No. 16-13004

IN THE

United States Court of Appeals for the Eleventh Circuit

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

v.

GGNSC ADMINISTRATIVE SERVICES, *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the Northern District of Alabama
Case No. 2:12-cv-245

BRIEF FOR THE AMERICAN MEDICAL ASSOCIATION, THE NATIONAL HOSPICE AND PALLIATIVE CARE ORGANIZATION, THE NATIONAL ASSOCIATION FOR HOME CARE AND HOSPICE, THE AMERICAN ACADEMY OF HOSPICE AND PALLIATIVE MEDICINE, AND THE HOSPICE AND PALLIATIVE NURSES ASSOCIATION AS AMICI CURIAE IN SUPPORT OF APPELLEES AND AFFIRMANCE

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United States v. GGNSC Administrative Services
No. 16-13004

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rules 26.1-1, 28-1(b), and 29-2, amici curiae certify that, in addition to the individuals and entities identified in appellees' brief, the following individuals and entities have an interest in the outcome of this case:

American Academy of Hospice and Palliative Medicine

American Medical Association

Dombi, William A.

Global Partners in Care (formerly known as the Foundation for Hospices in Sub-Saharan Africa)

Hogan Lovells US LLP

Hospice Action Network (formerly known as the Alliance for Care at the End of Life)

Hospice and Palliative Nurses Association

Keyserling, Jonathan

Liu, Frederick

National Association for Home Care & Hospice, Inc.

National Hospice Foundation

No publicly traded corporation has an interest in the outcome of this suit.

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STATEMENT OF INTEREST

The American Medical Association (AMA), an Illinois non-profit corporation founded in 1847, is the largest association of physicians and medical students in the United States.[1] Additionally, through state and specialty medical

[1] All parties have consented to the filing of this brief. No party or counsel for a party authored this brief in whole or in part. No party, counsel for a party, or

societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents, and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health. AMA members practice in every area of medical specialization and in every state of the United States.

The National Hospice and Palliative Care Organization (NHPCO) is the largest membership organization in the country representing the entire spectrum of non-profit and for-profit hospice and palliative care programs and professionals in the United States. It represents over 3,500 hospice locations and more than 44,000 hospice professionals, caring for the vast majority of the Nation's hospice patients. As such, it is committed to improving end-of-life care and expanding access to hospice care with the goal of creating an environment in which individuals and families facing serious illness, death, and grief will experience the best that humankind can offer. NHPCO has appeared as amicus curiae under its former name, the National Hospice Organization, in multiple previous cases, including *Swidler & Berlin v. United States*, 524 U.S. 399 (1998); *Vacco v. Quill*, 521 U.S. 793 (1997); *Washington v. Glucksberg*, 521 U.S. 702 (1997); and *Cruzan by Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990).

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person other than amici curiae, their members, and their counsel made any monetary contribution intended to fund the preparation or submission of this brief.

The National Association for Home Care & Hospice, Inc. (NAHC) is a not for profit trade association representing the interests of nearly 6,000 home and community based health care providers throughout the Nation, including hospices, home health agencies, and home care companies. The hospice members include non-profit, proprietary, public, and government-based entities. NAHC hospice members across the United States and the millions of individuals who receive their services have a direct interest in the outcome of this matter as the physician certification of a patient's terminal illness is at the core of every hospice patient's eligibility for Medicare. NAHC has directly participated in legislative and regulatory matters involving the Medicare hospice benefit along with numerous matters before the courts since its inception in 1982.

The American Academy of Hospice and Palliative Medicine (AAHPM) is the professional organization for physicians practicing Hospice and Palliative Medicine. AAHPM's nearly 5,000 members also include nurses and other health and spiritual care providers who are committed to improving the care and quality of life of patients with serious illness and their families. For close to 30 years, AAHPM has been dedicated to expanding access of patients and families to high-quality palliative care and advancing the discipline of Hospice and Palliative Medicine through professional education and training, development of a specialist workforce, support for clinical practice standards, research, and public policy.

