No.	

In the Supreme Court of the United States

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

Petitioners,

v.

UNITED STATES OF AMERICA, EX REL. MARJORIE PRATHER,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

Brian D. Roark
Counsel of Record
J. Taylor Chenery
Angela L. Bergman
Brian F. Irving
Bass, Berry & Sims PLC
150 3rd Ave. S., Ste. 2800
Nashville, TN 37201
(615) 742-6200
BRoark@bassberry.com

Counsel for Petitioners

QUESTIONS PRESENTED

This Court has affirmed False Claims Act (FCA) liability, 31 U.S.C. § 3729 et seq., under a theory of "implied false certification." See Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1995 (2016). For that expanded theory of fraud liability to apply, however, the contractor's violation must be material to the government's decision to pay the claim, and the contractor must know it is material. Id. at 1996, 2002. Despite that holding, the Sixth Circuit held that a relator's failure to plead any facts regarding an alleged regulatory violation's effect on the government's past payment of claims "has no bearing on the materiality analysis" and that scienter can be established even where the relator does not allege that the defendant knew that the regulatory violation was material to the government's decision to pay claims. That decision directly conflicts with published decisions in other circuits regarding the proper enforcement of the FCA's materiality and scienter elements.

The questions presented are:

- 1. Whether the failure to plead facts relating to past government practices in an FCA action can weigh against a finding of materiality.
- 2. Whether an FCA allegation fails when the pleadings make no reference to the defendant's knowledge that the alleged violation was material to the government's payment decision.

PARTIES TO THE PROCEEDING

Pursuant to Supreme Court Rule 14.1(b), the following list identifies all of the parties appearing here and before the United States Court of Appeals for the Sixth Circuit. The petitioners here, and appellees below, are Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC. The respondent here, and appellant below, is the United States of America ex rel. Marjorie Prather.

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Petitioners Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC (collectively, "Brookdale") provide the following disclosure.

Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Innovative Senior Care Home Health of Nashville, LLC (d/b/a Innovative Senior Care Home Health), and ARC Therapy Services, LLC (d/b/a Innovative Senior Care) are all owned by Brookdale Senior Living Inc. Brookdale Senior Living Inc. has no parent corporation. No publicly traded corporation owns 10% or more of the stock of Brookdale Senior Living Inc.

TABLE OF CONTENTS

QUESTI	ONS PRESENTED i
PARTIES	S TO THE PROCEEDING ii
RULE 29	0.6 STATEMENT ii
TABLE (OF AUTHORITIES vi
OPINIO	NS BELOW 1
JURISDI	CTION 1
STATUT	ORY PROVISIONS INVOLVED 1
INTROD	UCTION 1
STATEM	ENT 5
REASON	IS FOR GRANTING THE PETITION \dots 16
O1 M	TE DECISION BELOW CONFLICTS WITH THREE THER CIRCUITS' APPLICATIONS OF THE FCA'S ATERIALITY REQUIREMENT AND FURTHER EDENS AN EXISTING CIRCUIT SPLIT 16
A.	Three circuits recognize that the actual behavior of the government is critical to the materiality analysis at the pleading stage
В.	The Ninth and Sixth Circuits' materiality analysis conflicts with the analysis adopted by the First, Third, and Fourth Circuits

II.	THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN ESCOBAR AND DEEPENS A CIRCUIT SPLIT AS TO WHETHER THE FCA'S SCIENTER ELEMENT REQUIRES THAT THE DEFENDANT POSSESS KNOWLEDGE OF MATERIALITY
	A. Circuit courts have split deeply regarding whether the FCA requires that the defendant possessed knowledge of materiality
	B. The Sixth Circuit's interpretation of the scienter requirement conflicts with <i>Escobar</i> because it requires an FCA plaintiff to establish only that the defendant possessed knowledge of falsity.
III.	THE SIXTH CIRCUIT'S ERRONEOUS READING OF ESCOBAR RAISES ISSUES OF EXCEPTIONAL IMPORTANCE TO ALL GOVERNMENT CONTRACTORS. 32
	A. Wresting regulatory authority from the governing agencies stands to create substantial potential liability for all government contractors
	B. The Sixth Circuit's holding creates a double standard for pleading materiality in intervened and non-intervened actions.

Six wa fra ma	e government is already using the ath Circuit's decision to advocate for a stered-down pleading standard for and claims and a rejection of the ateriality analysis at the pleading stage.
CONCLUSIO	ON 36
APPENDIX	
Appendix A	Opinion and Dissenting Opinion in the United States Court of Appeals for the Sixth Circuit (June 11, 2018) App. 1
Appendix B	Memorandum Opinion, Order, and Judgment in the United States District Court for the Middle District of Tennessee, Nashville Division (June 22, 2017) App. 65
Appendix C	Order Denying Petition for Rehearing En Banc in the United States Court of Appeals for the Sixth Circuit (August 22, 2018) App. 108
Appendix D	31 U.S.C. § 3729 App. 110
	42 U.S.C. § 1395f(a)(2)(C) App. 114
	42 U.S.C. § 1395n(a)(2)(A) App. 116
	42 C.F.R. § 424.22 (eff. Feb. 18, 2011) App. 117

TABLE OF AUTHORITIES

CASES

553 U.S. 662 (2008)	
845 F.3d 1 (1st Cir. 2016) 20, 21, 25 Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001) 16 United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890 (9th Cir. 2017), 16 petition for cert. filed, 2017 WL 6812110 10 10 (Dec. 26, 2017) 10 10 United States ex rel. Harman v. Trinity Indus. Inc., 872 F.3d 645 (5th Cir. 2017) 28 United States ex rel. Hill v. City of Chicago, 772 F.3d 455 (7th Cir. 2014) 27 United States ex rel. Hobbs v. Medquest Assocs., Inc., 711 F.3d 707 (6th Cir. 2013) 25 United States ex rel. Loughren v. Unum Grp., 613 F.3d 300 (1st Cir. 2010) 27 United States ex rel. Marstellar v. Tilton, 880 F.3d 1302 (11th Cir. 2018) 28 United States ex rel. Miller v. Weston Educ., Inc.,	Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662 (2008)
274 F.3d 687 (2d Cir. 2001) 16 United States ex rel. Campie v. Gilead Scis., Inc., 862 F.3d 890 (9th Cir. 2017), petition for cert. filed, 2017 WL 6812110 (Dec. 26, 2017) passim United States ex rel. Harman v. Trinity Indus. Inc., 872 F.3d 645 (5th Cir. 2017) 28 United States ex rel. Hill v. City of Chicago, 772 F.3d 455 (7th Cir. 2014) 27 United States ex rel. Hobbs v. Medquest Assocs., Inc., 711 F.3d 707 (6th Cir. 2013) 25 United States ex rel. Loughren v. Unum Grp., 613 F.3d 300 (1st Cir. 2010) 27 United States ex rel. Marstellar v. Tilton, 880 F.3d 1302 (11th Cir. 2018) 28 United States ex rel. Miller v. Weston Educ., Inc., 28	, ,
862 F.3d 890 (9th Cir. 2017), petition for cert. filed, 2017 WL 6812110 (Dec. 26, 2017)	Mikes v. Straus, 274 F.3d 687 (2d Cir. 2001) 16
872 F.3d 645 (5th Cir. 2017)	862 F.3d 890 (9th Cir. 2017), petition for cert. filed, 2017 WL 6812110
772 F.3d 455 (7th Cir. 2014)	
Inc., 711 F.3d 707 (6th Cir. 2013)	
United States ex rel. Loughren v. Unum Grp., 613 F.3d 300 (1st Cir. 2010)	
613 F.3d 300 (1st Cir. 2010)	711 F.3d 707 (6th Cir. 2013) 25
880 F.3d 1302 (11th Cir. 2018)	•
	,
040 F.30 434 (0th 0th. 2010)	United States ex rel. Miller v. Weston Educ., Inc., 840 F.3d 494 (8th Cir. 2016) 29

