No. 20-371

IN THE

Supreme Court of the United States

CARE ALTERNATIVES,

Petitioner,

v.

UNITED STATES OF AMERICA; STATE OF NEW JERSEY EX REL. VICTORIA DRUDING; BARBARA BAIN; LINDA COLEMAN; RONNI O'BRIEN,

Respondents.

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

BRIEF IN OPPOSITION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

BRIEF IN OPPOSITION

Respondents Victoria Druding, Barbara Bain, Linda Coleman, and Ronni O'Brien hereby submit this brief opposing the petition for a writ of certiorari.

STATEMENT OF THE CASE

This case is about false claims on the Medicare Hospice Benefit, which occurred in 2006 and 2007. The Government only pays for hospice care if the providers follow Medicare's rules for reimbursement. At the relevant time, these included several procedural conditions, two of which are important here.

First, a physician must certify that the patient is terminally ill, *i.e.*, has a life expectancy of less than six months. 42 C.F.R. §§ 418.20(b), 418.22(b)(1). This certification happens at the beginning of the care period, and relates to the first 90 days of hospice care. After that, to continue receiving payments from the Government, a physician must periodically recertify the patient's continuing eligibility for hospice care. *Id*. § 418.22(a)(1).

Second, these certifications must be accompanied by "[c]linical information and other documentation that support the medical prognosis," which must be filed in the patient's medical records. 42 C.F.R. § 418.22(b)(2). This important requirement is the principal check on patients improperly being certified for hospice. For this reason, the inclusion of clinical information supporting a life expectancy of six months or less is a condition of payment for hospice care, separate from and independent of a signed physician certification. *See* 79 Fed. Reg. 50,452, 50,470 (Aug. 22, 2014) ("A hospice is required to make certain that the physician's clinical judgment can be supported by

clinical information and other documentation that provide a basis for the certification of 6 months or less if the illness runs its normal course."); 74 Fed. Reg. 39,384, 39,398 (Aug. 6, 2009) ("The medical record must include documentation that supports the terminal prognosis."); 70 Fed. Reg. 70,532, 70,534-35 (Nov. 22, 2005) ("A signed certification, absent a medically sound basis that supports the clinical judgment, is not sufficient for application of the hospice benefit under Medicare."); 64 Fed. Reg. 54,031, 54,038 (Oct. 5, 1999) ("A patient's medical record [must] contain complete documentation to support the certification made by the hospice physician or attending physician.").

After the events underlying this case occurred, additional requirements were added, including that physicians must include narratives supporting the prognosis, and that for recertifications beyond 180 days, a physician or nurse practitioner must have a face-to-face visit with the patient to gather clinical information to support the prognosis. *See* 42 C.F.R. § 418.22(a)(4), (b)(3); *see also* 75 Fed. Reg. 70,372, 70,463 (Nov. 17, 2010) (adding face-to-face requirement); 74 Fed. Reg. at 39,413 (adding narrative requirement).

Robust eligibility requirements for hospice are important for two reasons. First, electing hospice and palliative care means forgoing curative care. Permitting reimbursement for patients who are not terminally ill threatens to deprive those patients of care that is more appropriate for their conditions—and perhaps even life-saving. *See* 79 Fed. Reg. at 50,455-56. A terminal diagnosis is also often traumatic for the patient and the patient's loved ones.

Second, this area of health care historically has been rife with fraud. In the 1990s, the Department of Health and Human Services, in collaboration with the Health Care Financing Administration and the Administration on Aging, launched an initiative called "Operation Restore Trust." The project audited 12 large hospices in four States, reviewing medical records for 2,109 beneficiaries that had been in hospice care for over 210 days, and "concluded that 1,373 of the selected beneficiaries were ineligible for hospice because, at the time of initial diagnosis, they were not terminally ill as defined by Medicare regulations." Dep't of Health & Human Servs., Office of Inspector Gen., *Enhanced Controls Needed to Assure Validity of Medicare Hospice Enrollments* i (Nov. 1997), https://oig.hhs.gov/oas/reports/region5/59600023.pdf. In its first two years, focusing on just a handful of hospices in a small number of States, Operation Restore Trust identified more than $188 million in improper payments. *See* Andrew H. Smith, *Combating Health Care Fraud and Abuse in Medicare: Legislative Action and New Programs*, AARP Pub. Policy Inst. (Apr. 1, 1998), https://www.aarp.org/health/medicare-insurance/info-1998/aresearch-import-192-FS66.html.

Such fraud is not consigned to the past. Just last month, a hospice owner was sentenced for perpetrating a $150 million fraud scheme based on false hospice eligibility determinations. U.S. Dep't of Justice, *Owner of Texas Chain of Hospice Companies Sentenced for $150 Million Health Care Fraud and Money Laundering Scheme* (Dec. 16, 2020), https://www.justice.gov/opa/pr/owner-texas-chain-hospice-companies-sentenced-150-million-health-care-fraud-and-money. The regulations have become

more stringent over time to prevent and deter such fraud.

The hospice eligibility requirements can be enforced directly by the Centers for Medicare and Medicaid Services (CMS). They can also be enforced through the False Claims Act (FCA), which creates liability for anybody who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B).

The FCA's scienter requirement of acting "knowingly" can be satisfied with actual knowledge, deliberate ignorance, or recklessness. *See* 31 U.S.C. § 3729(b)(1)(A). Specific intent to defraud is not required. *Id*. § 3729(b)(1)(B). The knowledge standard ensures that the FCA does not "punish honest mistakes or incorrect claims submitted through mere negligence," while ensuring "that those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate." S. Rep. No. 99-345, at 7 (1986).

Respondents are former employees of petitioner Care Alternatives, a hospice provider in New Jersey. App.3. Respondents allege that in 2006 and 2007, petitioner knowingly presented false claims for hospice reimbursement to the Government by seeking reimbursement for care for patients who were not eligible under the governing regulations. App.7.

