed to Medicare was inconsistent with care actually provided to the patient, was not medically necessary, or was otherwise provided without a plan of care in place or a verbal order from the physician. Complaint ¶¶ 105-13. The Complaint also has an exhibit describing 489 known claims submitted to Medicare in violation of the condition of payment that the certification be obtained contemporaneously with the plan of care or as soon thereafter as possible. *Id*. ¶ 115-17. That was alongside a second exhibit detailing 771 claims submitted in violation of the Medicare requirement that an appropriate medical professional document a face-to-face encounter with the patient. *Id*. ¶ 118-20.

The Complaint alleges that the RAPs and final claims associated with these cases (as well as others) violated the False Claims Act, and that petitioners had unlawfully retained payments—also in violation of the False Claims Act. Complaint ¶¶ 121-31.

C. Procedural History

1. Respondent sued petitioners in 2012. Doc. 1. The United States declined to intervene in this action in 2014, Doc. 23 at 1, and the original complaint was then served.

2. After respondent filed a First Amended Complaint, petitioners moved to dismiss, arguing that the complaint did not adequately plead falsity and the presentment of a false claim. The United States filed a statement of interest, arguing against several points made in petitioners' motion. *See generally* Doc. 66. The district court nevertheless granted the motion to dismiss—but provided leave to amend. After a Second

Amended Complaint was filed, petitioners again successfully moved to dismiss, and judgment was entered in November 2015. *See* Pet. App. 11.

3. On respondent's appeal, the Sixth Circuit reversed. In *Prather I*, the court of appeals held, as relevant here, that: (1) "42 C.F.R. § 424.22(a)(2) permits a home-health agency to complete a physician certification of need after the plan of care is established, but that such a delay will be acceptable only if the length of the delay is justified by the reasons the home-health agency provides for it"; (2) petitioners' lengthy delays in obtaining certifications were not justified by their reasons for delay—*i.e.*, the accumulation of an administrative backlog due to aggressive solicitation; and (3) these regulatory violations rendered both the RAPs and final claims that petitioners submitted false. *Prather I*, 838 F.3d at 765-66.

4. While *Prather I* was pending, this Court decided *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). *Escobar* held that implied false certification claims are cognizable under the False Claims Act. *See id.* at 1999. To address defendants' concerns that implied false certification claims might expose them to sweeping and unpredictable liability, the Court clarified how the False Claims Act's materiality and scienter requirements function.

The Court explained that "materiality cannot rest on a single fact or occurrence as always determinative." *Escobar*, 136 S. Ct. at 2001 (quotation marks omitted). Instead, the Court stressed that materiality focuses upon "the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id*. at 2002 (quotation marks omitted). Thus, "a matter is material" if: (1) a reasonable person would attach importance to it in

determining a "choice of action," or (2) "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action," regardless of whether a reasonable person would do so. *Id.* at 2002-03 (quotation marks omitted). Importantly, a plaintiff does not have to demonstrate that the government necessarily would have denied payment; it is enough to show a likely effect.

To illustrate this standard, the Court identified at least four potentially relevant factors—and it did not suggest that this list was exclusive. Whether a requirement is designated a "condition of payment" is "relevant" to the materiality inquiry, albeit "not automatically dispositive." *Escobar*, 136 S. Ct. at 2003. Other relevant factors include whether the government took action when it had actual knowledge of similar violations, *id*. at 2003-04, whether the violation goes to the "essence of the bargain," *id.* at 2003 n.5 (quotation marks omitted), and whether the violation is significant or instead "minor or insubstantial," *id.* at 2003.

