No. 21-

Supreme Court of the United States

HENRY MCINNIS,

Petitioner,

V.

UNITED STATES OF AMERICA,

Respondent.

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

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

Did the lower court err in finding pervasive fraud as to "false" hospice certifications—following the Third Circuit as opposed to the Eleventh Circuit—thereby expanding regulatory liability contrary to the Social Security Act and First Amendment?

PARTIES TO THE PROCEEDING

Petitioner is Henry McInnis, who was the defendant in the district court and the appellant in the appeals court.

Respondent is the United States of America, the plaintiff in the district court and the appellee in the appeals court.

CORPORATE DISCLOSURE STATEMENT

Petitioner is an individual.

DIRECTLY RELATED PROCEEDINGS

United States of America v. Rodney Mesquias and Henry McInnis, No. 20-40869 (5th Cir., opinion and judgment entered on March 24, 2022)

United States of America v. Rodney Mesquias and Henry McInnis, No. 1:19-CR-9-1 (S.D. Tex., final judgment of conviction and sentence entered on February 3, 2021)

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PETITION FOR A WRIT OF CERTIORARI

Henry McInnis respectfully petitions the Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit.

INTRODUCTION

The opinion below expands liability to healthcare providers and other regulated industries for certification fraud. This case specifically involves certifications by doctors to Medicare that patients are eligible for hospice. Unlike traditional Medicare fraud cases in which doctors expressly certified that services complied with specified requirements (e.g. "the services shown on this form were medically indicated and necessary for the health of the patient"), the Government has recently expanded its prosecution of regulatory violations through "implied false certification" in cases where the Government lacks evidence that the defendant submitted a claim or certification to Medicare. Implied false certification is premised on the legal fiction that by sending a bill to the government an individual or business is deemed after-the-fact to have made fraudulent certifications as to esoteric regulations, such as Medicare coding rules, which the defendant had no idea about or that were expressly limited by statute to certifying individuals with technical expertise such as doctors.

The rules for the Medicare Hospice Benefit state: "Certification will be based on the physician's or medical director's clinical judgment." 42 C.F.R. § 418.22(b). Courts including the Eleventh Circuit have properly interpreted this regulation to require objective falsity before finding that a certification was

fraudulent. The lower court, following the Third Circuit, has deepened a circuit split by not only dispensing with objective falsity but applying its "pervasive fraud" rule to the hospice provider's entire file system, magically turning $19,000 of false certifications into $150 million. This approach obviously helps the Government secure spectacular convictions, and it has plunged the industry into deep uncertainty about what, if anything, remains of the certification rules and guidance issued by CMS that have been followed for forty years.

Should the Court deny certiorari once again on this long percolating issue, the hospice industry, its 2 million vulnerable patients, and every regulated industry will face unlimited liability and potentially widespread disruption of essential services.

OPINIONS BELOW

The opinion of the court of appeals (App. A) is reported at 29 F.4th 276 (5th Cir. 2022). The orders of the district court (App. B, C) are not reported.

JURISDICTION

The court of appeals issued its judgment on March 24, 2022. App. A. This petition is due on June 22, 2022. The Court's jurisdiction is invoked under 28 U.S. Code § 1254.

REGULATORY PROVISION INVOLVED

"*Certification will be based on the physician's or medical director's clinical judgment. . . . The c*ertification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. . . . The *physician* must include a brief narrative explanation. . . . All certifications and recertifications must be signed and dated by the *physician(s)*." 42 C.F.R. § 418.22(b) (emphasis added).

STATEMENT

I. Factual Background

Henry McInnis was an office administrator for Merida Health Care Group, a hospice chain in Texas. He was assigned to Merida's branch office Harlingen, a town on the border with Mexico, performing unskilled office tasks such as answering the phone. He has a high school education. He received roughly $70,000 per year in compensation. ROA.51812. [1]

The Government charged McInnis, spectacularly, of defrauding the United States of $150 million. This number, however, represented the total amount of Medicare billings for the Merida's entire hospice chain statewide. ROA.7738. The Government alleged that six patients had not been properly "certified" for hospice, thereby incurring Medicare charges of $19,895.39. The Government also brought three

[1] "ROA" refers to the record on appeal in United States of America v. Rodney Mesquias and Henry McInnis, No. 20-40869 (5th Cir., No. 21-50792 (5th Cir.)

counts predicated on falsely certified patients: conspiracy to commit Medicare fraud (Count 1), conspiracy to launder proceeds of Medicare fraud (Count 8); and conspiracy to produce false records of Medicare claims (Count 11). The Government did not allege or prove at trial that hospice services were not provided in exchange for the $150 million payments to Merida's more than 9,000 patients. App. B.