United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29 (1st Cir. 2017), cert. denied,
(Apr. 16, 2018) (No. 16-1442)
United States ex rel. Petratos v. Genentech Inc., 855 F.3d 481 (3d Cir. 2017) 4, 18, 19, 20
United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730 (10th Cir. 2018) 29
United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 838 F.3d 750 (6th Cir. 2016) 10, 19, 31, 36
United States ex rel. Sheet Metal Workers Int'l Ass'n, Local Union 20 v. Horning Invs., LLC, 828 F.3d 587 (7th Cir. 2016) 28
United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262 (5th Cir. 2010) 16
United States v. Bollinger Shipyards, Inc., 775 F.3d 255 (5th Cir. 2014) 27, 28
United States v. Bornstein, 423 U.S. 303 (1976)
United States v. King-Vassel, 728 F.3d (7th Cir. 2013) 29
United States v. Sanford-Brown, Ltd., 788 F.3d 696 (7th Cir. 2015) 16
United States v. Sci. Applications Intern. Corp., 626 F.3d 1257 (D.C. Cir. 2010) 5, 26, 28

United States v. Triple Canopy, Inc., 857 F.3d 174 (4th Cir. 2017), cert. dismissed, 138 S. Ct. 370 (2017)
United States v. United Healthcare Ins. Co., 848 F.3d 1161 (9th Cir. 2016) 29
Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) passim
Vt. Agency of Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000) 6
STATUTES AND REGULATIONS
28 U.S.C. § 1254(1)
31 U.S.C. §§ 3729-30
31 U.S.C. § 3729 et seq
31 U.S.C. § 3729(a)(1)(A)
31 U.S.C. § 3729(a)(1)(G)
31 U.S.C. § 3729(b)(1)(A)
31 U.S.C. § 3729(b)(4)
31 U.S.C. § 3730(a) 6
31 U.S.C. § 3730(b)(1) 6
31 U.S.C. § 3730 (d)(1)–(2) 6
42 C.F.R. § 405.1633 (eff. Jul. 9, 1975) 8
42 C F R 8 409 42

42 C.F.R. § 409.43(c)(3)
42 C.F.R. § 409.43(d)
42 C.F.R. § 424.13(b)
42 C.F.R. § 424.22 (eff. Feb. 18, 2011) 1, 12
42 C.F.R. § 424.22(a)(1)
42 C.F.R. § 424.22(a)(2) 4, 8, 12
42 C.F.R. § 424.22(c)
42 U.S.C. § 1395f(a)(2)(C)
42 U.S.C. § 1395h
42 U.S.C. § 1395k(a)(2)(A) 6
42 U.S.C. § 1395n(a)(2)(A)
42 U.S.C. § 1395u(a)
42 U.S.C. § 1395x(m) 6
42 U.S.C. § 1395ddd(a)–(b) 8
42 U.S.C. § 1395kk-1
OTHER AUTHORITIES
Brief for the United States of America as Amicus Curiae Supporting Appellant, <i>United States ex</i> rel. Ruckh v. Salus Rehab., LLC, 2018 WL 3621854 (11th Cir. Jul. 20, 2018)
Federal Health Insurance Program for the Aged Certification and Recertification, 32 Fed. Reg. 668, 670 (Jan. 4, 1967) (to be codified at 20 C.F.R. pt. 405)

Federal Health Insurance for the Aged Certification
and Recertification, 32 Fed. Reg. 9537, 9539
(Jun. 12, 1967) (to be codified at 20 C.F.R. pt.
$405) \dots 7, 8$
HHS-OIG, A-02-14-01005, MEDICARE COMPLIANCE
REVIEW OF HOME HEALTH VNA for 2011 and
2012 (Jul. 14, 2016)
HHS-OIG, SEMIANNUAL REPORT TO CONGRESS
(2018)
Statement of Interest of the United States, <i>United</i>
States ex rel. Roshan v. E. Tex. Med. Ctr., et al.,
No. 6:16-cv-1128 (E.D. Tex. Oct. 5, 2018) 35

OPINIONS BELOW

The Sixth Circuit's opinion is reported at 892 F.3d 822. Pet. App. 1–64. The Sixth Circuit's order denying rehearing *en banc* is not reported. Pet. App. 108–109. The relevant opinion and order of the district court is published at 265 F. Supp. 3d 782. Pet. App. 65–107.

JURISDICTION

The Sixth Circuit issued its opinion on June 11, 2018. The court denied Brookdale's petition for rehearing *en banc* on August 22, 2018. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

This petition involves provisions of the False Claims Act, 31 U.S.C. §§ 3729-30, as well as other statutes and regulations governing home health services, 42 U.S.C. § 1395f(a)(2)(C), 42 U.S.C. § 1395n(a)(2)(A), 42 C.F.R. § 424.22 (eff. Feb. 18, 2011). The relevant provisions are reproduced at Pet. App. 110–120.

INTRODUCTION

The False Claims Act, 31 U.S.C. § 3729 et seq., "imposes significant penalties on those who defraud the Government." Universal Health Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 1995 (2016). In Escobar, this Court confirmed that FCA liability may attach under a theory of implied false certification where a government contractor submits claims for payment while falsely representing that it has complied with its statutory, regulatory, or contractual obligations. Id. at 1999. Such liability, however, is limited to those misrepresentations that are "material"

to the Government's payment decision " *Id*. at 2002. The Court noted that the materiality standard is "rigorous," "demanding," and is focused on the actual effect that the violation has on the government's payment of claims, as opposed to whether the government would be "entitled to refuse payment were it aware of the violation." *Id*. at 2003–04, 2004 n.6.

Likewise, the FCA imposes a "rigorous" scienter requirement. *Id.* at 2002. It requires that a relator allege facts showing that the defendant "knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 1996. The Court recognized that the rigorous materiality and scienter requirements serve gatekeeper functions for screening viable FCA claims and that strict enforcement of those requirements can effectively address "concerns about fair notice and open-ended liability." *Id.* at 2002.

In the instant case, the Sixth Circuit reverts the state of the law with respect to the FCA's materiality and scienter requirements to pre-*Escobar* standards. Although the relator was afforded leave to amend her complaint specifically to address the materiality requirement articulated in *Escobar*, the relator alleged no facts about the government's past payment practices or enforcement efforts with respect to the alleged regulatory violation or any factual allegations about whether and why the alleged violation would cause the government to deny a claim for payment. Nonetheless, the Sixth Circuit held that the relator's pleading no allegations about past government action "has no bearing on the materiality analysis." Pet. App. 22–23.