Discussing the past government action factor, the Court explained that "proof 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." *Escobar*, 136 S. Ct. at 2003. "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.*

With respect to scienter, the Court said less. Early in its opinion, the Court stated that for purposes of

establishing implied certification liability, "[w]hat matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Escobar*, 136 S. Ct. at 1996. The Court also noted that the False Claims Act's definitions of "knowing" and "knowingly" are broad: they cover not only actual knowledge, but also "deliberate ignorance" and "reckless disregard" of the truth or falsity of information. *See id.* (quoting 31 U.S.C. § 3729(b)(1)(A)). Thus, the Court explained that if "a reasonable person would realize the imperative" of compliance with a particular requirement (in the Court's hypothetical, providing a gun that worked to the military), then "a defendant's failure to appreciate the materiality of that condition would amount to 'deliberate ignorance' or 'reckless disregard' of the 'truth or falsity of the information' even if the Government did not spell this out." *Id*. at 2001-02.

5. On remand, respondent filed the Third Amended Complaint to account for changes to the law articulated by *Escobar*. Petitioners successfully moved to dismiss the Complaint on materiality grounds, and respondent appealed.

6. In the second appeal, the Sixth Circuit held that the Complaint adequately pleads materiality and scienter. Analyzing materiality, the court of appeals began by quoting, at length, from this Court's decision in *Escobar*. Pet. App. 15. The court recognized that the inquiry is "holistic," and that no factor is individually dispositive or necessarily required. *Id*. at 15-16 (quotation marks omitted). Based on the parties' arguments, the Sixth Circuit considered three factors here: that the certification timing requirement is an

express condition of payment, past government action, and the essence of the bargain.

The Sixth Circuit *first* held that the timing certification requirement is an express condition of payment for the Medicare program. The court recognized that this was "a relevant factor in determining materiality," even though it was not dispositive. Pet. App. 16.

Regarding the *second* factor—government action—the Sixth Circuit again began with a lengthy quotation from *Escobar*, reciting this Court's entire discussion of this factor. Pet. App. 20. The court of appeals then held that the Complaint was silent about what the government has done in past cases involving violations of the certification timing requirement at issue here, and it held that "[w]ithout allegations regarding past government action taken in response to known non-compliance with 42 C.F.R. § 424.22(a)(2), this factor provides no support for the conclusion that the timing requirement is material." Pet. App. 21.

The court of appeals refused, however, to draw a "negative inference" from the Complaint's silence about past government action. Pet. App. 21. It explained that "it would be illogical to require a relator (or the United States) to plead allegations about past government action in order to survive a motion to dismiss when such allegations are relevant, but not dispositive" of the materiality inquiry. *Id*. at 21-22. The court further held that it would "improperly inverse[] the pleading standard" to draw a negative inference from the Complaint's silence—because at the pleading stage all inferences should be drawn in the non-moving plaintiff's favor. *Id*. at 22. Finally, the court noted that the Complaint affirmatively alleges that the government did not know

of the violations at the time it paid petitioners' claims; the Sixth Circuit held that this lack of knowledge meant that "the government's response to the claims submitted by the defendants—or claims of the same type also in violation of 42 C.F.R. § 424.22(a)(2)—has no bearing on the materiality analysis." Pet. App. 22-23 (citing Complaint ¶ 125). That holding echoed the position of the United States, which filed an amicus brief arguing that in this case "the past government action factor does not weigh for or against a finding of materiality" because the Complaint pleads that the government was unaware of the violations when it paid the claims, and does not otherwise comment on past government action. C.A. U.S. Amicus Br. 14.

Third, the Sixth Circuit held that the certification timing requirement went to the "essence of the bargain" between petitioners and the government. The court explained that "[w]hether the party on the other side of a transaction complied with the regulations aimed at preventing unnecessary or fraudulent certifications is a fact that a reasonable person would want to know before entering into that transaction." Pet. App. 24. The court also cited the agency documents, discussed *supra* pp. 3-4, as evidence that "the government has consistently emphasized the importance of the timing requirement." Pet. App. 26.

Finally, the Sixth Circuit found the scienter element satisfied. The court began by quoting *Escobar*, explaining that "'False Claims Act liability for failing to disclose violations of legal requirements' will not attach unless 'the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.'" Pet. App. 28 (quoting *Escobar*, 136 S. Ct. at 1996). The court found a litany of allegations

supporting the conclusion that petitioners acted with reckless disregard to their compliance with the timing certification requirement—including allegations that respondent and others were directed to perform only cursory reviews of charts and claims, allegations that reported problems were swept under the rug, and allegations that petitioners acted as if their conduct was improper. *Id*. at 28-29. The court thus determined that petitioners "acted with 'reckless disregard' as to the truth of their certification of compliance and to whether these requirements were material to the government's decision to pay." *Id*. at 30-31.