At trial, the Government's case consisted of testimony from several cooperating witnesses that a large—and indeterminate fraction—of these patients had been "falsely certified" as eligible for hospice care and had thereby received excess care to which they were not entitled. To prove up this claim, the Government submitted roughly 100,000 pages of medical forms. It is undisputed that the forms show that more than a dozen doctors had certified in their own "clinical judgment" that the patients were eligible for hospice. No medical testimony was offered from these or any doctor to controvert any of the certifications (in fact, the Government de-designated its potential medical expert). The jury convicted McInnis of seven substantive counts of fraud in the amount of $19,895.39 and the three derivative counts. App. C.

At sentencing, over Appellant's objection, the district court adopted the PSR including a 24-level enhancement for loss greater than $65,000,000 and a corresponding 4-level enhancement for health care fraud involving loss greater than $20,000,000. ROA 119803. The district judge denied Appellant's request for a hearing. In the absence of medical testimony or analysis that would permit the court to extrapolate the number of claims reasonably corresponding to claims for the six patients in Count 2 – 7, the court

simply assumed it was futile and calculated the loss amount based on all billings, more than doubling McInnis's guideline score. He was sentenced to 15 years in prison. App. C.

REASONS FOR GRANTING THE WRIT

I. The Question Has National Importance

The question here has paralyzed the hospice industry, leaving millions of vulnerable patients in a cloud of uncertainty as to the legality of the basic eligibility criteria set forth by the Government itself.

The hospice industry is highly standardized, consisting of roughly five thousand businesses distributed across fifty states and completely dominated by a single government payor, the Centers for Medicare and Medicaid Services (CMS).[2] CMS requires each provider to accept identical contract terms set forth in the Social Security Act. 42 U.S.C. § 1395f. Buried in an annual notice referenced in the CMS regulations is the essential term of every hospice contract, for every patient, a per diem amount: $203.40 per patient.[3] Indeed, every one of the Nation's two million hospice patients is assigned the same value regardless of medical need. As economists have noted since the 1980s, this absurd payment model is an extreme example of a fee-for-service healthcare system without any of the benefits. In any event, the

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[2] National Hospice and Palliative Care Organization, NHPCO Facts and Figures (Aug. 20, 2020), www.nhpco.org.

[3] 42 U.S.C. § 1395f; 42 C.F.R. Subpart G; www.cms.gov/HospiceWebPricer.

result is staggering inefficiency, and a tendency for ever-expanding fraud investigations. Although the Government suggested throughout trial that Merida's entire business model of recruiting noncancerous hospice patients was illegal, it is a business model that the Government created, set forth in 42 U.S.C. § 1395f. For-profit hospices universally, openly, and aggressively recruit longer-living patients, in particular noncancerous dementia patients.

The lower court's opinion creates uncertainty not only for the financial stability of the hospice system but also CMS's actual rules for preventing fraud. CMS requires hospices to comply with 300 elements of compliance with Medicare fraud prevention rules.[4] The Social Security Act further provides the Department of Health and Human Services an array of enforcement tools, in addition to discretion to simply deny coverage for ineligible hospice patients, including civil monetary penalties and the authority to exclude individuals and hospice companies. *See, e.g.*, HHS, Civil Monetary Penalty Authorities, https://oig.hhs.gov/fraud/enforcement/civil-monetary-penalty-authorities/ (last visited July 27, 2021) (listing 25 separate statutory authorities for civil monetary penalties).

Hospice providers have spent decades developing compliance policies and training staff to implement CMS's antifraud regime. The bedrock principle of these compliance programs is that hospice

[4] NAHC, Hospice Performance On Health And Safety Surveys Concerns Recommendations (2019).

administrators can and must rely on doctors' "clinical judgment," leaving it to medical boards to determine whether that judgment was based on sound medicine or, perhaps, improperly influenced by Medicare's perverse payment incentives or other business pressures.