Although courts routinely consider what allegations are lacking from a complaint when addressing a defendant's motion to dismiss, particularly when analyzing allegations under Rule 9(b)'s heightened standard to plead fraud with particularity, the Sixth Circuit held that to consider the absence of allegations in this context would be to "dr[aw] a negative inference" in favor of the defendant. Pet. App. 21. Instead, the court held that the rigorous and demanding materiality requirement was satisfied because the court determined that the regulation (1) was labeled a condition of payment and (2) was a "mechanism of fraud prevention." Pet. App. 27.

Through this holding, the Sixth Circuit aligns itself with the Ninth Circuit, which similarly found that relators had sufficiently pled materiality where there was "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 907 (9th Cir. 2017), *petition for cert. filed*, 2017 WL 6812110 (Dec. 26, 2017) (No. 17-936).

The Sixth and Ninth Circuits stand in stark contrast to three other circuits that recognize that allegations of past government action—or the lack thereof—are relevant to the holistic, multi-factor materiality analysis required under *Escobar*. The latter circuits appropriately heed this Court's guidance in *Escobar* that the government's actual behavior, as opposed to its abstract legal rights to deny a claim, is critical to evaluating whether a party has defrauded the government intentionally. In particular, and in direct contrast to the opinion below, the Third Circuit

has held that the relator's failure to plead any past government payment denials based on the underlying violation, any previous successful claims based on that violation, or any previous court decision upholding the relator's theory of liability "militates against a finding of materiality." *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 490 (3d Cir. 2017).

The Sixth Circuit's holding, on the other hand, incentivizes relators to choose not to plead any allegations about past government payment practices or enforcement efforts, thereby effectively removing that factor from the materiality analysis at the pleading and motion to dismiss stage. That perverse incentive directly contradicts this Court's instruction in *Escobar* that the materiality analysis is not too factintensive to consider on a motion to dismiss and allows a relator or the government to satisfy the materiality requirement merely by pleading that the regulation at issue is a condition of payment and could be used to prevent fraud. *See Escobar*, 136 S. Ct. at 2004 n.6. That low standard is not the one that this Court set forth in *Escobar* for implied certification cases.

Regarding scienter, the Sixth Circuit found that the scienter requirement was adequately pled by allegations that implied Brookdale was "on notice that [its] claim-submission process was resulting in potential compliance problems" and "acted with 'reckless disregard' with respect to [its] compliance with 42 C.F.R. § 424.22(a)(2)." Pet. App. 29–30. The Sixth Circuit departed from the scienter requirement established in *Escobar* and now directly conflicts with the D.C. Circuit, which has held that scienter requires showing "that the defendant knows (1) that it violated

a contractual obligation, and (2) that its compliance with that obligation was material to the government's decision to pay." *United States v. Sci. Applications Intern. Corp.*, 626 F.3d 1257, 1271 (D.C. Cir. 2010) (*SAIC*).

This Court's review is warranted to resolve the direct, irreconcilable, and growing circuit split with respect to two separate issues and to provide government contractors with certainty regarding their potential FCA liability for submitting claims for payment that do not involve any affirmative misrepresentation by the contractor. Allowing the Sixth Circuit's opinion to stand sanctions using the FCA as an all-purpose anti-fraud statute where materiality is satisfied merely because the underlying regulation is labeled a condition of payment and can be said to act as a "mechanism of fraud prevention." Pet. App. 27. This precedent also permits an FCA claim to move forward even where the defendant reasonably believed that the violation at issue was minor or insubstantial and not material to the government's decision to pay claims.

STATEMENT

Petitioners Brookdale Senior Living Communities, Inc., Brookdale Living Communities, Inc., Brookdale Senior Living Inc., Innovative Senior Care Home Health of Nashville, LLC, and ARC Therapy Services, LLC respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Sixth Circuit.

1. The FCA was originally enacted in 1863 to prevent contractors during the Civil War from submitting fraudulent or false claims for payment to the U.S. Government. See United States v. Bornstein, 423 U.S. 303, 309 (1976). The FCA imposes liability on a person who, among other possible violations, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or, in relevant part, who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]" 31 U.S.C. §§ 3729 (a)(1)(A), (a)(1)(G).

Suits may be filed directly by the government or by private citizen "relators," who file under the FCA's *qui tam* provisions. 31 U.S.C. §§ 3730(a), (b)(1). A suit under the FCA can represent a financial windfall for relators, who may be rewarded with a portion of any money recovered from the suit—between 15 and 30 percent of the proceeds of the action, plus attorneys' fees and costs. 31 U.S.C. § 3730 (d)(1)–(2).

Damages under the FCA are "essentially punitive in nature." *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784–85 (2000) (noting that the FCA's treble damages provision "reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers").

2. This case involves the provision of home health services between 2010 and 2012. Medicare beneficiaries who are homebound are eligible to receive certain medically necessary services, such as skilled nursing and therapy services, at home. 42 U.S.C. §§ 1395k(a)(2)(A), 1395x(m). To qualify for home health services, Medicare beneficiaries must (1) be

homebound, (2) be under the care of a physician, (3) need intermittent skilled nursing care, physical therapy, or speech language pathology services, (4) be under a plan of care established and periodically reviewed by a physician, and (5) have a face-to-face encounter with a physician during the relevant time period. 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A); 42 C.F.R. § 409.42. CMS will pay for home health services only if a physician certifies that the eligibility requirements have been met. 42 U.S.C. §§ 1395f(a)(2)(C), 1395n(a)(2)(A).

Home health services are unique in that they are a form of care that is not provided in an institutional or medical setting but in the patient's home. Thus, the physician is involved throughout a patient's receipt of services but is not present alongside the home health agency personnel who provide care, as a physician would be for inpatient or outpatient hospital services. Home health regulations take into account the flexibility required by this arrangement, allowing the initiation of care and initial billing of services on verbal physician orders, 42 C.F.R. § 409.43(d), and requiring a completed, signed, and dated plan of care only "[b]efore the claim for each episode for services is submitted for the final percentage prospective payment." 42 C.F.R. § 409.43(c)(3).

At issue in this case is the timing of the physician certification of eligibility for home health services. The government first promulgated regulations regarding the physician certification in 1967. See Federal Health Insurance Program for the Aged Certification and Recertification, 32 Fed. Reg. 668, 670 (Jan. 4, 1967) (to be codified at 20 C.F.R. pt. 405); Federal Health

Insurance for the Aged Certification and Recertification, 32 Fed. Reg. 9537, 9539 (Jun. 12, 1967) (to be codified at 20 C.F.R. pt. 405). Those initial regulations stated that the certification should be obtained at the time the plan of care is established or "as soon thereafter as possible." *Id*.