7. After rehearing was denied, petitioners filed the Petition in this Court.

REASONS TO DENY THE WRIT

I. The First Question Presented Does Not Warrant This Court's Review.

The first question presented is "Whether the failure to plead facts relating to past government practices in [a False Claims Act] action can weigh against a finding of materiality." Pet. i. In essence, this question asks whether the Sixth Circuit correctly understood one factor in the holistic materiality standard described in this Court's recent decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). This Court recently denied petitions for certiorari in two cases posing essentially indistinguishable questions. *See Gilead Scis., Inc. v. United States ex rel. Campie*, No. 17-936, 2019 WL 113075 (2019); *United States ex rel. Harman v. Trinity Indus., Inc.*, No. 17-1149, 2019 WL 113076 (2019).

The *Campie* case may be particularly instructive: petitioners here identify it as a relevant decision (Pet. 23-

24); the petition in *Campie* was supported by several amicus briefs; the Court called for the views of the Solicitor General; the United States explained in detail why the purported circuit split is illusory (commenting, in the process, on this case) and why the question presented does not otherwise warrant this Court's review; and this Court followed the government's recommendation and denied certiorari. All of petitioners' principal arguments in favor of certiorari have thus already been considered and rejected. Rather than repeat all the salient points, this brief focuses on the key reasons that this case presents a particularly bad candidate for review.

A. The Question Presented Is Inherently Factbound and Unlikely to Ever Be Case-dispositive.

Petitioners' articulation of the question presented is rather watered down: they ask only whether a complaint's silence about past government practices "*can* weigh against a finding of materiality." Pet. i (emphasis added). Even if the answer to this question were "yes," that would merely establish that in some cases, it is *possible* for the complaint's silence to matter. A host of questions would remain unresolved, including the most important ones: does the complaint's silence matter in a particular case? If so, how much does it matter? And how should it be weighed against allegations in favor of materiality?

Obviously the answers to those questions will vary depending on myriad case-specific factors, *e.g.*, which legal requirement is at issue, how pervasive the violations were, etc. Indeed, petitioners themselves acknowledge that "[b]ecause the materiality analysis is

holistic and no one factor is dispositive, pleading past government action *is not a requirement* for pleading materiality." Pet. 22 (emphasis added). All they are willing to say is that "failure to plead facts about past government action with respect to the alleged violation *can and often should* weigh against finding materiality." *Id*. (emphasis added). It would be hard to imagine a more wishy-washy position: petitioners do not argue that a failure to plead facts about past government action *always* weighs against materiality. They just think it can, and perhaps even should.

The upshot is that if the Court were to grant certiorari, the most it could do is provide factbound guidance about the materiality of a single condition for Medicare payment: the certification timing requirement in 42 C.F.R. § 424.22(a)(2). But of course, there is no need for this Court to issue that guidance. If petitioners are correct that the government truly does not care about this condition, they can seek evidence confirming their view and then file a motion for summary judgment or contest the matter at trial. If petitioners succeed (proving in the process that the certification timing requirement is not material), it is unlikely that anybody else would bother to bring another case about a violation of this requirement.

B. There Is No Circuit Split.

There is no circuit split about the first question presented. To be clear, no circuit court has ever held that the certification timing requirement in 42 C.F.R. § 424.22(a)(2) is immaterial as a matter of law. Thus, petitioners can only even attempt to articulate a split at a higher level of generality. They try to do so by arguing that the First, Third, and Fourth Circuits would have

drawn a negative inference from a relator's silence about past government action regarding a particular regulatory requirement. But that is incorrect.