> Certification will be based on the *physician's or medical director's clinical judgment*. . . . The certification must specify that the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course. . . . The *physician* must include a brief narrative explanation. . . . All certifications and recertifications must be signed and dated by the *physician(s)*.

42 C.F.R. § 418.22(b) (emphasis added). Indeed, the *only* thing hospice administrators can rely on is the doctor's clinical judgment: "CMS has considered and expressly declined to impose defined criteria that would govern the physician's exercise of judgment." *AseraCare, Inc.*, 938 F.3d at 1301.

The lower court's opinion and circuit split cast doubt on forty years of CMS guidance and drastically undermine the compliance policies developed by every hospice provider. As the Eleventh Circuit explained, imposing fraud liability for hospice certifications on top of CMS's already onerous requirements is an extreme intrusion by the judiciary.

> Congress and CMS could have imposed a more rigid set of criteria for eligibility determinations that would have minimized

> the role of clinical judgment. Instead, they were careful to place the physician's clinical judgment at the center of the inquiry. . . . In any event, the FCA is an inappropriate instrument to serve as the Government's primary line of defense against questionable claims for reimbursement of hospice benefits.

AseraCare, Inc., 938 F.3d at 1301. Another court, addressing a similar sprawling hospice certification case, noted the vast potential consequences, not only for the industry but for courts. *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833, at *1 (N.D. Tex. Jun. 20, 2016). The judge reasonably noted that even if the hospice's "aggressive marketing and enrollment policies were ill-advised," the core principle of the Medicare hospice benefit remained: "eligibility depends on physician judgment." *Id.* at 62. Neither lay observations of patient health nor expert statistical analyses of cold medical records could render such clinical judgments fraudulent en masse. *Id.*[5]

The circuit split as to this expansive new form of documentation fraud has fragmented the hospice industry and had a chilling effect on other highly regulated industries. As a broad coalition of industries explained to this court in a cert-stage amicus brief in

[5] The Eleventh Circuit referred merely to civil liability under the FCA. The Healthcare Fraud Act, far more than the civil FCA, "is not an appropriate vehicle for policing technical compliance with administrative regulations." *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681-82 (5th Cir. 2003) (en banc) (Jones, et al. concurring).

Care Alts. v. United States, 141 S. Ct. 1371 (cert denied, Feb. 22, 2021):

> Fearing retrospective second-guessing of their clinical judgment, physicians may be reluctant to certify a patient as terminally ill unless the patient is nearly certain to die within six months. Other physicians, in turn, may hesitate to refer potential patients to hospice. By threatening to limit the availability of the Medicare hospice benefit, the decision could deprive millions of terminally ill individuals and their families of hospice care's undisputed benefits.

Brief for the American Medical Association, National Hospice and Palliative Care Organization, National Association for Home Care & Hospice, American Academy of Hospice and Palliative Medicine. *Id.* The U.S. Chamber of Commerce further warned that the novel expansion of fraud liability to hospice certifications

> has implications far beyond the hospice context. It potentially affects any entity, public or private, that receives federal funds in myriad contexts: government contractors working under cost-reimbursement contracts; medical providers delivering services based on their good-faith medical judgments; researchers submitting claims for grant funds based on their scientific opinions; and any business attempting to navigate the complex statutory, regulatory, or contractual regime

> that governs their receipt of government funds.

141 S. Ct. 1371, Brief of the U.S. Chamber of Commerce.

The circuit split creates further uncertainty as to other recordkeeping standards applicable to hospice providers—standards that Congress and the CMS have explicitly chosen not to require. Throughout this case, as in other recent cases, the Government has asserted that hospice providers must maintain *unlimited* records regarding not only the terminal illness but all illnesses suffered by hospice patients. Or as one of its investigators testified at trial:

> Oftentimes, patients who have terminal illnesses have other conditions that are also affecting the outcome of that patient. Not only do they have other illnesses, they have, what we call, secondary conditions. Certifications for terminal illness require sufficient documentation on all those conditions.