That requirement has not changed since 1967. The current regulations also require that the physician meet face-to-face with the patient within the required timeframe. 42 C.F.R. § 424.22(a)(1). The regulations still require that the physician certification be "obtained at the time the plan of care is established or as soon thereafter as possible." *Id.* § 424.22(a)(2).¹

A home health agency is not required to submit the physician certification when it bills Medicare, nor does CMS request the timing of the certification on its claim form. Instead, home health agencies retain supporting records and present them when requested. 42 C.F.R. § 424.22(c). CMS maintains several layers of audits, inspections, and reviews through contractors and related agencies to ensure compliance with regulations. See, e.g. 42 U.S.C.A. § 1395ddd(a)–(b) (establishing the Medicare Integrity Program, including reviews and audits of home health agencies); 42 U.S.C. §§ 1395h,

¹ This timing requirement stands in contrast to physician certification requirements for other services, like inpatient admissions, which have a "hard" deadline for completion. 42 C.F.R. § 424.13(b) (specifying a certain number of days required for the certification, no later than 20 days into the hospital stay). It is also in contrast with now-repealed regulations for "presumed coverage" for home health services that required a written and signed certification before the first billable visit. *See* 42 C.F.R. § 405.1633 (eff. Jul. 9, 1975).

1395u(a), 1395kk-1 (authorizing administration and payment of claims under Medicare Part A and Part B and the use of Medicare administrative contractors). The Office of the Inspector General for the Department of Health and Human Services (HHS-OIG), for example, routinely publishes detailed reports and findings relating to the post-payment review of claims at home health companies and sets priorities for enforcement actions. See, e.g. HHS-OIG, A-02-14-01005, MEDICARE COMPLIANCE REVIEW OF HOME HEALTH VNA FOR 2011 AND 2012, (Jul. 14, 2016); HHS-OIG, SEMIANNUAL REPORT TO CONGRESS (2018).

3. Relator Prather worked as a utilization review ("UR") nurse for Brookdale Senior Living Inc. from September 2011 through November 2012. Pet. App. 72. Relator alleges that until September 2011, each Brookdale home health agency submitted its own claims directly to Medicare. Third Am. Compl. ¶ 76, ECF No. 98. In September 2011, however, Brookdale centralized billing for most agencies to its corporate office in Tennessee. Id. At that time, there was a backlog of about 7,000 unbilled Medicare claims, worth approximately \$35 million. Pet. App. 73. Relator was hired as a UR nurse to assist in reviewing the held claims for "items that needed to be completed before the claim could be released for final billing to Medicare," which included that orders were signed, face-to-face documentation was complete, and therapy reassessments had been done. Pet. App. 73–74.

Relator does not allege that Brookdale ever submitted a final claim for payment without a signed physician certification. Relator does not allege that Brookdale ever backdated physician certifications to misrepresent the timing of the signature. Nor does Relator allege that a physician ever certified a patient's eligibility to receive home health services that were not medically necessary. Relator's sole theory of liability is that from 2011 through 2012 Brookdale sometimes submitted bills for home health services where the physician's signature on the certification was not obtained at the time the plan of care was established or "as soon thereafter as possible." Pet. App. 81–82.

On a previous appeal in this case, the Sixth Circuit determined that this theory sufficiently pled the falsity of the home health claims. United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 838 F.3d 750, 765 (6th Cir. 2016) (*Prather I*). Although no court or government agency had defined "as soon thereafter as possible" in the fifty-year history of the regulation, the Sixth Circuit held in a 2-1 decision that a delay in completing the certification is permitted "only if the length of the delay is justified by the reasons the home-health agency provides for it." Prather I, 838 F.3d at 765. The Sixth Circuit did not rely on any government payor decisions, opinions, or enforcement actions in making this determination. Based on statutory interpretation and the court's own finding that a deadline "makes it more difficult to defraud Medicare," the Sixth Circuit held that Relator sufficiently pled a violation of the regulation, satisfying the falsity element of an FCA claim where a home health agency violates this timing-and-explanation requirement. Id. at 764–66.

The United States earlier had declined to intervene in the *qui tam* in April 2014. Pet. App. 10. Despite filing Statements of Interest with the district court and an Amicus Brief with the Court of Appeals, the Department of Justice has refused to take a position on the materiality of the timing-and-explanation requirement created by the Sixth Circuit panel. Likewise, CMS has taken no position on the pending litigation, has not cited to the decision in any pending appeals, and has taken no action to apply the regulation according to the interpretation from the Sixth Circuit.

4. On remand from the first appeal, Brookdale indicated its intention to move to dismiss the Second Amended Complaint in light of this Court's recent decision in *Escobar*. The district court granted leave for Relator to file a Third Amended Complaint to comply with that decision. With respect to materiality, Relator added the conclusory allegation that "[t]he United States, unaware of the falsity of the claims that Defendants submitted, and in reliance on the accuracy thereof, paid Defendants and other health care providers for claims that would otherwise not have been allowed." Pet. App. 21. Relator did not allege that the Government had ever denied payment to Brookdale or any other home health agency for violating the timing-and-explanation requirement in the fifty-year history of the regulation. Relator did not allege that the Government had ever required any explanation or justification for delays in obtaining the physician signature. Nor did Relator plead any facts to establish why or how the Government would have altered its payment decision had it been aware of a delay in obtaining the physician's signature before submitting a claim for medically necessary home health services.

The United States District Court for the Middle District of Tennessee granted Brookdale's motion to dismiss. Pet. App. 104. The district court considered "all of the factors identified in *Escobar* as relevant to the question of materiality." Pet. App. 103. First, the district court held that while the provision at issue was an express condition of payment, that was "not dispositive to liability under the FCA." Pet. App. 93. Next, the district court considered Brookdale's argument that Relator "fails to allege that the government has ever denied a claim based on a violation of the timing requirements of § 424.22." Pet. App. 93.

In analyzing the past government action factor, the district court rejected the United States' argument that "CMS's failure to act is relevant only where it is shown that CMS approved payment with actual knowledge of the alleged misrepresentations " Pet. App. 93–94. The district court observed that "the timing requirement . . . has been part of the Medicare regulations for fifty years, and home health care is a huge industry making up a significant portion of the millions of Medicare claims submitted every year." Pet. Thus, considering "the sheer volume of claims, the relator's inability to point to a single instance where Medicare denied payment based on violation of § 424.22(a)(2), or to a single other case considering this precise issue," the district court concluded that this factor "weighs strongly in favor of a conclusion that the timing requirement is not material." Pet. App. 95.

After reviewing relevant Medicare regulations and guidance, the district court further concluded that while "the physician certification itself is clearly an essential and material component of the bargain between home health providers and Medicare," Relator "has not pointed to facts in the record, including conduct on the part of CMS, legal precedent, or relevant Medicare guidance supporting a conclusion that the timing requirement is likewise material." Pet. App. 103. The district court stated that while the Sixth Circuit might believe the timing requirement to be a mechanism of fraud prevention, "numerous CMS publications from the relevant time period" indicate that it is not. Pet. App. 101.

5. A divided panel of the Sixth Circuit again reversed. The panel majority held that the timing-and-explanation requirement was material because it is an "express condition of payment" and is "a mechanism of fraud prevention." Pet. App. 27. Crucially, the panel majority held that where the Relator failed to plead facts about whether or how any violation of this regulation had ever affected past government payment decisions, the past government action factor of the materiality analysis could not be considered and could not weigh against finding materiality.

Finally, the panel majority held that Relator adequately pled scienter because her "factual allegations support the inference that the defendants were on notice that their claim-submission process was resulting in potential compliance problems." Pet. App. 30.