1. The First Circuit agrees with the Sixth. To support its conclusion that no negative inference was warranted in this case, the Sixth Circuit relied explicitly on precedent from the First Circuit—specifically, the *Escobar* case after remand from this Court. Pet. App. 21-22. *Escobar* was about noncompliant mental health care services provided to a teenager who later passed away. The complaint did not include allegations about other violations of the relevant regulatory requirements or the government's response to those violations, and the First Circuit explained (in language quoted by the Sixth Circuit here) that:

> We see no reason to require Relators at the Motion to Dismiss phase to learn, and then to allege, the government's payment practices for claims unrelated to services rendered to the deceased family member in order to establish the government's views on the materiality of the violation. Indeed, given applicable federal and state privacy regulations in the healthcare industry, it is highly questionable whether Relators could have even accessed such information.

United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 112 (1st Cir. 2016). *Escobar* thus stands plainly for the proposition that no negative inference is warranted from failure to include allegations about the government's past practices.

The cases petitioners cite, on the other hand, are distinguishable. In *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7

(1st Cir. 2016), the issue was not materiality at all, but instead causation: the relator did not allege that the defendant's misrepresentations caused the Food and Drug Administration (FDA) actually to approve a medical device, and therefore did not plead that the misrepresentations caused the payment of claims. The First Circuit stressed, however, that the FDA had not taken action despite six years of knowledge of the claims, and it noted that specific problems arise when courts second-guess the FDA in particular. *Id*. at 8-9. The court also stressed that its ruling was narrow and factbound, explaining that it did not reach every False Claims Act case, but instead meant only that "the absence of official action by the FDA establishing such causation leaves a fatal gap in this particular proposed complaint." *Id*. at 9.

The First Circuit's decision in *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 unpersuasive. *Nargol* involved allegations that FDA approval for a medical device was obtained by fraud. The complaint affirmatively alleged "that Relators told the FDA about every aspect of the design of the [medical] device that they felt was substandard, yet the FDA allowed the device to remain on the market." *Id*. at 35. The First Circuit explained that the evidence against materiality "becomes compelling when an agency armed with robust investigatory powers to protect public health and safety is told what Relators have to say, yet sees no reason to change its position." *Id*. It therefore dismissed the case in light of the relator's own concessions.

Both *D'Agostino* and *Nargol* are discussed in detail in the certiorari-stage papers in *Campie*. There, both the respondents and the United States explained why those cases are not part of a circuit conflict about materiality.

As relevant here, there are multiple reasons why *D'Agostino* and *Nargol* do not conflict with the decision below, and do not indicate that the First Circuit would have decided this case differently.

First, neither *D'Agostino* nor *Nargol* purported to overrule or even question the First Circuit's analysis in *Escobar*, which is plainly consistent with the decision below. Second, both *D'Agostino* and *Nargol* involved FDA approval of medical devices—a fact that is missing here, and was important because of the FDA's careful scrutiny of medical device approvals. And finally, in both of these cases, the court of appeals concluded that the FDA had actual knowledge of the alleged violations, and knowingly maintained approval of the relevant medical devices anyway. Here, by contrast, the Complaint alleges that the government had no knowledge during the relevant time period. Pet. App. 22 (citing Complaint ¶ 125). That is a critical distinction: as this Court explained in *Escobar*, the government's payment decisions are relevant only when it has "actual knowledge that certain requirements were violated." 136 S. Ct. at 2003-04. Without that knowledge, a negative inference makes no sense—and the First Circuit certainly did not hold otherwise.

2. The Third Circuit case petitioners cite is also distinguishable. In *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 485 (3d Cir. 2017), the relator alleged that a pharmaceutical manufacturer had suppressed certain safety data in order to make a drug appear safer than it was. But the relator also effectively conceded that the misrepresentations were not material. Thus, the relator "essentially concede[d] that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance." *Id*. at 490. He

"acknowledge[d] that the FDA would not 'have acted differently had Genentech told the truth.'" *Id*. Indeed, he did not even "claim that Genentech's safety-related reporting violated any statute or regulation." *Id.* Moreover, the relator admitted that he had disclosed "'material, non-public evidence of Genentech's campaign of misinformation' to the FDA and Department of Justice in 2010 and 2011," but the government had taken no action. *Id*.