ROA. The lower court tacitly affirmed this supplemental requirement in its reference to testimony about documentation of diagnoses. The underlying contention is that documentation inconsistent with an internal guideline for claims processors called a Local Coverage Determination (LCD) is "false."

In reality, the sole documentation required by the Medicare rules for hospice certification is a sheet of paper containing a signed certification stating that (1)

"the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course" and (2) a "brief narrative explanation of the clinical findings that supports a life expectancy of 6 months." 42 C.F.R. § 418.22 (b)(3). The suggested sample narrative provided by CMS is 5 sentences.[6] Although the preceding subsection states that "clinical information and other documentation that support the medical prognosis must accompany the certification," 42 C.F.R. § 418.22(b)(2), the narrative can satisfy that provision. Doctors simply need to keep whatever clinical documentation they find relevant to the prognosis in the medical record. Importantly, there is no minimum requirement for documentation beyond the brief narrative. As the Eleventh Circuit has explained, "supporting" documentation does not mean "sufficient" to meet any criteria or standard:

> Congress said nothing to indicate that the medical documentation presented with a claim must prove the veracity of the clinical judgment on an after-the-fact review. And CMS's own choice of the word "support"—instead of, for example, "demonstrate" or "prove"—does not imply the level of certitude the Government wishes to attribute to it.

AseraCare, 938 F.3d at 1290. The rules thus give providers wide latitude in interpreting the minimal documentary requirement for certifications. Even

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[6] *See* https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/se1628.pdf.

those minimal requirements are widely disregarded; CMS reports that for 10% of hospice stays, certifying doctors fail to provide a narrative at all.[7] It should be noted that CMS did at one time propose requiring clinical documentation and establishing objective criteria, but Congress flatly preempted this proposal and amended the Medicare Act in 2000 to state: "the certification regarding terminal illness . . . shall be based on the physician's or medical director's clinical judgment." H.R. 4577, 114 Stat. 2763 (2000).

Accordingly, CMS rules now provide that hospice certifications are based on the doctor's "subjective . . . medical findings." 42 C.F.R. § 418.102. CMS has since repeatedly affirmed that no specific documentation is required. 70 Fed. Reg. 70,532, 70,535 (Nov. 22, 2005) ("We are removing the word 'specific' and changing 'findings' to 'information'"); 73 Fed. Reg. 32,088 (June 5, 2008) ("We have removed the term 'criteria' in order to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness."). The rules for certification of terminal illness simply "do not provide objective standards or criteria to cabin such determinations." *Wall*, 2016 WL 3449833, at *62.

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[7] Suzanne Murrin, Hospices Should Improve Their Election Statements and Certifications of Terminal Illness, U.S. Dep't of Health & Human Servs. Office of Inspector Gen. (Sept. 2016), https://oig.hhs.gov/oei/reports/oei-02-10-00492.pdf;
Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance with Medicare Coverage Requirements (OEI-02-06-00221; 09/09) (hhs.gov); National Association for Home Care & Hospice, Hospice-Performance-On-Health-And-Safety-Surveys-Concerns-Recommendations.pdf (2020).

Despite the above voluminous guidance from Congress and the CMS that no additional documentation is required, the Government has repeatedly asserted in fraud cases—now with the blessing of two circuit courts—that the Local Coverage Determination: Hospice Determining Terminal Status is a relevant standard for certification of hospice patients. The LCD is a document published by private claims contractors to determine whether hospice services are covered by Medicare.[8] It has no medical validity or legal relevance in certification cases. The Government expert's testimony on noncompliance with LCD's was error. *See Wall*, 2016 WL 3449833, at *60 n.n.134, 138 (expert's description of LCDs was "rife with errors"); *AseraCare*, 938 F.3d at 1288 (approving limiting instruction that "the jury was not permitted to conclude that Dr. Liao's testimony was more credible because he made reference to the LCD criteria, or that *AseraCare*'s claims were false if they failed to conform to those criteria").