Judge McKeague dissented, writing that "[t]wo years ago, the majority invented a more stringent timing-and-explanation requirement out of whole cloth" and now "decides both that this requirement (created by the court in 2016) was somehow material to the government's decision to pay claims in 2011 and 2012, and that the defendants knew, seven years ago, that it was material—even though Prather identifies no authority in support of that position." Pet. App. 32.

Even accepting the majority's "timing-and-explanation requirement," Judge McKeague reasoned that to satisfy the materiality requirement, Relator must "plead facts connecting the defendant's insufficient justifications to Medicare's decision to pay." Pet. App. 45. In other words, Judge McKeague would have required Relator to "explain, with particularity, if and how the specific violation would have influenced the government's payment decision." Pet. App. 45–46. Judge McKeague noted that Relator did not identify "any governmental statements disapproving of Brookdale's alleged excuses, neither as a per se matter or in the context of these particular delays." Pet. App. 53.

Describing materiality under *Escobar* as the "lodestar by which the courts separate the careless from the nefarious," Judge McKeague underscored that enforcing this requirement at the pleading stage is critical for enforcing the notice-providing function of Rule 9. Pet. App. 45. If Relator cannot explain how a specific violation would have influenced the government's payment decision, "Brookdale is left to guess about how it has allegedly defrauded the government." Pet. App. 46.

Judge McKeague concluded that "[w]ithout concrete evidence of the government's payment history or any helpful regulatory guidance," the relator must provide additional factual allegations regarding why the regulatory violation was material. Pet. App. 55. However, where the timing-and-explanation requirement "sprung, fully formed, from the minds of two federal judges" it is unsurprising that the relator had "no history, commentary, or guidance she can use to demonstrate materiality." Pet. App. 59.

For similar reasons, Judge McKeague observed that the majority misapplied the FCA's scienter requirement. Judge McKeague "struggle[d] to see how Brookdale can be held responsible for recklessly disregarding such a specific requirement when nothing—absolutely nothing—in the existing law required it to provide affirmative justifications for late signatures during the billing process." Pet. App. 61. Relator's allegations regarding scienter also failed, Judge McKeague reasoned, because allegations relating to general compliance issues had "no relationship to the signatures" and therefore did not show "that Brookdale knew omitting the explanations would influence the government's payment decisions or that it recklessly disregarded that possibility." Pet. App. 60–61.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW CONFLICTS WITH THREE OTHER CIRCUITS' APPLICATIONS OF THE FCA'S MATERIALITY REQUIREMENT AND FURTHER WIDENS AN EXISTING CIRCUIT SPLIT.

Before this Court's decision in *Escobar*, multiple circuit courts had determined that the implied false certification theory of liability was not viable under the FCA. See United States v. Sanford-Brown, Ltd., 788 F.3d 696, 711–12 (7th Cir. 2015); United States ex rel. Steury v. Cardinal Health, Inc., 625 F.3d 262, 270 (5th Those courts stated that regulatory Cir. 2010). violations should not be enforced under the FCA and instead are "for the agency—not a court—to evaluate and adjudicate." Sanford-Brown, Ltd., 788 F.3d at 712. Those courts were concerned that the FCA would be used as a "blunt instrument to enforce compliance" with all regulations. Id. (quoting Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001)); see also Steury, 625 F.3d at 268.

In Escobar, this Court held that implied false certification is a viable theory but that it may only apply if the underlying statutory, regulatory, or contractual violation is material to the government's payment decision. Escobar, 136 S. Ct. at 2002. In doing so, the Court recognized that the materiality standard plays a significant role in cabining potential liability under the FCA and preventing its transformation into an "all-purpose antifraud statute" or "a vehicle for punishing garden-variety breaches of contract or regulatory violations." Id. at 2003 (quoting Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 672 (2008)).

This Court rejected that materiality was too fact intensive for courts to dismiss FCA cases at the pleading stage, instead stating that the standard is a "familiar and rigorous one." *Id.* at 2004 n.6.

The Court stated that it is not sufficient to find materiality where the government "would have the option to decline to pay if it knew of the defendant's noncompliance." Id. at 2003. Instead, the "rigorous" and "demanding" materiality analysis focuses on the actual behavior of the government in light of statutory, regulatory, or contractual violations. Id. at 2003, 2004 n.6. The Court explained that materiality "cannot be found where noncompliance is minor or insubstantial." Id. at 2003. It noted that "the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive." *Id.* Proof of materiality may include "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." Id.

This case asks the inverse—whether a court may consider in its materiality analysis the failure to plead facts regarding the government's response to the mine run of cases involving noncompliance with the particular statutory, regulatory or contractual requirement.

In short, the Sixth Circuit approach precludes courts from considering a relator's failure to plead what this Court specifically identified as proof of materiality. *Escobar*, 136 S. Ct. at 2003. The Sixth Circuit erred by holding that the failure to plead past government action concerning a regulation that has existed nearly

as long as the Medicare program itself can have no bearing on the materiality analysis. The analysis envisioned in *Escobar* is turned on its head where a court considers only the abstract legal rights to deny a claim and forecloses analyzing the actual action *or inaction* of the government in light of a potential violation.

This holding has deepened an already existing circuit split regarding the application of *Escobar* at the pleading stage. The Sixth Circuit's holding that the lack of any allegations about past government action "has no bearing on the materiality analysis," Pet. App. 22–23, is directly opposed to the Third Circuit, which held that "where a relator does not plead that knowledge of a violation could influence the Government's decision to pay, the misrepresentation likely does not have a natural tendency to influence payment' as required by the statute." Petratos, 855 F.3d at 490 (internal alterations omitted) (quoting 31 U.S.C. § 3729(b)(4)). "At a minimum, this would be 'very strong evidence' that the misrepresentation was not material." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003). To support its finding of immateriality, the court in Petratos explicitly considered that the relator "fail[ed] to plead that CMS 'consistently refuses to pay' claims like those alleged [here]." Id. (quoting Escobar, 136 S. Ct. at 2003).

The Sixth Circuit's analysis is in contrast to the published opinions of at least three other circuits and goes even further than the Ninth Circuit, which employs a similarly permissive pleading standard for materiality.

A. Three circuits recognize that the actual behavior of the government is critical to the materiality analysis at the pleading stage.

The majority of circuit courts applying Escobar, including the First, Third, and Fourth Circuits, have held that pleading facts showing that the government's payment decision would be affected by the violation in question is critical to the materiality analysis at the pleading stage. This is true both for cases where the underlying conduct is known to the government, but also where it is not known. These courts reject a reading of Escobar that might significantly expand FCA liability to situations where the government may have the "option to decline" payment for the underlying violation or where the government has signaled no interest in the issue. Escobar, 136 S. Ct. at 2003. These courts instead require relators to plead some facts showing that the government would not have paid the claims at issue had it known of the underlying deficiencies.

In *Petratos*, the relator alleged that Genentech, a drug manufacturer, concealed information about one of its cancer drugs that would have revealed severe side effects. *See* 855 F.3d at 485. Like in *Prather*, there were no allegations that the government knew about the underlying misrepresentations until after the suit was filed. The Third Circuit affirmed dismissal of the suit on materiality grounds.