The Hospice and Palliative Nurses Association (HPNA) was established in 1986 and is the national professional organization that represents the specialty of palliative nursing, which includes hospice and palliative nurses. HPNA has over 11,500 members and 50 chapters nationally. HPNA works together with the Hospice and Palliative Credentialing Center and the Hospice and Palliative Nurses Foundation to promote its mission, to advance expert care in serious illness, and its vision, to transform the care and culture of serious illness.[2]

Amici's members are directly involved in deciding whether patients should be certified as terminally ill under the Medicare statute. Amici thus have a substantial interest in when such certifications can be deemed "false" under the False Claims Act.

STATEMENT OF THE ISSUE

When can a physician's clinical judgment regarding a patient's life expectancy, based on the normal course of a terminal illness, be considered false?

SUMMARY OF THE ARGUMENT

Every year, over a million Americans with terminal illnesses turn to hospice care, so that they might live their remaining time in peace and comfort. The Medicare hospice benefit, created in 1982, helps the vast majority of those Americans afford such care. For a patient to be eligible for the benefit, a physician

[2] For more information about HPNA, see http://hpna.advancingexpertcare.org.

must certify that in his or her clinical judgment, the patient is terminally ill—meaning that the patient has a life expectancy of six months or less if the illness runs its normal course. The question in this case is when such a certification can be considered "false" under the False Claims Act.

A conclusion cannot be false if it is reasonable, and a conclusion is reasonable so long as it is consistent with the facts. Sometimes, the facts may allow for only one reasonable conclusion; other times, they may allow for more than one. When it comes to how long a patient is expected to live, the range of reasonable conclusions can be quite broad. That is so for three main reasons. First, assessing a patient's life expectancy entails a judgment about the future, and there is uncertainty inherent in any prediction. That is why the Medicare statute and regulations demand only that a prognosis be based on an illness's "normal course." *Infra* pp. 13-15. Second, numerous factors may influence when a person will die, making a patient's life expectancy especially challenging to predict. That is why the Medicare statute and regulations ask only that physicians exercise their best "clinical judgment" in certifying that a patient has a six-month prognosis. *Infra* pp. 15-19. And third, personal knowledge of a patient, especially information gleaned from face-to-face consultations, can be difficult to reduce to writing, so the determination of a physician reviewing only the written record often years later may well differ from the prognosis of a physician who actually saw the patient in

person or consulted with clinical professionals who did. That is why the Medicare regulations require only that each certification be accompanied by documentation that "support[s]" the prognosis. *Infra* pp. 19-21.

Given the many factors that may lead to reasonable disagreement over how long a patient will live, the District Court correctly held that "[a] mere difference of opinion between physicians, *without more*, is not enough to show falsity." Mem. Op., Doc. 497, at 2 (Mar. 31, 2016). Rather, to prove that a certification was false, a plaintiff must show that the prognosis fell outside the range of reasonableness—in other words, that no reasonable physician would have certified the patient as terminally ill. *See infra* pp. 11-12 (citing dictionaries defining "false").

The Government contends that the reasonableness of a conclusion has no bearing on whether it is false. U.S. Br. 22, 32-33. That remarkable position defies not only common sense, but also the text of the Medicare statute and regulations. And if accepted, the Government's position would end up hurting the very people the Medicare hospice benefit is supposed to help: Fearing the prospect of litigation instigated by bounty-seeking relators, physicians may be reluctant to certify patients as terminally ill except in the most obvious of cases, leaving many deserving patients without the means to pay for hospice care. Because that is the opposite of what Congress intended, the Government's position should be rejected, and the judgment of the District Court affirmed.