This case is at summary judgment. In support of their allegations, respondents have presented evidence of both falsity and knowledge. Respondents'

expert witness, Dr. Robert Jayes—a graduate of Harvard Medical School and faculty member at the George Washington University School of Medicine, who is Board Certified in Geriatrics as well as Hospice and Palliative Medicine, who has worked in the hospice industry—reviewed the medical records of 47 of petitioner's patients. *See* Respondents' CA3 Br. 11. This comprised 28 patients identified in the complaint, and 19 additional patients who had been on hospice for one year or more in 2006 to 2007. *See id.* Those 47 patients were on hospice for a total of 587 certification periods (*i.e.*, the initial two 90-day periods, and additional 60-day periods). *See id.*

Dr. Jayes concluded, based on the medical records accompanying the certifications, that for 206 out of the 587 hospice certification periods, the records did not support a prognosis of terminal illness. *See* Respondents' CA3 Br. 11; *see also* App.7. Dr. Jayes was asked repeatedly whether any reasonable physician could have disagreed with his assessment, and he said no. *See* Respondents' CA3 Br. 35-36 (citing examples). The Third Circuit recognized as much, noting that in Dr. Jayes' view, "for those periods, any reasonable physician would have reached the conclusion he reached." App.7.

Dr. Jayes' report and testimony did not stand alone. Respondents also presented evidence that petitioner's medical directors (who can recertify patients for continuing hospice care) did not attend required meetings preceding recertification, and then signed hospice certifications in bulk. Respondents presented evidence that medical directors were inattentive and did not review required documents. Respondents presented evidence of a company-wide

campaign to "bring in bodies," as well as instructions to employees to alter medical records to include previously missing information after those records had purportedly been relied upon to support hospice eligibility, as well as a practice of only including information in patient charts that supported hospice eligibility, while omitting information that would undermine eligibility. Indeed, petitioner conducted audits showing that patient medical records frequently failed to include information that supported hospice eligibility under Medicare's rules. This evidence was all summarized on pages 12-13 and 36-52 of respondents' opening brief in the court of appeals.

The district court held that the evidence did not create a genuine issue of material fact about whether petitioner's claims to Medicare were false or fraudulent. App.65. The court held that to be actionable, a claim for hospice eligibility must be "objectively false," meaning that the physician's clinical judgment "must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment." App.59 (quotation marks omitted).

Applying that standard, the district court found the evidence, other than Dr. Jayes' report, unpersuasive, App.62-64—and it concluded that Dr. Jayes' report did not create an issue of material fact because it reflected only a difference of opinion about whether particular patients were hospice eligible, App.64-65. Because the court found "no factual evidence that [petitioner's] certifying doctor was making a knowingly false determination," App.64, it granted summary judgment to petitioner, App.65. The

court did not reach any element of FCA liability other than falsity.

A panel of the Third Circuit (Hardiman, Greenaway, and Bibas, JJ.) unanimously reversed. App.1-2. The court of appeals framed the issue this way:

> The central question on appeal is whether a hospice-care provider's claim for reimbursement can be considered "false" under the FCA on the basis of medical-expert testimony that opines that accompanying patient certifications did not support patients' prognoses of terminal illness. The answer is a straightforward yes.

App.9.

The Third Circuit specifically rejected two aspects of the district court's analysis. First, it disagreed with the district court's premise that opinions cannot be false. App.11. The court explained that under the common law of fraud and this Court's precedents, "an opinion can be considered 'false' for purposes of liability." *Id*. Because the FCA does not define the phrase "false or fraudulent," these background rules apply here. Indeed, the Third Circuit noted that clinical judgments have been deemed fraudulent even in criminal cases. *See* App.16-17 (citing *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018)).

Second, the Third Circuit disagreed that the element of falsity requires "objective falsity," as the district court used that term—for two reasons. First, the "objective falsity" standard improperly conflates falsity and scienter, relying on evidence of what the defendant knew to establish whether the defendant's

opinion was false. App.11-12. Second, the "objective falsity" standard is at odds with precedents recognizing "legal falsity" under the FCA, *i.e.*, cases in which a claim is false because it falsely represents compliance with material conditions of payment. App.14.

In this regard, the Third Circuit focused on the legal requirement that a certification for hospice eligibility must be accompanied by "[c]linical information and other documentation that support the medical prognosis." App.15 (citation omitted). The court explained that "disagreement between experts as to a patient's prognosis may be evidence" that petitioner failed adequately to document the patient's prognosis; "its relevance need not be limited to evidence of the accuracy of another physician's judgment." *Id*.

The Third Circuit acknowledged that its understanding of falsity was inconsistent with the Eleventh Circuit's decision in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), which required a showing of objective falsity in the hospice context. The Third Circuit cautioned, however, that objectivity was still "relevant for FCA liability" under its analysis; the difference is that in the Third Circuit, "objectivity speaks to the element of *scienter*, not *falsity*." App.21.

To sum up, the Third Circuit held that "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." App.14. But that, alone, is not enough to create liability. Instead, the plaintiff must also prove

the other elements of FCA liability, including scienter, before liability will attach. *See* App.21-22.

Based on this reasoning, the Third Circuit vacated the district court's decision granting summary judgment and remanded for proceedings consistent with its opinion. Its decision was "limited" to "the falsity element." App.22. The court of appeals did not reach respondents' "other arguments regarding whether the evidence they submitted met the District Court's erroneous 'objective' falsity test," nor "opine as to [respondents'] odds of surviving summary judgment on the other prima facie elements, which the District Court did not reach." App.22-23. Instead, the Third Circuit "remand[ed] for consideration of the other elements of FCA liability." App.23.

Rehearing en banc was denied, App.24-25, and the petition followed.