In addressing the pleadings, the court noted that "there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured." *Id.* at 490

(alterations in original) (quoting the findings of the district court). The court stated that "where a relator does not plead that knowledge of a violation could influence the Government's decision to pay, the misrepresentation likely does not 'have a natural tendency to influence payment' as required by the statute." *Id.* at 490 (internal alterations omitted) (quoting 31 U.S.C. § 3729(b)(4)). "At a minimum, this would be 'very strong evidence' that the misrepresentation was not material." *Id.* (quoting *Escobar*, 136 S. Ct. at 2003).

The court rejected the relator's argument that he sufficiently pled materiality by alleging that the defendants' misstatements caused individual physicians to prescribe medications that they otherwise would not have. Such evidence of causation cannot substitute for allegations of materiality, which asks "whether the government's payment decision is affected" *Id.* at 492. Like the district court in this case, the Third Circuit held that the relator's failure to plead past government payment denials of similar claims or to identify "a single successful claim" under the relator's theory of liability "or a court decision upholding such a theory" weighed against finding materiality. *Id.* at 490.

The First Circuit similarly rejected an argument that false statements were material where they "could have" influenced the government's FDA approval of the drug at issue, requiring that the relator plead facts showing that underlying misrepresentations are "material to the government's payment decision itself." *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016). In *D'Agostino*, the relator could not claim that FDA

approval for certain devices was "fraudulently obtained" where he failed to plead that the FDA took any action, either to investigate, audit, or withdraw approval for certain devices after learning of misrepresentations by the defendants. *Id.* at 8. In denying the relator's request to amend his complaint as futile, the First Circuit stated that the relator "may well misconstrue" materiality under *Escobar* and "[t]o rule otherwise would be to turn the FCA into a tool with which a jury of six people could 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." *Id.* at 7–8.

The First Circuit reaffirmed that view in a similarly situated case also resting on alleged false statements to the FDA. See United States ex rel. Nargol v. DePuy Orthopaedics, Inc., 865 F.3d 29, 36 (1st Cir. 2017), cert. denied, (Apr. 16, 2018) (No. 16-1442). In that case, the relator alleged that DePuy Orthopaedics made material false statements to the FDA that influenced CMS's decision to pay for certain medical devices. The First Circuit specifically considered the relator's failure to plead facts regarding subsequent actions by the FDA. Where there was "no allegation that the FDA withdrew or even suspended product approval upon learning of the alleged misrepresentations," this was "very strong evidence that those requirements are not material." *Id*. at 35. This evidence was particularly "compelling" when the FDA "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.

These courts have rightly focused their materiality analyses on the actual behavior of the government. In a case in the Fourth Circuit, the relator alleged that the defendant failed to provide adequate security services at Al Asad Airbase in Iraq. *United States v. Triple Canopy, Inc.*, 857 F.3d 174, 175 (4th Cir. 2017), cert. dismissed, 138 S. Ct. 370 (2017). The relator alleged that "Triple Canopy brought in guards from Uganda who were unable to meet . . . marksmanship requirement[s]" and falsified scorecards indicating that they did. *Id.* at 175–76. The government intervened and filed its own complaint. *See id.* at 176.

The Fourth Circuit found that the government's complaint successfully stated a claim and that the government had pled materiality sufficiently. See id. at 178. In addition to finding the omissions material due to "common sense" and Triple Canopy's covering up the misrepresentations, the court also relied on the government's actions. Id. The court found highly relevant to the materiality analysis that the government "did not renew its contract" and then "immediately intervened" in the underlying action. Id. at 179.

These courts understood that the failure to plead facts about past government action with respect to the alleged violation can and often should weigh against finding materiality. Because the materiality analysis is holistic and no one factor is dispositive, pleading past government action is not a requirement for pleading materiality. But allegations of past government action—or the lack thereof—at least should be relevant to the materiality analysis. Considering whether an FCA complaint includes such allegations comports with this

Court's decision in *Escobar* and ensures reasonable limits on FCA liability.

B. The Ninth and Sixth Circuits' materiality analysis conflicts with the analysis adopted by the First, Third, and Fourth Circuits.

The Sixth Circuit now joins the Ninth Circuit in refusing to consider as relevant to the materiality analysis a complaint's lack of allegations of any past government action with respect to the alleged violation at issue. A court's refusal to consider that pleading failure in determining materiality allows a relator or the government to ignore or disregard the past government action factor at the pleading stage simply by electing not to plead any such allegations. By focusing solely on the potential legal rights of government entities to deny payment, as opposed to their action or inaction in the face of regulatory noncompliance, these circuits have created a separate and lower standard that cannot be reconciled with the analyses of the First, Third, and Fourth Circuits as discussed above.

In *Campie*, the Ninth Circuit reversed the lower court's dismissal of the relators' implied false certification claims. *See* 862 F.3d at 895. The relators alleged that Gilead bought unapproved ingredients from an unapproved manufacturing facility for certain HIV drugs, which allegedly resulted in the submission of false claims. *See id.* at 899.

In analyzing materiality, the Ninth Circuit rejected Gilead's argument that the claims were not material because past government actions showed that the FDA continued to approve the drugs despite knowing of the violations. See id. at 906. The court acknowledged that "[a]lthough it may be that the government regularly pays this particular type of claim in full despite actual knowledge that certain requirements were violated, such evidence is not before us." Id. at The relators had elected not to plead facts relating to the government's payment practices, but the Ninth Circuit did not consider that lack of allegations as part of its materiality analysis. The relators stated a viable claim because they alleged "more than the mere possibility that the government would be entitled to refuse payment if it were aware of the violations" Id. In other words, the Ninth Circuit determined that the regulatory violation could constitute fraud, even where the FDA had declined to do so.

The Sixth Circuit, citing *Campie* in its analysis, goes even further. It states categorically that where a relator elects not to plead facts relating to the government's past actions with respect to the underlying violation, the lack of such allegations "has no bearing on the materiality analysis." Pet. App. 22–23. As such, district courts in the Sixth Circuit now may not consider a relator's or the government's failure to plead facts relating to past government actions. That holding applies to all FCA cases even where, as here, the regulation at issue has existed for decades, and public information about the government's enforcement actions during that time period—or lack thereof—is readily available. In the Sixth Circuit, if a relator or the government chooses not to plead past government actions—which they now are highly incentivized not to do—the court's materiality analysis is limited to whether a regulation is designated a "condition of payment," Pet. App. 16, and whether the court deems the regulation to go to the "essence of the bargain," Pet. App. 23, between the government and the defendant or can act as a "mechanism of fraud prevention." Pet. App. 27. This returns the Sixth Circuit to the standard for pleading materiality that was in place prior to Escobar. See, e.g., United States ex rel. Hobbs v. Medquest Assocs., Inc., 711 F.3d 707, 717 (6th Cir. 2013) (holding that false certification liability turns on whether the regulation in question is a "condition of payment" or a "condition of participation").

Courts have recognized *Campie*'s incompatibility with the majority view that a lack of allegations about past government action can be relevant to the materiality analysis. The First Circuit observed that the Ninth Circuit's decision in *Campie* "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 (citing *D'Agostino*, 845 F.3d at 8). The court further stated that "it offers no solution to the problems of proving that the FDA would have made a different approval decision in a situation where a fully informed FDA has not itself even hinted at doing anything. Instead, it decides not to deem these problems to be fatal on a Rule 12(b)(6) motion, even if, apparently, no plausible solutions can be envisioned, even in theory." *Id*.