ARGUMENT

I. A GROWING NUMBER OF AMERICANS RELY ON THE MEDICARE HOSPICE BENEFIT EACH YEAR.

The idea behind hospice care is both realistic and compassionate: When facing a life-limiting illness, an individual should be able to choose services that focus on "caring, not curing." NHPCO, *Facts and Figures: Hospice Care in America* 3 (2015) (*Facts and Figures*).[3] The goal of hospice care is to help terminally ill individuals live the remainder of their lives in peace and comfort, while giving family members the support they need to cope with their loved one's impending death. *See id.* To achieve that goal, hospices are required to employ an "interdisciplinary" approach, combining "expert medical care, pain management, and emotional and spiritual support." *Id.* And in carrying out that approach, hospices rely on a "broad spectrum of professional and other care-givers"—including physicians, nurses, counselors, therapists, and volunteers. 48 Fed. Reg. 56,008, 56,008 (Dec. 16, 1983); *see also* 42 C.F.R. § 418.3 (defining "[h]ospice care" to mean a "comprehensive set of services . . . identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members"); *Facts and Figures*, *supra*, at 3 (describing the "interdisciplinary" hospice team).

[3] *Available at* http://www.nhpco.org/sites/default/files/public/Statistics_Research/2015_Facts_Figures.pdf.

The first hospice opened in the United States in 1974. *Facts and Figures*, *supra*, at 8. Not long after, Congress recognized the potential advantages of hospice care for Americans approaching the end of life. *See* 79 Fed. Reg. 50,452, 50,466 (Aug. 22, 2014). So in 1982, Congress created the Medicare hospice benefit, which pays a capitated rate per day for hospice care. *See* Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 122, 96 Stat. 324, 356; 42 U.S.C. §§ 1395d(a)(4), 1395x(dd). To be eligible for the benefit, a patient must be certified as "terminally ill," 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.20, and waive rights to other Medicare payments, including for curative care related to the terminal illness. 42 C.F.R. § 418.24(d).

Certification of a patient's terminal illness must occur at various periods, *id.* § 418.21(a), and be accompanied by "[c]linical information and other documentation that support the medical prognosis," as well as the certifying physician's "brief narrative explanation of the clinical findings that supports [the prognosis]." *Id.* § 418.22(b)(2), (3). At the beginning of the first 90-day period, *both* the patient's attending physician (if the patient has one) *and* either the medical director of the hospice or the physician member of the patient's interdisciplinary team must certify that the patient is terminally ill. *Id.* § 418.22(c)(1). Based on a comprehensive assessment of the patient, the interdisciplinary team must then prepare a plan of care, which it reviews and revises at least as often as every 15

days. *Id.* § 418.56(d). The patient may continue receiving hospice care for a second 90-day period and an unlimited number of 60-day periods after that, *id.* § 418.21(a)(2), (3), so long as a physician "continues to properly and conscientiously recertify" the patient as terminally ill. Letter from Nancy-Ann Min DeParle, Adm'r, Ctrs. for Medicare & Medicaid Servs. (CMS), to Karen Davie, President, Nat'l Hospice & Palliative Org. 1 (Sept. 12, 2000); *see also* 42 C.F.R. §§ 418.22(c)(2), 418.102(c). When deciding whether to recertify a patient, physicians typically have the benefit not only of their own face-to-face consultations with the patient, but also of information obtained in person by other members of the interdisciplinary team. *See* 42 C.F.R. §§ 418.22(a)(4), 418.56(d). Indeed, a hospice physician or nurse practitioner must conduct a face-to-face consultation with each patient who is anticipated to reach a third benefit period, *id.* § 418.22(a)(4), and the "clinical findings of that visit [must be] provided to the certifying physician." *Id.* § 418.22(b)(4).

Today, an ever growing number of Americans call upon the Medicare hospice benefit at the end of their lives. *See Facts and Figures*, *supra*, at 4. In 1982, there were only 25,000 patients served by hospice programs in the United States. NHPCO, *Patients Served by Hospice in the US: 1982 to 2014* (2016).[4] In

[4] *Available at* http://www.nhpco.org/sites/default/files/public/Statistics_Research/Patients_Served.pdf.