REASONS TO DENY THE WRIT

The question presented by the petition is "[w]hether a physician's honestly held clinical judgment regarding hospice certification can be 'false' under the False Claims Act based solely on a reasonable difference of opinion among physicians." Pet. i. As explained in greater detail below, that isn't really the question the Third Circuit decided, and it isn't the question at the heart of this case. But even if it were, the question would not warrant this Court's review. Put simply, the question does not matter because the FCA's scienter requirement shields reasonable, honestly held clinical judgments from FCA liability, even if such judgments are "false" under the FCA because the Government would not pay the claim. That is true in the Third Circuit, and

everywhere else, too. A closer examination of the contentions in the petition only reinforces the case against certiorari.

I. This Court's Review Is Not Warranted to Resolve a Circuit Split.

The petition argues that the Third and Eleventh Circuits disagree about the meaning of falsity in FCA hospice cases, and then it asserts that there is "disarray" among the circuits about the meaning of falsity generally. Pet. 15-22. This is wrong. In reality, there is broad consensus among the circuits that when a defendant submits a claim for reimbursement that is not in fact reimbursable, the claim is false. For liability to attach, the claim must also be presented with scienter.

In the hospice context, the Third and Eleventh Circuits have a minor difference in approach—but the standard for liability in both courts is effectively the same. Both courts hold that claims for reimbursement for hospice care can be false, including when a certification of terminal illness is wrong. And both require a showing of knowledge before a false certification of terminal illness will lead to liability. The principal difference is that the Third Circuit separates these elements into falsity and scienter, and the Eleventh Circuit mashes them together under the rubric of "objective falsity."

That difference in formulation *should* never matter because both courts consider the same types of evidence to answer the same questions. The difference has mattered in two anomalous cases—this one and the Eleventh Circuit's *AseraCare* case—because the district courts in these cases chose *only* to address the

element of falsity, putting off consideration of all the other elements. Had the district courts considered FCA liability as a whole, they functionally would have been applying the same legal rule. Consequently, petitioner is simply wrong to suggest that the standards for liability vary across circuits, such that cases that survive in the Third Circuit would fail in the Eleventh. In fact, this case would have survived summary judgment in any circuit.

A. Certiorari Is Not Warranted to Address a Conflict with the Eleventh Circuit's *AseraCare* Decision.

In *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019), the Eleventh Circuit considered an unusual summary judgment appeal. There, the Government intervened in a hospice fraud case, which survived summary judgment. *See id.* at 1284. The district court decided to bifurcate the trial into two phases—one about falsity, and one about the remaining elements—a procedure that was unprecedented in the history of FCA trials. *See id.* at 1286. The Government was required to pick and choose which evidence would relate to falsity, and which would relate to scienter, and to present that evidence at different times—which the Government noted was unworkable because some evidence related to both. *See id.* Nevertheless, the district court worried that evidence of the defendant's scienter—including evidence that the defendant's policies promoted cursory review of patient records to facilitate improper enrollments to hospice—would be "unduly prejudicial" on the question of falsity, *id.* at 1287, and therefore sought to prevent the Government from introducing it as proof of falsity in the first phase of the trial. *See id.*

Proceeding in this anomalous fashion, the court held a trial on the element of falsity, where the Government relied heavily on the testimony of its expert, Dr. Liao, who testified that "the medical records of the patients at issue did not support AseraCare's 'terminal illness' certifications because they did not reveal a life expectancy of six months or less." *AseraCare*, 938 F.3d at 1287. But, according to the court of appeals, "Dr. Liao never testified that, in his opinion, no reasonable doctor could have concluded that the identified patients were terminally ill at the time of certification. Instead, he only testified that, in his opinion, the patients were not terminally ill." *Id*. The Eleventh Circuit also noted that Dr. Liao changed his own view about whether certain patients were terminally ill over time. *See id.* at 1287-88. The Government also presented testimony from the relators and evidence about AseraCare's policies—but only for "context," and not as proof of falsity. *Id.* at 1288.

Notwithstanding the obstacles in the Government's path, it won the first trial when the jury found that for 104 of the 123 patients at issue, AseraCare had submitted false claims. 938 F.3d at 1289. But on a post-trial motion, the district court determined that it had given the jury improper instructions, threw out the verdict, and granted summary judgment to AseraCare. *See id.* at 1290.

The Government appealed, and the Eleventh Circuit reversed. The court of appeals considered two questions, explaining that its "primary task on appeal [was] to clarify the scope of the hospice eligibility requirements, which are set out in the federal Medicare statute, 42 U.S.C. § 1395f, and its

implementing regulation, 42 C.F.R. § 418.22." *AseraCare*, 938 F.3d at 1291. Its "secondary task [was] to determine whether the district court's formulation of the falsity standard was consistent with the law and properly applied." *Id*.

On the first question, the Eleventh Circuit determined that "the clinical judgment of the patient's attending physician (or the provider's medical director, as the case may be) lies at the center of the eligibility inquiry." 938 F.3d at 1293. The court held that the documentation requirement set forth in 42 C.F.R. § 418.22(b)(2) did not require the medical records actually to prove the prognosis, nor unequivocally demonstrate that the patient was likely to die within six months. 938 F.3d at 1293-94. Instead, it held that the eligibility criteria were satisfied if the physician's judgment "represents a reasonable interpretation of the relevant medical records." *Id*. at 1294.

Regarding the second question, the Eleventh Circuit held that a "claim cannot be 'false'—and thus cannot trigger FCA liability—if the underlying clinical judgment does not reflect an objective falsehood." *AseraCare*, 938 F.3d at 1296-97. The court elaborated that "[o]bjective falsehood can be shown in a variety of ways." *Id*. at 1297. These include where "a certifying physician fails to review a patient's medical records or otherwise familiarize himself with the patient's condition before asserting that the patient is terminal," as well as "where a plaintiff proves that a physician did not, in fact, subjectively believe that his patient was terminally ill at the time of certification." *Id*. Moreover, the test is met "when expert evidence proves that no reasonable physician could have

concluded that a patient was terminally ill given the relevant medical records." *Id*. On the other hand, "the mere difference of reasonable opinion between physicians, without more, as to the prognosis for a patient seeking hospice benefits does not constitute an objective falsehood." *Id*. at 1301 (footnote omitted).