The Government has actually disavowed the lower court's and Third Circuit's judicially imposed recordkeeping requirements, after a controversial proposal in 2010 that would have required certifications to include evidence from three categories of criteria listed in the hospice LCDs (L13653, L25678, L29881). 75 Fed. Reg. 70,371 (Nov. 17, 2010). After public outcry and claims that the

[8] *See* 42 U.S.C. § 1395y(a)(1)(C) (hospice benefit limited to reasonable and necessary services) & (l)(6)(B) (coverage defined by LCD).

proposal constituted an unlawful delegation of legislative power, CMS retracted the suggestion, citing Congress's Statutory Clarification of 2000: "The illustrative clinical findings mentioned above are not mandatory national policy. We reiterate that certification or recertification is based upon a physician's clinical judgment, and is not an exact science." 76 Fed. Reg. 26,806 (May 9, 2011). To date, the LCDs have never been validated and have been discredited by the medical community as a tool for prognosis.[9] But because reimbursement is based on the LCDs, hospices have "rigidly adhered to LCDs as a 'standard,' . . . fearful of regulatory retribution against their medical licensure, refusing to certify patients for hospice care unless every LCD box could be checked."[10] The rogue circuit-courts recordkeeping requirement has created a vicious circle resulting in a "skewed distribution of hospice admissions, with most patients dying within days to weeks (rather than weeks to months), and a smaller fraction of seemingly similar patients at the time of referral and admission living well beyond 6 months."[11] CMS has so far

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[9] Moore, D Helen, "Evaluation of the Prognostic Criteria for Medicare Hospice Eligibility" (2004), https://scholarcommons.usf.edu/etd/1167; Fine, P. G. "Hospice Underutilization in the US: The Misalignment of Regulatory Policy and Clinical Reality." Journal of Pain and Symptom Management 56.5 (2018): 808-815.

[10] Fine, P. G. "Hospice Underutilization in the US: The Misalignment of Regulatory Policy and Clinical Reality." Journal of Pain and Symptom Management 56.5 (2018): 808-815.

[11] *Id.*

declined to adopt or even to fund research into a medically valid standard for estimating 6-month life expectancy." [12] The "science of prognostication is in its infancy. . . . There are no empirically validated predictors of life expectancy beyond an experienced physician's clinical judgment."[13] In practice, hospice physicians resort to rules of thumb, e.g. "the 'surprise' question, 'Would I be surprised if this patient died in the next year?'"[14] Given the total absence of objective and generally accepted certification standards, asking a lay jury to determine whether certifying doctors' subjective judgments were false or fraudulent based

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[12] E.g. 2020 Regulatory Blueprint for Action, National Association for Home Care & Hospice, https://www.nahc.org/wp-content/uploads/2020/12/2020-Regulatory-Blueprint.pdf ("Criteria for determining a prognosis of six months or less (eligibility for hospice services) is not a matter to be decided at the local level, but rather by a set of scientifically determined variables, signs, and symptoms for discrete diagnoses based on research and clinical judgment.").

[13] Fine, P. G. "Hospice Underutilization in the US: The Misalignment of Regulatory Policy and Clinical Reality." Journal of Pain and Symptom Management 56.5 (2018): 808-815; Rector T, Taylor BC, Sultan S, Shaukat A, Adabag S, Nelson D, Capecchi T, MacDonald R, Greer, N, Wilt TJ. Life Expectancy Calculators, VA ESP Project #09-009 (2016) ("We found no true external validation studies of the reviewed mortality prediction models. None of the models have been externally validated for general primary care use.").

[14] Martin, Emily J.; Widera, Eric, Prognostication in Serious Illness. Medical Clinics of North America (2020); Vasista, A; Stockler, MR; Martin, A; Lawrence, NJ; Kiely, BE, Communicating prognostic information: what do oncologists think patients with incurable cancer should be told?. Internal Medicine Journal (2020).

on lay testimony or even post hoc medical reviews was inappropriate, and at minimum should not have been imported en masse into the guideline calculation under the theory that Merida's entire filing system was fraudulent due to alleged pervasive recordkeeping deficiencies. As one commentator put it, "It is difficult to conceive of a greater abuse of discretion than seeking to enforce compliance of the . . . coverage criteria before even defining and notifying providers of the parameters and interpretations to be imposed."[15] Imposing criminal fraud liability for lax recordkeeping regarding certifications would be even more unfair, given the widespread confusion even among CMS's own contractors about what documentation is actually required.