2014, there were 1.6 to 1.7 million hospice patients across the country. *Facts and Figures*, *supra*, at 4. And the vast majority (1.3 million) relied on the Medicare hospice benefit to pay for services, CMS, *Medicare Hospice Transparency Data (CY2014)*, tbl.1 (2016) (CMS Data)[5]—making Medicare "the predominate source of payment for hospice care." *Facts and Figures*, *supra*, at 10; *see also id.* (reporting that the Medicare hospice benefit paid for 90.3% of patient days in hospice in 2014); *id.* at 4 ("By 2007 the proportion of Medicare decedents accessing three or more days of hospice services had increased to 30.1%."). Of those Medicare hospice beneficiaries, 29% had a primary diagnosis of terminal cancer; the rest had other terminal illnesses, such as dementia, heart disease, and lung disease. *See* CMS Data, *supra*, tbl.1; *Facts and Figures*, *supra*, at 7. Half of all hospice patients received hospice care for shorter than 17.4 days, with only a tenth remaining in hospice for longer than 180 days. *Facts and Figures*, *supra*, at 5; *see also* CMS Data, *supra*, tbl.1 (reporting that only 13% of Medicare hospice beneficiaries in 2014 had more than 180 days of hospice care).

[5] *Available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-10-06.html

II. A CLAIM FOR MEDICARE HOSPICE BENEFITS SHOULD NOT BE CONSIDERED FALSE UNLESS NO REASONABLE PHYSICIAN WOULD HAVE CERTIFIED THE PATIENT AS TERMINALLY ILL.

A. A Reasonable Conclusion Cannot Be False.

The False Claims Act prohibits "knowingly" presenting a "false" claim for payment of federal funds. 31 U.S.C. § 3729(a)(1)(A). The issue in this case is when a claim for payment of Medicare hospice benefits is "false" under the Act.

As noted, a claim for payment of Medicare hospice benefits is reimbursable only if the patient is certified as "terminally ill." 42 U.S.C. § 1395f(a)(7)(A); 42 C.F.R. § 418.20. And a patient may be certified as terminally ill only if a physician concludes, based on the physician's "clinical judgment," that the patient has "a life expectancy of 6 months or less if the terminal illness runs its normal course." 42 C.F.R. § 418.22(b). The question, then, is when such a "clinical judgment regarding the normal course of the individual's illness" can be considered false. *Id.*

Although the Act does not define what "false" means, Congress presumably gave the term "its ordinary meaning." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2002 (2012). And the term "false" is ordinarily understood to mean "inconsistent with the facts." False, *Merriam-Webster Dictionary* (2015);[6] *see also* False, *Webster's Third New International Dictionary* 819 (2002) ("not based on

[6] *Available at* http://www.merriam-webster.com/dictionary/false.

facts or correct premises: not well founded"); False, *Webster's New International Dictionary* 914 (2d ed. 1934) ("[n]ot well founded").

Sometimes there is only one conclusion consistent with the facts, making any other wrong. If a patient stepped on a scale and the scale read 150 pounds, there would be only one conclusion consistent with those facts: The patient weighs 150 pounds. If a thermometer placed under the patient's tongue read 98.6 degrees Fahrenheit, there would, again, be only one reasonable conclusion—that the patient has a body temperature of 98.6 degrees. When readily verifiable things like these are at issue, there is no room for reasonable disagreement.

In other situations, though, the facts may allow for more than one possible conclusion. After examining a patient's cholesterol levels, for example, one physician might prescribe more exercise along with medication; another physician might prescribe only more exercise. Neither physician's prescription is wrong if the facts support both courses of action. Some issues, therefore, give rise to reasonable disagreement. And the range of reasonable disagreement may vary, depending on the issue; the facts might support many different conclusions, or only a few. Whatever the scope of that range, any conclusion that falls within it is reasonable—and thus cannot be considered false. *See United States ex rel. Phalp v. Lincare Holdings, Inc.*, 116 F. Supp. 3d 1326, 1360 (S.D. Fla. 2015) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which

reasonable minds may differ cannot be false." (internal quotation marks omitted)); Mem. Op., Doc. 497, at 2; Appellees' Br. 26-27.