Nevertheless, the Eleventh Circuit reversed the grant of summary judgment to the defendant. The court recognized that the unprecedented bifurcated trial structure had prevented the Government from presenting evidence showing AseraCare's knowledge of falsity, which spoke to the "objective falsity" standard. Accordingly, the court held that "it is only fair that the Government be allowed to have summary judgment considered based on all the evidence presented at both the summary judgment and trial stages." 938 F.3d at 1304. It remanded for that consideration, and the case settled on remand before any further decision was rendered.

Against that backdrop, any conflict between the Third Circuit and Eleventh Circuit's statements about the meaning of falsity does not warrant this Court's review—and especially does not warrant it in this case.

Even taking the petition's claimed split at face value, the most that can be said is that there is a 1-1 split about the quantum of evidence required to survive summary judgment in FCA cases about hospice eligibility, arising out of two interlocutory decisions, each of which only considered one of the elements of an FCA action. Such a shallow split on such a niche question does not warrant this Court's immediate review. For the reasons that follow, the split is even less compelling than that.

First, the standard for falsity in the Third and Eleventh Circuits is not different in any important way. Both courts agree, for example, that "Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." App.14 (quoting *United States ex rel. Walker v. R&F Props. of Lake Cnty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005)). Under that standard, the claims in this case are false because they were not reimbursable. Both courts also agree that opinions can be false. *Compare* App.11 (explaining that opinions can be false when they are not sincerely held or when they have no basis), *with AseraCare*, 938 F.3d at 1302 (explaining that opinions can be false if they are not sincerely held, if they are not based on actual exercises of medical judgment, if the physician knows facts that undermine the opinion, or if no reasonable physician could have reached the same opinion).

Second, even if the Third and Eleventh Circuits' standards for *falsity* differ in hospice cases, the standard for FCA *liability* in both circuits is essentially the same. In the Eleventh Circuit, a terminal illness prognosis is actionable when it is "objectively false." That happens when the prognosis is not subjectively believed by the person offering it; when the person offering the prognosis has not actually reviewed the relevant medical records; or when no reasonable physician could have found the patient terminally ill. *See AseraCare*, 938 F.3d at 1297. These situations correspond to the FCA's scienter definition—which the Third Circuit uses "to limit the possibility that hospice providers would be exposed to liability under the FCA any time the

Government could find an expert who disagreed with the certifying physician's medical prognosis." App.12. A prognosis that the physician does not subjectively believe is made with actual knowledge of its falsity. A prognosis made without reviewing the underlying materials, or that no reasonable physician could give, is either reckless or made with deliberate indifference to its truth or falsity. Thus, the conditions that trigger liability in the Eleventh Circuit also trigger liability in the Third Circuit, and vice versa. That is why the Third Circuit noted that "objectivity" was still "relevant for FCA liability," and explained that *AseraCare* supported this aspect of its decision. App.21.

Third, the petition elides that the disagreement between the Third and Eleventh Circuits is not really about the question presented, but is instead about the meaning and significance of the documentation requirement in 42 C.F.R. § 418.22(b)(2)—which provides that "[c]linical information and other documentation that support the medical prognosis" must accompany hospice eligibility certifications—and whether and when a violation of that requirement renders a claim for payment false.

The Third Circuit held that this requirement is violated if the documentation does not actually confirm the prognosis, consistent with the Government's view. *See* App.6. The Third Circuit held that this is an independent requirement of reimbursement, that violation of this requirement renders a claim for reimbursement legally false, and that a plaintiff's expert's opinion that the information in the medical record does not support the prognosis

therefore gives rise to a factual question about falsity. *See* App.14-15.

The Eleventh Circuit held that the regulation merely requires the physician or provider to include documentation, but does not require the documentation actually to prove the prognosis. *See AseraCare*, 938 F.3d at 1293-94. Thus, the Eleventh Circuit focused on a difference of opinion between the plaintiff's expert witness and the certifying physician, as opposed to the adequacy of the documentation. *See id.* at 1295-96.

This matters because it shows that the split between the Third and Eleventh Circuits is not as clean as the petition suggests, and has essentially no relevance outside the narrow hospice context. It also creates a vehicle problem because, to decide the question presented, the Court would first have to decide an even narrower, even less certworthy question about how the requirements for hospice reimbursement worked in 2007. *See* Part II, *infra*.

Finally, any question about the legal rule is purely academic in this case because the summary judgment record includes evidence that would satisfy the Eleventh Circuit's standard for objective falsity. As the Third Circuit noted, Dr. Jayes testified that no reasonable physician could have disagreed with his assessment of the periods he found ineligible. App.7; *cf. AseraCare*, 938 F.3d at 1297 ("A claim may also reflect an objective falsehood when expert evidence proves that no reasonable physician could have concluded that a patient was terminally ill given the relevant medical records."). As explained above, there was other evidence, too—including that medical directors skipped meetings and signed certifications in

bulk, and that the company pressured people to falsify records and chart only negative health indicators. Thus, even if the Third Circuit had applied the Eleventh Circuit's objective falsity standard, it would have reversed the grant of summary judgment. Far from being "outcome determinative," the purported split has no bearing on the outcome of this case.

The dispute is not irrelevant only *in this case*; it also does not matter *generally* because nobody is bringing fraud cases predicated solely on a difference of opinion between physicians. The Government did not do so in *AseraCare* (which is why the Eleventh Circuit vacated the summary judgment order in that case), respondents did not do so here, and petitioner has not identified a case in which the plaintiff relied solely on a difference of opinion at summary judgment.