Lastly, the lower court's extreme flexibility toward false certification claims opens the door to infringement of hospice patients' First Amendment rights. Given that Congress has granted hospice doctors unfettered discretion to exercise their own clinical judgment in determining hospice eligibility, free from interference by federal prosecutors, the Government cannot suddenly dictate the content of those judgments. In *United States v. Caronia*, 703 F.3d 149, 169 (2d Cir. 2012), the court held the First Amendment barred prosecution of pharmaceutical salesmen for alleged fraudulent off-label "misbranding" where off-label use was otherwise

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[15] Timothy Blanchard, *Symposium: Medicare Medical Necessity Determinations Revisited: Abuse Of Discretion And Abuse Of Process In The War Against Medicare Fraud And Abuse*, 43 St. Louis L.J. 91, 120-121 (1999).

permitted. The court concluded: "The government cannot use a criminal conspiracy charge as a subterfuge to circumvent statutes and FDA regulations, and to justify imposing criminal liability for speech the governing law permits." End-of-life discussions warrant additional protection under the Free Expression Clause. Hospice regulations directly involve religious expression, requiring hospices to designate a "pastoral or other counselor" to care for hospice patients. 42 C.F.R. §§ 418.56(a); 418.3; 418.54(c)(7); 418.66(d)(1); 488.110. Spiritual counseling is made available as a "core hospice service." 42 C.F.R. §§ 418.64(d)(3). The Supreme Court has long held that the First Amendment precludes the use of fraud statutes in the context of end-of-life spiritual counseling. *See United States v. Ballard*, 322 U.S. 78, 86-88 (1944) (prosecution for false claims made to terminally ill patients about incurable diseases was unconstitutional). The Court characterized such prosecution as direct threat to religious expression: "The miracles of the New Testament, the Divinity of Christ, life after death, the power of prayer are deep in the religious convictions of many. If one could be sent to jail because a jury in a hostile environment found those teachings false, little indeed would be left of religious freedom." *Id.* In this context of the Medicare Hospice Benefit, Congress has appropriately provided broad leeway for doctors to determine life expectancy according to "subjective" findings, 42 C.F.R. § 418.102, and to coordinate discussion of those findings with chaplains and counselors according to each patient's "physical, psychosocial, emotional, and spiritual needs." 42

C.F.R. § 418.54 (c). A driving reason for this flexible policy is the vast disparity in utilization of hospice services among religious and racial groups, generally attributed to the secular and nihilistic manner in which prognoses are discussed by the medical community.[16] Even the term "hospice," for instance, has a negative connotation for Spanish speakers, meaning a place for orphaned children. The Government broadly attacked the use of chaplains to facilitate care across Merida's patient population in South Texas, arguing variously that chaplains were giving patients false hope or false fear: "Counseling them on God's plan for death. It wasn't their time to die. Some patients were being deceived that they didn't have to die to be on hospice; other patients were being deceived that they were dying when they weren't." ROA.6772. Needless to say these arguments were all based on hearsay about unrecorded private conversations between chaplains and hospice patients. By broadly affirming the Government's false certification theory in its entirety, the lower court gave the Government carte blanche to dictate as well as criminalize the manner in which doctors express subjective clinical judgments regarding a patient's life expectancy or the content of end-of-life discussions between chaplains and patients.

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[16] NAHC, 2020 Regulatory Blueprint for Action; Robert Bulanda, Note, A Step Toward Normalizing End-of-Life Care: Implications of the Palliative Care and Hospice Education and Training Act (PCHETA), 39 N. Ill. U. L. Rev. 330 (2019).

II. Circuit Courts Are Sharply Divided

As noted above, the Eleventh Circuit has interpreted the hospice certification standard under 42 C.F.R. § 418.22 (b) ("Certification will be based on the physician's or medical director's clinical judgment.") to hold that fraudulent certification requires "an objectively verifiable fact at odds with the exercise of that judgment." 938 F.3d 1278, 1301 (11th Cir. 2019).

The lower court reached the opposite conclusion, while noting that "stronger evidence—of lies, kickbacks, and fabrication—is present here." App. A. In other words, there was fraud because there was fraud. (It should be noted that McInnis was not charged with kickbacks.) Summarizing the Government's testimony, the court concluded that McInnis

> orchestrated a scheme of certifying patients for home health and hospice care regardless of their eligibility. They certified all patients who came to their facilities, regardless of eligibility. After the patients were certified once, defendants recertified them indefinitely, again without consideration of their eligibility. An estimated 70 to 85 percent of the Merida Group's patients were ineligible for the care they received.