B. There Can Be A Broad Range Of Reasonable Conclusions Regarding How Long A Patient Is Expected To Live.

This case does not involve something as simple as a patient's weight or body temperature. Nor does it involve something as comparatively straightforward as how to lower a patient's cholesterol. Rather, this case involves something far more complicated: How long is a patient expected to live if the patient's terminal illness runs its normal course? For three reasons, the range of reasonable answers can be quite broad.

First, the question calls for a *prognosis*, not a *diagnosis*. It asks the physician to make a judgment about what will happen in the future. And just as it is more difficult to predict whether a baseball team will win its next game than to determine whether it won its last, it is more difficult to predict how a patient will be doing in the future than to evaluate how the patient is doing today. That task is more difficult still when the question is not how the patient will be doing tomorrow, but how the patient will be doing six months from now. Some uncertainty is inherent in any prediction, and much can change in the period that Congress prescribed. *See* 70 Fed. Reg. 70,532, 70,538 (Nov. 22, 2005) (explaining that "the impact of a hospice's services may sometimes lead to brief periods of improvement").

Both Congress and the agency charged with administering the Medicare statute have acknowledged and accounted for that uncertainty. Soon after Congress created the Medicare hospice benefit, the Department of Health and Human Services (HHS) promulgated regulations specifying what a physician had to certify for a patient to be eligible for the benefit. 48 Fed. Reg. at 56,027 (codified at 42 C.F.R. §§ 418.3, 418.20, 418.22). Mirroring the statutory text, those regulations required a physician to certify that the individual's "life expectancy is six months or less." *Id.* (codified at 42 C.F.R. § 418.22(b)(1)); *see also* Pub. L. No. 97-248, § 122(d)(3), 96 Stat. at 361 (similar). The General Accounting Office (GAO) subsequently found that "many physicians" were concerned that the statement required "certainty" in their prognoses. 55 Fed. Reg. 50,831, 50,832 (Dec. 11, 1990); *see also* GAO, *Medicare: Program Provisions and Payments Discourage Hospice Participation* 2, 20 (1989). And because such certainty was impossible, many physicians simply chose not to refer their patients to participate in a Medicare hospice program. GAO, *supra*, at 2.

In light of the GAO's findings, HHS amended its regulations in 1990. "[T]he establishment of long term prognoses always involves some uncertainty," HHS explained. 55 Fed. Reg. at 50,832. And physicians should not be "discourage[d] . . . from certifying terminal illness" just because the "statement seem[s] to require certainty." *Id.* at 50,831-32. HHS thus inserted the words "if

the illness runs its normal course" at the end of the required statement. *Id.* at 50,834 (codified at 42 C.F.R. § 418.22(b)). And in doing so, HHS clarified that a certification need not be based on "certain knowledge of the patient's prognosis." *Id.* at 50,832. Congress subsequently amended the statute similarly to make clear that a physician's "clinical judgment" need only be based on an illness's "normal course." Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, § 322, 114 Stat. 2763, 2763A-501 (codified at 42 U.S.C. § 1395f(a)). With those amendments, Congress and HHS accepted that, for a given patient, there could be a range of reasonable prognoses: Though physicians might reach differing conclusions about how long the patient will live, none of those conclusions would necessarily be *false*.