Nevertheless, petitioner wants the Court to believe that if the result below stands, the floodgates will open, and innocent hospice providers will face unwarranted liability. That is pure speculation, and it is baseless. Indeed, hospice fraud enforcement is nothing new. Ever since Operation Restore Trust in the 1990s, the Government has been pursuing providers who seek payment for ineligible beneficiaries. But the industry has not collapsed; on the contrary, it is booming. For example, the National Hospice and Palliative Care Organization (NHPCO) reports that the number of for-profit hospice providers grew by 24.7% from 2014 to 2018. *See* NHPCO, *Facts and Figures* 21 (2020), https://www.nhpco.org/wp-content/uploads/NHPCO-Facts-Figures-2020-edition.pdf. In that same period, there were multiple high-profile enforcement actions against hospices that improperly certified ineligible patients. *See, e.g.*, U.S.

Dep't of Justice, *Caris Agrees To Pay $8.5 Million Court Settle False Claims Act Lawsuit Alleging That It Billed for Ineligible Hospice Patients* (June 25, 2018), https://www.justice.gov/usao-edtn/pr/caris-agrees-pay-85-million-court-settle-false-claims-act-lawsuit-alleging-it-billed; U.S. Dep't of Justice, *Chemed Corp. and Vitas Hospice Services Agree to Pay $75 Million to Resolve False Claims Act Allegations Relating to Billing for Ineligible Patients and Inflated Levels of Care* (Oct. 30, 2017), https://www.justice.gov/usao-cdca/pr/chemed-corp-and-vitas-hospice-services-agree-pay-75-million-resolve-false-claims-act; U.S. Dep't of Justice, *Organizer of $9 Million Scam Sentenced to 8 Years in Federal Prison in Scheme to Provide Hospice to Patients Who Were Not Terminally Ill* (June 20, 2016), https://www.justice.gov/usao-cdca/pr/organizer-9-million-scam-sentenced-8-years-federal-prison-scheme-provide-hospice. These examples, which represent just a small sampling of enforcement activity, show that fraud enforcement has not chilled the provision of hospice care—and there is no reason to think the decision below will change that trend.

FCA liability is also not a major concern for compliant hospices. Nobody wants to bring an FCA case against a hospice that gets all or nearly all of its certification decisions right, *i.e.*, where the patients certified as terminally ill actually are terminally ill. The chances of proving liability would be slim, and the damages would be minimal even in a successful case. Consequently, the only hospices that face any litigation risk are the ones that certify a significant number of ineligible patients.

Petitioner does not attempt to quantify how often this occurs, or how often erroneous certifications are

made in good faith. But a concentration of significant, good-faith certification errors in a single hospice ought to be rare. To be sure, predicting the end of life is not an exact science; nobody thinks that doctors can forecast the precise hour of a patient's death, for example. But the process isn't pure guesswork, either. The regulations require a physician to assess whether, if a patient's disease runs its normal course, the patient has a life expectancy of six months or less. *See* 42 C.F.R. § 418.22(b)(1). That judgment is informed by decades or centuries of experience with the normal course of various diseases. CMS and its contractors also issue guidance and coverage determinations to help. *See, e.g.*, 78 Fed. Reg. 48,234, 48,247 (Aug. 7, 2013) (explaining that local coverage determinations "are intended to be used to identify any Medicare beneficiary whose current clinical status and anticipated progression of disease is more likely than not to result in a life expectancy of six months or less"). Based on these inputs, many physicians can say with reasonable accuracy whether a patient is expected to survive for six months or less. Moreover, after the events that gave rise to this case, the Government imposed additional requirements, *e.g.*, that physicians must include narratives explaining how the clinical findings support their determinations, and also that a physician or nurse practitioner must perform a face-to-face visit before recertification, and document how the data obtained in the visit supports recertification. *See* 42 C.F.R. § 418.22(a)(4), (b)(3). If a hospice complies with those requirements, it will make good-faith errors in certification even less likely than they were before.

If, despite those resources and requirements, a hospice still erroneously certifies a significant number of patients as terminally ill, even that would not be enough to support an FCA case in the Third Circuit. If the hospice honestly and in good faith complied with every procedural requirement, that compliance will be documented in the medical records, and will support a scienter defense. If all the plaintiffs have in response is an expert witness who disagrees with the defendant's certification decisions (but concedes that they are reasonable), the plaintiffs will not survive summary judgment on scienter. Indeed, they may not even be able to plausibly *allege* scienter, because good faith mistakes are not actionable under the FCA.

FCA defendants also have unique defenses. Most particularly, if the defendant convinces the Government that a case is at odds with the Government's interests, the Government can move to dismiss the case—and such motions are almost always granted. *See* 31 U.S.C. § 3730(c)(2)(A); *see United States v. UCB, Inc.*, 970 F.3d 835, 842 (7th Cir. 2020) (granting the Government's motion and noting that only two, including the decision under review, had ever been denied). The Government is obviously mindful of the equities on both sides of hospice certification—and so if petitioner's predictions were accurate, one would have expected the Government to intercede on petitioner's behalf. Here, it is worth noting that the Government did not move to dismiss this case. Instead, it filed an *amicus* brief in the Third Circuit supporting respondents.

In sum, scaremongering about widespread meritless litigation, second-guessing of good-faith medical judgments, or chilling of beneficial behavior is

unwarranted. The FCA's scienter requirement and other features, along with practical reality, provide ample checks against that possibility.

B. There Is No "Disarray" Regarding Falsity Generally.

The petition argues (at 19-22) that the circuits are in "disarray" over when opinions can be false. If petitioner could have said the circuits were "split," it would have—but it cannot, and so it uses "disarray" as a euphemism that means "not really split." As such, petitioner's argument is almost self-refuting. Indeed, the degree to which petitioner strains to puff up the issue only highlights how shallow and unimportant the claimed split truly is. In fact, the claimed "disarray" is all smoke and mirrors, too, because none of the cited cases adopt reasoning inconsistent with the decision below.