Again, this case is different. It does not involve the FDA; it does involve clear violations of express conditions of payment, enshrined in statutes, regulations, and guidance; and the Complaint here expressly denies that the government knew of the fraud—a fact that the relator in *Petratos* conceded.

3. Finally, petitioners argue that the Fourth Circuit applies a different rule than the Sixth. In support, they cite *United States v. Triple Canopy, Inc*., 857 F.3d 174 (4th Cir.), *cert. dismissed*, 138 S. Ct. 370 (2017). But in *Triple Canopy*, the court did not draw a negative inference from the complaint's silence about the government's actions. Indeed, the court found materiality—and it did so principally based on "common sense," *i.e.*, its own understanding that a reasonable government would not pay for security guards who cannot shoot straight. *Id*. at 178-79. The court also noted that the government's condemnation of the defendant's action weighed in favor of materiality—but of course, that does not mean that the Fourth Circuit would have drawn a negative inference at the pleading stage if the government had not acted.

The Sixth Circuit used indistinguishable common-sense reasoning here, explaining that "[w]hether the party on the other side of a transaction complied with the

regulations aimed at preventing unnecessary or fraudulent certifications is a fact that a reasonable person would want to know before entering into that transaction." Pet. App. 24. Its analysis is fully consistent with the Fourth Circuit's reasoning and conclusion.

* * *

At bottom, the purported circuit split is illusory. Different courts are applying the same *Escobar* materiality standard. When they reach different results, it is because of factual variations in the cases before them, not legal disagreements about the meaning of the statute. Petitioners have not identified a single circuit that has actually decided a case like this one differently—and none would have.

C. The Sixth Circuit's Decision Is Consistent with This Court's Precedents.

Certiorari should also be denied because the Sixth Circuit's decision—both as to the government action inquiry in particular and as to materiality generally—is consistent with this Court's precedents.

1. With respect to government action, the Sixth Circuit correctly held that because no aspect of the holistic materiality test is dispositive, relators are not required to make allegations about past government conduct in unrelated cases. Pet. App. 21-22. Indeed, petitioners concede that this "is not a requirement for pleading materiality." Pet. 22.

There are many reasons why relators may not include allegations about past government action that would not support an inference of immateriality. For example:

- There may not be any publicly available information about the government's knowledge or past payment decisions;
- Even if that information exists, it may not be complete or easily accessible;
- The defendant's conduct in a given case might be different from past cases (*e.g.*, more egregious or pervasive);
- A particular type of fraud may be:
    - novel;
    - rare; or
    - difficult to detect

  and therefore not often discussed in government literature;
- Other factors may be more salient to the materiality inquiry for case-specific reasons.

In light of this reality, petitioners' "negative inference" rule would create a substantial risk of legal error: it would increase the probability that courts—lacking the benefit of real facts—would erroneously deem myriad legal requirements immaterial as a matter of law, even if those requirements actually are important to the government's payment decisions. That surely was not what this Court intended in *Escobar*.

The Sixth Circuit also correctly reasoned that drawing a negative inference from a complaint's silence about past government action is contrary to the general rule that the allegations in a complaint should be taken as true and viewed "in the light most favorable to" the plaintiff at the motion-to-dismiss stage. *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). Petitioners' rule would therefore be antithetical to the rules of notice

pleading, as well as the principle that a court considering the sufficiency of the pleadings should limit itself to those pleadings.

Petitioners' negative-inference rule would also be difficult to administer because every time a plaintiff did not discuss some aspect of materiality (whether government action or another prong of the holistic test), a defendant would have grounds to argue that the complaint's silence about that factor should give rise to a negative inference that the fraud was not material as a matter of law. It is not at all clear how courts would or could resolve those arguments without evidence to guide them.