Extensive disagreement among circuits as to whether the failure to plead facts regarding past government action with respect to the underlying violation can weigh against a finding of materiality presents a compelling reason for this Court to grant review.

II. THE DECISION BELOW CONFLICTS WITH THIS COURT'S DECISION IN ESCOBAR AND DEEPENS A CIRCUIT SPLIT AS TO WHETHER THE FCA'S SCIENTER ELEMENT REQUIRES THAT THE DEFENDANT POSSESS KNOWLEDGE OF MATERIALITY.

Like the FCA's materiality requirement, the FCA's rigorous scienter requirement "help[s] to ensure that ordinary [violations of statutory, regulatory, or contractual requirements] are not converted into FCA liability." *SAIC*, 626 F.3d at 1271. "[C]oncerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *Escobar*, 136 S. Ct. at 2002 (quoting *SAIC*, 626 F.3d at 1270).

In *Escobar*, this Court held that FCA liability in implied false certification cases turns on "whether the defendant *knowingly* violated a requirement that the defendant *knows* is material to the Government's payment decision." *Id.* at 1996 (emphasis added). The FCA defines "knowing" and "knowingly" as "actual knowledge," "deliberate ignorance," or "reckless disregard." 31 U.S.C. § 3729(b)(1)(A). Thus, to establish scienter under the FCA, a relator must show that the defendant knew (1) that it violated a legal requirement and (2) that that requirement was material to the government's payment decision.

Despite the language in the *Escobar* opinion, circuits have split deeply regarding the proper standard for adequately pleading knowledge under the FCA. Because 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, the Sixth Circuit is in conflict with the D.C. and Eleventh Circuits about whether the FCA's scienter requirement requires the plaintiff to establish the defendant's knowledge of materiality. The Sixth Circuit instead joins five circuits in not requiring allegations that establish knowledge of materiality. This Court's review is warranted to clarify how the rigorous scienter requirement should be enforced.

A. Circuit courts have split deeply regarding whether the FCA requires that the defendant possessed knowledge of materiality.

Prior to *Escobar*, circuit courts analyzing scienter under the FCA generally required a relator or the government to allege only that the defendant possessed knowledge of its legal violation. See, e.g., United States v. Bollinger Shipyards, Inc., 775 F.3d 255, 259-60 (5th 2014) ("To meet the 'requisite scienter' requirement, the United States must plead that Bollinger acted with knowledge of the falsity of the statement "); United States ex rel. Hill v. City of Chicago, 772 F.3d 455, 456 (7th Cir. 2014) ("[W]ithout knowledge of falsity there cannot be a knowingly false claim"). In fact, the First Circuit explicitly rejected the argument that a defendant must possess knowledge of materiality to establish FCA scienter. See United States ex rel. Loughren v. Unum Grp., 613 F.3d 300, 312–13 (1st Cir. 2010) ("Unum's claim that the FCA requires that a defendant have knowledge that a claim was materially false is a misreading of the statute and of *Allison Engine*.").

There was one exception. In *SAIC*, which this Court cited approvingly in *Escobar*, the D.C. Circuit held that "[e]stablishing knowledge under [§ 3729(a)(1)(A)] on the basis of implied certification requires the plaintiff to prove that the defendant knows (1) that it violated a contractual obligation, and (2) that its compliance with that obligation was material to the government's decision to pay. If the plaintiff proves both, . . . then it will have established that the defendant sought government payment through deceit, surely the very mischief the FCA was designed to prevent." *SAIC*, 626 F.3d at 1271.

Since *Escobar* was issued, the Eleventh Circuit has joined in holding that the FCA's "scienter requirement means that a plaintiff must show that the defendant had actual knowledge of or recklessly disregarded a condition's materiality." *United States ex rel. Marstellar v. Tilton*, 880 F.3d 1302, 1312 (11th Cir. 2018) (remanding case to district court for reconsideration in light of *Escobar*).

However, in addition to the Sixth Circuit, five other courts of appeals applying the FCA's scienter requirement since Escobar have failed to require the plaintiff to show knowledge of materiality. See United States ex rel. Harman v. Trinity Indus. Inc., 872 F.3d 645, 657 (5th Cir. 2017) ("[T]he relator must demonstrate that the defendant 'acted with knowledge of the falsity of the statement" (quoting Bollinger Shipyards, 775 F.3d at 259–60)); 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) ("[T]he defendant must 'have acted with actual knowledge, or with deliberate ignorance or reckless

disregard to the possibility that the submitted claim was false." (quoting *United States v. King-Vassel*, 728 F.3d 707, 712 (7th Cir. 2013))); United States ex rel. Miller v. Weston Educ., Inc., 840 F.3d 494, 500 (8th Cir. 2016) ("Fraudulent inducement requires a plaintiff to show . . . the defendant knew the statement was false"); United States v. United Healthcare Ins. Co., 848 F.3d 1161, 1176 (9th Cir. 2016) (scienter satisfied by allegation that the defendant "failed to make simple inquiries which would alert him that false claims are being submitted"); United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730, 743 (10th Cir. 2018) ("Dr. Polukoff adequately alleges that Dr. Sorensen performed unnecessary PFO closures on patients and then knowingly submitted false certifications to the federal government that the procedures were necessary ").

Thus, the majority of appellate courts conducting the scienter analysis since *Escobar* have ignored *Escobar*'s directive that a defendant must know that its violation is material to the government's payment decision. This Court must intervene to directly address that FCA scienter in an implied certification case requires the plaintiff to show that the defendant possessed knowledge of materiality.

B. The Sixth Circuit's interpretation of the scienter requirement conflicts with *Escobar* because it requires an FCA plaintiff to establish only that the defendant possessed knowledge of falsity.

In concluding that the scienter requirement was satisfied, the panel majority relied on allegations that Relator and other UR nurses "were instructed to review the claims only cursorily" and "raised concerns about the defendants' compliance with Medicare regulations," and that Brookdale knew some physicians might not sign certifications after patient discharge. Pet. App. 29. "All these factual allegations," the panel majority reasoned, "support the inference that [Brookdale was] on notice that [its] claim-submission process was resulting in potential compliance problems." Pet. App. 30. Because Brookdale allegedly failed to investigate that noncompliance, the panel majority found that Brookdale "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." Pet. App. 30-31.

The panel majority's scienter analysis conflicts with *Escobar* because it does not require any independent showing that the defendant possessed knowledge of materiality. To the contrary, the panel majority found scienter satisfied despite the complete lack of any factual allegation that Brookdale actually knew or was on notice that noncompliance with the signature-and-timing requirement would affect the government's payment decision. Thus, for the panel majority, FCA scienter was satisfied merely by the allegation that

Brookdale was "put on notice that [it] may be violating regulations." Pet. App. 31 n.11.