Petitioner argues that the Tenth Circuit's decision in *United States ex rel. Polukoff v. St. Mark's Hospital*, 895 F.3d 730 (10th Cir. 2018), exemplifies the "disarray" because the Third Circuit cited *Polukoff* approvingly, while the Eleventh Circuit distinguished it in *AseraCare*. Pet. 20. The fact that the Eleventh Circuit distinguished *Polukoff*, however, belies any conflict between *Polukoff* and *AseraCare*.

Indeed, *Polukoff* is very distinguishable. The case was not about hospice eligibility at all, nor was it about when expert disagreement creates factual disputes regarding falsity. Instead, the case was at the pleading stage, and concerned whether a complaint plausibly alleged that heart surgeries were not "reasonable and necessary" under the Medicare statute. *See Polukoff*, 895 F.3d at 734-35. The district court reasoned that

because the physician who performed the surgery believed they were appropriate, claims for reimbursement could not be false. *See id.* at 741. The Tenth Circuit rejected that argument, holding that Medicare's "reasonable and necessary" requirement is not a free-floating call for a clinical judgment, but is instead a term of art that invokes specific criteria established by the Government—including whether, for example, a consensus of medical professionals believes that a particular service is appropriate to treat a particular condition. *See id.* at 742-43. *Polukoff* accordingly has nothing to do with the issues in this case, except insofar as it stands for the uncontroversial proposition that a defendant cannot always evade liability by claiming that clinical judgments are beyond question.

The petition next cites *United States ex rel. Riley v. St. Luke's Episcopal Hospital*, 355 F.3d 370, 376 (5th Cir. 2004), another non-hospice case, for the proposition that "the FCA requires a statement known to be false, which means a lie is actionable but not an error." The petition argues that *Riley* is in play because the district court cited approvingly to it, and "the Third Circuit criticized that reliance as improper." Pet. 21 (citing App.8-9). But aside from a single citation in the "Factual and Procedural Background" section of its opinion, the Third Circuit did not discuss *Riley* at all, much less criticize the Fifth Circuit's reasoning. That is unsurprising because the Fifth Circuit found that the relator's complaint stated a claim, using reasoning that supports the Third Circuit's emphasis on scienter here. Thus, the Fifth Circuit held that "Riley's complaint does sufficiently allege that statements were known to be false, rather

than just erroneous, because she asserts that Defendants ordered the services knowing they were unnecessary." *Riley*, 355 F.3d at 376. And, like the Third Circuit in this case, the Fifth Circuit was clear that the requirement that the defendant act "knowingly" relates to scienter, not falsity. *See id.* at 377 ("These allegations satisfy the FCA's requirement that Defendants 'know' that the record, statement, or claim is false.").

The petition next cites *United States v. Paulus*, 894 F.3d 267 (6th Cir. 2018), to argue that the Sixth Circuit holds that opinions can almost never be false. Not so fast. *Paulus* was a criminal case in which the defendant was accused of misreading angiograms to find arterial blockage (stenosis) that was not really there, so as to justify placing stents that were not medically necessary. *See id.* at 270-72. The defendant argued that the degree of stenosis was a matter of opinion, and the Sixth Circuit disagreed, explaining that whether an artery is blocked is a fact, not an opinion. *See id*. at 276. The court acknowledged that it might be hard for the Government's experts to prove that the defendant was knowingly lying about whether arteries were blocked. But the court explained that "however imprecise the science might be, the reliability and believability of expert testimony, once that testimony has been properly admitted, is exclusively for the jury to decide." *Id*. at 277 (cleaned up). The court thus affirmed the jury's fraud verdict.

Along the way, the Sixth Circuit noted that although "opinions—when given honestly—are almost never false," such "opinions are not, and have never been, completely insulated from scrutiny. At the very

least, opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion." *Paulus*, 894 F.3d at 275. The court did not attempt to catalogue all the ways opinions can be false, however, because the determination before it was one of fact, not opinion.

To the extent *Paulus*—a criminal case outside the FCA context—is relevant, it confirms the Third Circuit's holding in this case that an expert's review of medical records can support a factual finding that those records do not support a diagnosis (there, stenosis; here, terminal illness). Indeed, the Third Circuit discussed *Paulus* at length for that proposition. App.16-17.

The petition finally cites *Winter ex rel. United States v. Gardens Regional Hospital & Medical Center, Inc.*, claiming (at 21) that the Ninth Circuit acknowledged "confusion" among the circuits about when opinions can be false. 953 F.3d 1108, 1118-19 (9th Cir. 2020), *petition for cert. pending*, No. 20-805 (filed Dec. 3, 2020). That is a stretch. On the relevant pages, the Ninth Circuit did not acknowledge any confusion. Instead, it rejected the "objective falsity" standard, just like the court below. Then, the court stated that "[w]e are not alone in concluding that a false certification of medical necessity can give rise to FCA liability," and cited the decision below, *Riley*, and *Polukoff* as support. *Id.* at 1118. The court went on to explain that "our decision today does not conflict with *AseraCare* for two reasons": First, *AseraCare* did not hold that opinions can never be false, but instead only held that disagreement among physicians, without more, was insufficient; second, *AseraCare* was limited

to the hospice context, where the statute and regulations expressly called for a clinical judgment—a requirement not present in medical necessity cases generally. *Id.* at 1118-19. Far from bemoaning "confusion," the Ninth Circuit had no trouble reconciling the relevant circuit precedents.