2. With respect to materiality more generally, the Sixth Circuit correctly found the element satisfied in this case, as the Complaint pleads that the certification timing requirement is essential to the bargain between providers and the government, and is an express condition of payment—a factor that this Court deemed "relevant, but not automatically dispositive," of the materiality inquiry. *Escobar*, 136 S. Ct. at 2003.

That makes sense. It ought to be the rare case in which violations of an *express condition* for government payments are deemed immaterial as a matter of law. Such a result would mean that a federal agency is paying out public funds illegally. Courts should not lightly conclude that agencies behave lawlessly—especially at the pleading stage, when the complaint alleges otherwise.

To be sure, *Escobar* did not adopt the broad rule that every violation of every express condition of payment is material *per se*. The Court was deterred from doing so by two hypothetical scenarios: (1) if the government "designat[ed] every legal requirement an express

condition of payment," thus exposing entire industries to unpredictable liability for any violation of any statute or regulation; and (2) the government designating some plainly non-germane and unimportant requirement a condition of payment—for example, "a requirement that contractors" that provide health care services "buy American-made staplers." 136 S. Ct. at 2002, 2004. To account for these scenarios, the Court held that "not every undisclosed violation of an express condition of payment automatically triggers liability." *Id*. at 2001.

None of that is cause for concern here because, as the Sixth Circuit found, the requirement at issue here goes to the "essence of the bargain" between petitioners and the government. This case is not about the provenance of staplers, or about minor paperwork problems. It is about the widespread and brazen violation of an express condition of the Medicare program designed to ensure that the government only pays for medically necessary services. The importance of the certification timing requirement is clear—and as described in the Complaint, it is documented in the statute, the regulations, and in agency guidance. Moreover, although the Complaint does not assert separate theories of liability based on the provision of medically unnecessary care, it does allege that such care was provided and billed to the government—which should come as no surprise, since petitioners systematically circumvented a safeguard against that kind of fraud.

The bottom line is that the Sixth Circuit correctly found that the Complaint pleads materiality. Of course, petitioners may, after discovery, file a motion for summary judgment or contest materiality at trial. But a relator need not prove her case at the pleading stage. The Complaint here alleges plausible violations of federal law,

and is more than adequate to inform petitioners of the allegations against them and permit them to prepare a defense.

II. The Second Question Presented Does Not Warrant This Court's Review.

The second question presented is about scienter. Petitioners argue that "the Sixth Circuit did not require Relator to show that Brookdale knew its compliance with the timing-and-explanation requirement was material to the government's decision to pay," and that this decision conflicts with decisions from other courts of appeals. Pet. 26-27. This issue, too, does not warrant this Court's review.

A. The Sixth Circuit Adopted the Rule Petitioners Advocate, and Correctly Applied It to Deny the Motion to Dismiss.

1. First of all, the Sixth Circuit expressly adopted the rule that petitioners claim it eschewed. Opening its scienter discussion by quoting this Court's decision in *Escobar* (the same language petitioners quote and italicize on page 26 of their Petition, and then immediately accuse the Sixth Circuit of ignoring), the Sixth Circuit stated: "'False Claims Act liability for failing to disclose violations of legal requirements' will not attach unless 'the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.'" Pet. App. 28 (quoting *Escobar*, 136 S. Ct. at 1996). After reviewing the Complaint, the court then concluded that petitioners "acted with 'reckless disregard' as to the truth of their certification of compliance *and to whether these requirements were material to the government's decision to pay*." *Id*. at 30-31 (emphasis added). Petitioners are

dissatisfied with how the Sixth Circuit applied the rule to the facts of this case. But there is no doubt that the Sixth Circuit applied the rule petitioners want.

2. In reality, petitioners have no cause to complain. As they know, the False Claims Act's scienter requirement can be satisfied by showing that the defendant "act[ed] in deliberate ignorance" or "reckless disregard" of pertinent information, and does not require any "proof of specific intent to defraud." 31 U.S.C. § 3729(b)(1)(A), (B). This Court explained in *Escobar* that sometimes a defendant will be deemed to have acted with deliberate ignorance or reckless disregard of the materiality of a requirement "even if the Government [does] not spell this out." 136 S. Ct. at 2001-02.