Interpreted this way, the scienter requirement cannot effectively address concerns about fair notice and open-ended liability in implied false certification cases because it allows a plaintiff to impose FCA liability on a defendant regardless of the defendant's understanding of the consequences noncompliance. Under the panel majority's analysis, defendants can be held liable under the FCA for violations they reasonably believe only to be "minor or insubstantial," or when they have no knowledge "that the Government consistently refuses to pay claims in the mine run of cases based on [such] noncompliance." Escobar, 136 S. Ct. at 2003. This is not the type of behavior the FCA is meant to punish. "[B]illing parties are often subject to thousands of complex statutory and regulatory provisions. Facing False Claims Act liability for violating any of them would hardly help would-be defendants anticipate and prioritize compliance obligations." *Id.* at 2002.

Judge McKeague explained in his dissent why the panel majority's scienter analysis led to an over-expansion of FCA liability in this case. "The timing-and-explanation requirement did not exist until we decided *Prather I* in 2016 [B]efore *Prather I*, no one had any reason to think that this regulation required HHAs to submit explanations for late signatures I struggle to see how Brookdale can be held responsible for recklessly disregarding such a specific requirement when nothing—absolutely nothing—in the existing law required it to provide affirmative justifications for late signatures during the

billing process." Pet. App. 61. Had the panel majority required Relator to show Brookdale's knowledge of materiality, the district court's dismissal would have been upheld because Relator offers no such allegations in her complaint.

- III. THE SIXTH CIRCUIT'S ERRONEOUS READING OF ESCOBAR RAISES ISSUES OF EXCEPTIONAL IMPORTANCE TO ALL GOVERNMENT CONTRACTORS.
 - A. Wresting regulatory authority from the governing agencies stands to create substantial potential liability for all government contractors.

Where the materiality analysis centers on the abstract legal rights of the payor rather than on the government agency's actions in practice, relators and courts are able to substitute their judgment as to what constitutes fraud, as seen in the opinion below. Refusing to consider as relevant to materiality whether the relator offers any allegations about the government's actual payment practices threatens to widely expand potential liability under the FCA and undermine protections embedded in the formal regulatory structure.

In establishing the "timing-and-explanation" requirement for physician certification documents as material for home health claims, the Sixth Circuit relied on the designation of the regulation as a condition of payment, the court's previous analysis that the regulation was a mechanism for "fraud prevention," and the fact that a physician certification was mentioned in name only in some OIG reports. Pet.

App. at 25, 27. Critically, the Sixth Circuit deemed irrelevant whether any of the publicly available OIG reports analyzing home health claims, ALJ or federal court opinions analyzing claims denials, or any other adjudications relating to home health claims could provide Relator with any facts to support whether the government ever has or likely would deny claims based on the timing of the physician's certification. The absence of such facts is unsurprising, however, since the requirement "sprung, fully formed, from the minds of two federal judges" and not from CMS. Pet. App. at 59.

Now, 12,000 home health agencies across the country are left to determine whether this new requirement applies to the more than \$18 billion in home health claims paid by Medicare each year. See MedPac, Health Care Spending and the Medicare Program 111 (June 2018). As this requirement did not come through notice-and-comment rule making, the agencies have no mechanism for obtaining guidance or clarification on the requirement. Instead, they stand to be potentially liable for fraud.

Home health agencies will be forced to choose whether to follow the consistent, decades-long practice of obtaining the certification before submitting the final bill for services or to follow the "timing-and-explanation" requirement as it has now been established in the Sixth Circuit.

However, the potential liability is far broader than just for home health agencies. If all that is required to establish materiality under the FCA is a condition of payment label and a court's pronouncement that the regulation is a "mechanism of fraud prevention," there is virtually no limitation on potential liability for government contractors or on the type of regulation that might be used to support such liability.

The Sixth and Ninth Circuits' approach returns the materiality analysis to a pre-*Escobar* standard and transfers regulatory authority from government agencies to relators and courts. Judge McKeague's admonition to "[l]eave rulemaking to the legislators and administrators" is well taken. Pet. App. 60.

B. The Sixth Circuit's holding creates a double standard for pleading materiality in intervened and nonintervened actions.

Refusing to consider a relator's failure to plead facts regarding the government's actual behavior in light of the alleged underlying violation also creates a double standard for pleading materiality in cases where the United States intervenes as opposed to cases where it Had the United States declines to intervene. intervened in this case, or in *Campie*, a court would expect the United States to plead facts about whether it has ever denied payment based on the violations at issue or instituted any enforcement actions based on As noted above, courts have such violations. considered as part of the materiality analysis the government's actions taken after learning of the violations. See Triple Canopy, 857 F.3d at 179.

By refusing to consider the absence of such allegations in this case, the Sixth Circuit adopted a lower, watered-down standard for a relator to plead materiality in a declined case. That holding risks creating two separate bodies of case law depending on whether the government intervenes in the action.

Moreover, a materiality analysis that does not consider the actual behavior of the government when a relator elects to plead no facts about such actions or inactions incentivizes relators to omit adverse facts, including that the government has never enforced a particular regulation in the manner that the relator alleges gives rise to fraud. In also invites relators to base FCA claims on trivial regulations that have never been the basis for claim denials or enforcement actions with full confidence that that fact cannot even be considered at the pleading stage or stop relators from reaching the discovery phase on their claims.

C. The government is already using the Sixth Circuit's decision to advocate for a watered-down pleading standard for fraud claims and a rejection of the materiality analysis at the pleading stage.

Finally, the importance of this case is underlined by the government's behavior in its wake. In multiple statements of interest and briefs as amicus curiae, where the government has officially declined intervention in the case but maintains an "interest" in the outcome of the litigation, it has advocated for a materiality standard that seeks to move the law back to pre-Escobar standards. See Statement of Interest of the United States at 2, United States ex rel. Roshan v. E. Tex. Med. Ctr., et al., No. 6:16-cv-1128 (E.D. Tex. Oct. 5, 2018) (Roshan SOI); Brief for the United States of America as Amicus Curiae Supporting Appellant,

United States ex rel. Ruckh v. Salus Rehab., LLC, 2018 WL 3621854 at *20 (11th Cir. Jul. 20, 2018).

In *Roshan*, the Department of Justice cited *Prather* for the proposition that FCA materiality requires only that the relator adequately plead "any one of the *Escobar* materiality factors" in order to survive a motion to dismiss. *Roshan SOI* at 4. Thus, the government's position is that a relator may plead only that the provision is a condition of payment and that that pleading satisfies the materiality standard.

Further, it appears that the government is taking the position that the decisions in *Prather* and *Campie* suggest that "the holistic nature of the materiality inquiry can render it inappropriate for resolution as a matter of law." *Ruckh*, 2018 WL 3621854 at *20. That argument is at odds with the clear language of *Escobar*, which expressly rejected any assertion that a rigorous materiality analysis is "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.

It is clear that the Department of Justice intends to use *Prather* as a key weapon in seeking to return the materiality analysis to pre-*Escobar* standards where regulatory violations are material just because the government says they are. This Court's intervention is required to prevent further deterioration of the materiality standard.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

BRIAN D. ROARK

Counsel of Record

J. TAYLOR CHENERY

ANGELA L. BERGMAN

BRIAN F. IRVING

Bass, Berry & Sims PLC

150 3rd Ave. S., Ste. 2800

Nashville, TN 37201

(615) 742-6200

BRoark@bassberry.com

Counsel for Petitioners

November 20, 2018