In sum, there is absolutely no tension between the decision below and any of the cases petitioner cites. The Eleventh Circuit's rule for hospice cases may be slightly different than other circuits' rules for non-hospice cases, but there is no conflict because the circuits all agree that opinions, including clinical judgments, can be false, and the Eleventh Circuit's alternative rule is limited to the hospice context. The claimed "disarray" is illusory, and any minor variances in verbiage will vanish without this Court's intervention.

II. This Case Is a Bad Vehicle.

This case is a bad vehicle to consider the question presented for four reasons. First, the case is old, involving conduct that occurred in 2006 and 2007. The hospice certification requirements have changed since then. They now include face-to-face meetings and individualized written narratives. *See* 42 C.F.R. § 418.22(a)(4), (b)(3). These measures were implemented to curb excessive certifications for hospice care. If the Court is going to take a hospice case, it would make more sense to hear one that arises under the modern criteria, so the Court can provide more relevant guidance to the lower courts, CMS, and litigants about future conduct.

Second, the case is interlocutory, and no court has yet considered all the elements of FCA liability. As the

Third Circuit explained, the factors the Eleventh Circuit considers under its "objective falsity" analysis are still relevant to scienter. App.21. Neither the district court nor the Third Circuit has evaluated scienter in this case, and the Third Circuit remanded for the district court to consider it in the first instance. App.23. This cuts against review for two reasons. First, it would make little sense to consider the falsity in a vacuum—and doing so risks creating confusion about the way the FCA's elements all work together. Second, this Court's review may ultimately not be necessary at all. If petitioner prevails on scienter grounds (or another element), the case will be over. But even if petitioner loses, it would be better to hear a case in which the Court has the benefit of the lower courts' consideration of all the elements of liability, and all the evidence in the record. Waiting for final judgment is the better approach either way.

Third, although petitioner touts this case as a useful vehicle to clarify falsity generally, it would be a bad idea to consider falsity through the idiosyncratic lens of hospice eligibility. The hospice regime is unusually deferential to physicians' clinical judgments. Other judgments—*e.g.*, determinations of medical necessity—receive no such deference. If the Court uses hospice certifications as an entrée to falsity, the Court's view of the legal landscape will be skewed, and negative unintended consequences may follow in the mine run of cases. "Disarray" becomes more likely, not less.

Finally, as explained above, the Third Circuit's holding that a clinical judgment can be false without a showing of "objective falsity" is only part of its decision. Separately, the court held that a claim for

hospice certification can be false if the clinical information in the documentation does not support the prognosis of terminal illness—because the documentation requirement is an independent condition of reimbursement. App.15 (holding that the claim for reimbursement would be false if petitioner "failed to meet *at least one* of the two regulatory requirements: (1) that a physician certified the patient is terminally ill and (2) that the certification is in accordance with section 418.22," which requires documentation).

Accordingly, even if petitioner were correct that an expert's disagreement with a terminal prognosis is not enough to render that clinical judgment false, that holding would only cover one out of the two requirements the Third Circuit found to be violated. The claim would still be false if the separate documentation requirement of 42 C.F.R. § 418.22(b)(2) was not met—and so the outcome of the case would not change. *See* App.15 ("[D]isagreement between experts as to a patient's prognosis may be evidence of [a violation of the documentation requirement]; its relevance need not be limited to evidence of the accuracy of another physician's judgment."). In order to reverse, the Court must not only decide the question presented, but also the separate question of whether and when a violation of the documentation requirement renders a claim for hospice reimbursement false—or, even more narrowly, whether the documentation requirement was violated in this case.

That question is plainly not certworthy, which is why the petition does not expressly present it. It is relevant only to the narrow context of hospice claims;

it relates to regulations that have since been amended; and it treads ground that this Court only recently considered in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016), where the Court held that a claim can be false based on noncompliance with a material regulatory requirement.

The Third Circuit's resolution of the documentation question was also correct. Petitioner argues the merits on pages 28-29 of the petition, making two points—but neither is persuasive.

First, petitioner argues that any time a physician's prognosis is reasonable, the documentation requirement is satisfied because the documentation "support[s]" every reasonable conclusion that could be drawn from it. Pet. 28. But the regulation does not say that a certification must be accompanied by "clinical information and other documentation that *could* support the medical prognosis." It requires the accompanying documentation to actually "support the medical prognosis." 42 C.F.R. § 418.22(b)(2). Thus, the question is not whether, in the certifying physician's clinical judgment, the documentation is adequate (a rule that would render the requirement toothless); the question is whether CMS would regard the documentation as adequate. That is how hospice claim review works in the real world. *See, e.g.*, *Solari Hospice Care*, 2013 WL 8744176, at *2-6 (Dep't of Health & Human Servs. June 17, 2013) (affirming ALJ's denial of payment for hospice care for three patients because a prognosis of six months or less was not supported by the medical records). Whether CMS would pay the claim based on the supporting

documentation is a factual question well-suited for expert testimony, among other proofs.

Second, petitioner stresses that CMS has reassured physicians that they will not be held liable for good-faith mistakes. Pet. 29. But that reassurance is predicated on compliance with the procedure for preparing a proper certification—which includes providing adequate supporting documentation. As explained above, this is an important accountability measure, and an independent, material condition of payment. *See supra* pp.1-2 (collecting authorities). That is why the Government takes the position that "clinical information in the patient's medical records supporting a life expectancy of six months or less is an independent condition of payment for hospice care separate and apart from a signed physician certification." U.S. CA3 Amicus Br. 4.

Of course, the key point for certiorari purposes is not the merits of this side question, but instead that petitioner's question presented is hidden behind another, even less certworthy question. If the Court wants to take a case about whether clinical judgments can be false, it should await a case that cleanly presents that question, without taking on the baggage of deciding what 42 C.F.R. § 418.22(b)'s documentation provision requires.