Here, the government *did* spell out the materiality of the certification timing requirement. Petitioners do not challenge the holding that the requirement is an express condition of payment for Medicare claims. Nor could they: the requirement is in a part of the Code of Federal Regulations entitled "CONDITIONS FOR MEDICARE PAYMENT," and is surrounded by other indicia of its importance. *See supra* pp. 3-4. Although petitioners protest that they had no idea this express condition of payment could be important to the government's payment decisions, the clues were everywhere, any reasonable person would have noticed them, and petitioners could only have failed to do so by being reckless.

The Sixth Circuit identified other indicia of scienter, too. These include that petitioners acknowledged that they could not force physicians to sign their post-hoc certifications (indicating that petitioners knew that what they were asking was wrong)—and also that petitioners instructed respondent and other reviewers not to look too

carefully for compliance problems, even when respondent and others flagged such issues (almost the textbook definition of "reckless disregard").

B. There Is No Circuit Split, and No Good Reason to Take Up This Issue Now.

Petitioners' purported circuit split is also illusory. Contrary to petitioners' claim that the circuits "have split deeply" over this question, the petition only cites one decision expressly rejecting the argument the defendant must know that a claim was material—and that case was decided six years before *Escobar*. Pet. 27 (citing *United States ex rel. Loughren v. Unum Grp.*, 613 F.3d 300, 312-13 (1st Cir. 2010)). The First Circuit has since changed course and followed *Escobar*, quoting directly from this Court's decision on remand. *See Escobar*, 842 F.3d at 109 ("Rather, '[w]hat matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision.'") (quoting *Escobar*, 136 S. Ct. at 1996) (alterations in original).

Petitioners argue that after *Escobar*, five courts of appeals "have failed to require the plaintiff to show knowledge of materiality." Pet. 28-29. But the cases petitioners cite do not comment one way or the other as to whether a defendant must know that it is violating a material requirement (indeed, it is not clear from the face of the opinions whether the defendants even made that argument). Instead, these cases state that the plaintiff must show that the defendant knew it was submitting false claims—but of course that is not mutually exclusive with requiring additional knowledge of materiality. So none of the five cases petitioners cite point to a circuit split.

In any event, two of the five cited cases were resolved in the defendant's favor, which means the courts had no reason to delve into knowledge of materiality. *See United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 647 (5th Cir. 2017) (resolved on materiality grounds), *cert. denied*, No. 17-1149, 2019 WL 113076 (2019); *United States ex rel. Sheet Metal Workers Int'l Ass'n, Local Union 20 v. Horning Invs., LLC*, 828 F.3d 587, 593 (7th Cir. 2016) (resolved on scienter grounds).

Three cited cases were not implied false certification cases at all. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 741 (10th Cir. 2018) (express false certification claim), *petition for cert. pending*, No. 18-911 (filed Jan. 14, 2019); *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1166 (9th Cir. 2016) (same); *United States ex rel. Miller v. Weston Educ., Inc.*, 840 F.3d 494, 499 (8th Cir. 2016) (fraudulent inducement claim). This distinction matters because in the implied certification context, defendants worry that by virtue of having submitted a claim for payment, they will be deemed to have certified compliance with some obscure and trivial regulation, and will then be on the hook for treble damages. In that context, it makes sense to require the plaintiff to show that the defendant knew the requirement was material to the government: that rule limits liability to violations of requirements that the defendants knew about or really should have known about. But in an express certification or fraudulent inducement case, this predictability concern vanishes: the defendant expressly agreed to comply with specific requirements, and therefore necessarily already knows the rules. Thus, proving that the defendant knew the materiality of those requirements should not be necessary.

Regardless, courts that have actually considered the question in any detail agree about the appropriate scienter standard after *Escobar*—and as more courts consider it, the existing tacit consensus will likely become more explicit. At this time, the Court can and should allow that process to continue, rather than wade back in and risk upsetting that emerging agreement.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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February 6, 2019