Id. Of course, McInnis did not certify anyone himself. Under the plain terms of 42 C.F.R. § 418.22(b), the certifications were done by Merida's twelve certifying doctors. ROA.37234, ROA.37259-62; ROA.5347-48; ROA.22213; ROA.15644; ROA.15872; ROA.25978; ROA.29321; ROA.1599. The lower court then cites the Fifth Circuit's pattern jury instructions for the

proposition that "circumstantial" estimates would suffice to establish that the patients were in fact ineligible. The circularity of that conclusion was explained clearly by the judge in the *Wall* case, with respect to similar testimony from a Government witness "summarizing his review of 291 patient files and conclusion that a large percentage of those patients were not eligible," along with voluminous anectdotes about standard business practices that encouraged certifications, and then suddenly extrapolating from the 291 files to several thousand "false" certifications. 2016 U.S. Dist. LEXIS 80160, at *15.

The Fifth Circuit and Third Circuit have thus adopted a expansive definition of false, allowing medical certifications that Congress has emphatically deferred to doctors' judgments to support civil and even criminal fraud liability. This is a dramatic expansion of fraud. *Cf. Deming v. Darling*, 20 N.E. 107, 108 (Mass. 1889) (Holmes, J.) (statements "open to difference of opinion" are not actionable as fraud).

Even assuming the lower court properly found fraud liability as to the handful of patients described, the application of that finding to nearly 10,000 other patients constitutes a much more consequential error. Indeed, the court acknowledged the gravity of the district court's failure to hear any evidence at sentencing to meet the Fifth Circuit's already expansive "pervasive fraud" criterion for determining loss: "We are troubled by that refusal. The momentousness of any sentencing, combined with the complexity of this $100 million-plus fraud scheme, would seem to have warranted allowing testimony absent some compelling reason to the contrary." App.

It was the Government's burden, of course, to put on evidence as to its 9,000 medical certifications. A lay guesstimate obviously does not cut it (particularly since the Government had available, as in every fraud prosecution, an expert who admitted he could easily perform a valid sample). ROA.

The lower court's "whole file system" approach to certification fraud flips the burden for certification fraud almost entirely on the defendent. *Cf.* 18 U.S.C. § 3664(e) (burden of proving "the amount of the loss" is on government).

The lower court's decision deepens an existing split as to whether pervasive fraud is ever appropriate. In *United States v. Rutgard*, 116 F.3d 1270 (9th Cir. 1997), a doctor was convicted of defrauding Medicare by certifying that procedures were medically necessary when they were not. *See id.* at 1281-86. As in this case, cooperating witnesses who worked at the clinic testified that *they* did not submit fraudulent bills, or "only occasionally doing recording or billing against their honest judgment because of [the defendant's] overriding directions." *Id.* at 1289. The district court concluded that the defendant's medical practice was "permeated with fraud" and found a loss of "virtually the entire proceeds" of the practice. *Id.* at 1275, 1294. The Ninth Circuit vacated the sentence, reasoning that "permeated with fraud" is a conclusion "too indefinite and conclusory to support a sentence." *Id.* at 1294. "As always, the burden is on the government to establish what services were not medically necessary." *Id.* In accordance with that principle, in a similar case, Judge Ricardo Hinojosa (former Chairman of the U.S. Sentencing Commission) recently examined the exact same issue and held the Government at minimum

must provide a list of the 12,000 patients that it specifically believed had been fraudulently diagnosed. *U.S. v. Zamora-Quezada, et. al.*, No. 7:18-cr-00855-1 (S.D. Tex. 2018). There is no basis for the lower court's concern that a lower court is "not required to sift through thousands of claims" before assigning liability for them. App. A. It is the Government's burden, generally easy to meet, and it has always been required.

CONCLUSION

The lower court and Third Circuit have created widespread uncertainty by drastically expanding liability for regulatory fraud. The Court should grant certiorari and resolve this split.

Respectfully submitted,

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