III. The Decision Below Is Correct.

Certiorari should also be denied because the decision below is correct. The statute provides for liability when a defendant knowingly presents "a false or fraudulent claim," or knowingly makes or uses "a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). The

Third Circuit held that "FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government." App.14. It relied on the element of scienter to shield good-faith judgments from liability.

In general, that is the right way to understand false claims. If a defendant presents a claim that the Government would not pay, that claim is false, regardless of the reason, *i.e.*, whether the claim is based on an untrue statement (factual falsity), or whether the claim is submitted in violation of a material condition of payment (legal falsity). If the defendant presents such a claim knowingly, the defendant is liable under the FCA.

This rule is consistent with the statutory text. The FCA does not define "false," and the plain meaning of the word is not limited to intentionally untrue statements, deceptive conduct, or even facts. Instead, it reaches claims "based on mistaken ideas" as well as those that are "inconsistent with the facts." *False*, Merriam-Webster, https://www.merriam-webster.com/dictionary/false (last visited Jan. 7, 2021). There is no basis in the statute to limit falsity to anything less than its full scope.

The Third Circuit's understanding of falsity also gives meaning to each subsection of the statute. The FCA imposes liability for false "claims," and separately for "false record[s] or statement[s] material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A), (B). It would make no sense to separate these violations if a false statement was the *sine qua non* of a false claim. That is the implication, though, of the "objective falsity" rule, under which a

claim based on an opinion cannot be false unless the opinion misstates a verifiable fact. The Third Circuit's rule, by contrast, preserves independent meaning for each subsection of the FCA's liability provision, as well as scienter.

The Third Circuit's rule also follows this Court's precedents, which hold that the FCA "reach[es] all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). The FCA's legislative history likewise explains that "[t]he False Claims Act is intended to reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services," and that false claims may "take many forms, the most common being a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." S. Rep. No. 99-345, at 9 (1986).

More recently, when defendants tried to limit the element of falsity, this Court rejected the argument. The Court explained that "[i]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements." *Universal Health Servs.*, 136 S. Ct. at 2002 (quotation marks omitted). The Third Circuit heeded this command in this case. App.12.

Limiting falsity to "objective falsity" also risks creating anomalous situations in which a defendant knows that it is claiming public funds that it should not receive, but cannot be held liable because the claim is based on an opinion or judgment. That outcome

would make little sense, and the Third Circuit wisely adopted a rule that forecloses it.

The petition's arguments in favor of the objective falsity rule lack merit. The petition's core theme is that an opinion does not become false merely because an expert disagrees with it. But nobody thinks that disagreement among experts makes an opinion false. What makes the opinion false is that it was wrong, *e.g.*, the doctor said the patient was terminally ill, but the patient was not terminally ill at the time. The expert's opinion may help a jury understand why the opinion was false—but it does not conclusively establish falsity. That is why a plaintiff cannot find an expert who disagrees with a certification decision and then immediately move for summary judgment on liability. That would be silly because, as petitioner points out, a party with money can often find an expert to agree with its view. Pet. 27. For that same reason, though, a defendant's expert cannot give the defendant a free pass out of liability merely by opining that a certification was reasonable. Instead, the jury should decide, considering evidence of falsity and also scienter.

The petition argues that the mere fact that a prediction turns out to be wrong does not make it false when made. Yes it does, because "wrong" and "false" mean the same thing in this context. If the physician says that the patient was terminally ill, and the patient was not terminally ill, the prediction was false when made. The prediction might not be *knowingly* false, as required to create FCA liability. But it is false. Under the contrary rule, even a knowingly wrong prediction could be insulated from liability—which Congress did not intend.

For the contrary proposition, petitioner cites *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015), a case interpreting Section 11 of the Securities Act of 1933, which creates liability under the securities laws if "any part of the registration statement, when such part became effective, contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k(a). The Court held that an opinion can trigger liability under Section 11 if it contains an embedded statement of fact (*e.g.*, that the speaker actually holds the opinion), or if a reasonable investor would understand an opinion, in context, to communicate facts about how the speaker formed the opinion. *See* 575 U.S. at 185, 189. Petitioner argues that these circumstances are the only ones under which an opinion could be false under the FCA, too.

That is wrong because the FCA does not resemble Section 11. It does not, for example, refer to an "untrue statement of a material fact." Instead, it refers to a "false or fraudulent claim," and it includes a scienter requirement to police the boundaries of liability. *Omnicare* is helpful because it shows that even statutes focused entirely on factual inaccuracy can be triggered by false opinions—but the range of misstatements and misdeeds that can trigger FCA liability is broader than the triggers for Section 11.

Independently, the petition's arguments miss the point because they focus on whether the physician's certification is a false statement. False statements are one basis for FCA liability. *See* 31 U.S.C. § 3729(a)(1)(B). But the statute independently creates

liability for presenting false *claims*. *Id*. § 3729(a)(1)(A). As explained above, these are claims that are ineligible for reimbursement—regardless of the reason why. The petition's arguments do not address this rule of legal falsity, and are unpersuasive for that reason.

Finally, even though the Third Circuit rejected the label of "objective falsity," its rule is rooted in objectively verifiable reality. Under the Third Circuit's rule, a claim is false if the Government would not pay it. Whether the Government would pay a particular claim is an objectively verifiable fact—not a matter of opinion. Thus, the Third Circuit's rule is not based on a battle of subjective judgments; it is based on facts about the Government's policies and practices.

The hospice context does not change that conclusion. As explained above, the judgments doctors make in hospice cases are not pure guesswork. *See supra* p.20. Moreover, hospice eligibility fraud is a serious concern; it threatens patient harm and has cost the Government hundreds of millions of dollars. *See supra* pp.3-4. Maintaining a basis for FCA liability when defendants knowingly submit ineligible claims is critical to protecting public health and the fisc.

Because the decision below correctly stated and applied the law, this Court should deny review.

CONCLUSION

Certiorari should be denied.

Respectfully submitted,

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