Second, the end of someone's life is an inherently difficult thing to predict, even when compared to other forward-looking prognoses. Indeed, "[i]t is difficult for even the most experienced clinicians to estimate a predicted time of survival for chronic, progressive illnesses." Jean S. Kutner et al., *Outcomes and Characteristics of Patients Discharged Alive from Hospice*, 52 J. Am. Geriatric Soc'y 1337, 1337 (2004); *see also* David Hui, *Prognostication of Survival in Patients with Advanced Cancer: Predicting the Unpredictable?*, 22 Cancer Control 489, 491 (2015) ("Because death is a probabilistic event, its exact timing cannot be predicted with certainty."). That is because numerous factors can influence when a

person will die, including not just the terminal illness itself, but other health conditions. *See* 42 C.F.R. § 418.25(b) (requiring the physician to consider "[c]urrent clinically relevant information supporting all diagnoses"); 79 Fed. Reg. at 50,469 (expecting the physician to take into account "the individual's whole condition"). And there is no simple formula for determining how much weight to give each factor. *See* 73 Fed. Reg. 32,088, 32,138 (June 5, 2008) (deciding against using the word "criteria" to describe what a physician should consider, so as "to remove any implication that there are specific CMS clinical benchmarks in this rule that must be met in order to certify terminal illness"); 79 Fed. Reg. at 50,469 (explaining merely that "the total person is to be assessed, including acute and chronic conditions, as well as controlled and uncontrolled conditions, in determining an individual's terminal prognosis").

Predicting the end of a patient's life thus entails a reasoned analysis of multiple variables. And the changing composition of hospice patients over the years has made that complex task even more difficult. The progression of terminal cancer is generally thought to be more predictable than many other terminal illnesses, *see* Kutner et al., *supra*, at 1337, but a growing percentage of hospice patients have non-cancer diagnoses, like dementia, heart disease, or lung disease. *Facts and Figures*, *supra*, at 7; *see also* Kutner et al., *supra*, at 1337 (reporting that the "percentage of hospice patients with a primary diagnosis of cancer has been

steadily declining since 1992," when the percentage was 75%). Predicting the course of those other illnesses can be particularly challenging. *See* Kutner et al., *supra*, at 1337-38 ("Persons with noncancer illnesses tend to have a dying trajectory characterized by exacerbations and remissions, with death occurring as an outcome of an exacerbation that is difficult to predict.").

The text of the Medicare statute and that of its implementing regulations reflect "the fact that making medical prognostications of life expectancy is not always exact." 70 Fed. Reg. at 70,534. In 2000, Congress amended the statute to clarify that certification of a patient as terminally ill "shall be based on the physician's or medical director's clinical judgment." Pub. L. No. 106-554, § 322, 114 Stat. at 2763A-501 (codified at 42 U.S.C. § 1395f(a)). And HHS later revised its regulations to incorporate the same language. 70 Fed. Reg. at 70,547 (codified at 42 C.F.R. § 418.22(b)). The word "judgment" implies the exercise of some discretion. And indeed, the emphasis on the physician's "clinical judgment" was meant to capture a basic truth: that predicting the end of someone's life is "not an exact science." 79 Fed. Reg. at 50,470; *see also id.* (acknowledging the "challenges in prognostication"); 70 Fed. Reg. at 70,533 (recognizing the "scientific difficulty in making a prognosis of 6 months or less"). Physicians are expected only to give it their "best" shot. 79 Fed. Reg. at 50,470.

As a consequence, patients will sometimes live longer than six months, even after having been certified as terminally ill. *See* Letter from Min DeParle, *supra*, at 1 (explaining that a patient may have the "good fortune to live longer than predicted"). The statute itself contemplates that possibility; twice Congress has amended the statute, in 1989 and in 1997, to provide more flexibility for patients whose prognoses improve, and to remove any limit on how long a patient can receive the hospice benefit. *See* 70 Fed. Reg. at 70,533 (discussing the Medicare Catastrophic Coverage Repeal Act of 1989); Letter from Nancy-Ann Min DeParle, *supra*, at 1 (discussing the Balanced Budget Act of 1997). Indeed, patients may receive the benefit for an "unlimited" amount of time, as long as their physicians continue to believe, based on their clinical judgment at the end of each recertification period, that they have a six-month prognosis. 42 C.F.R. §§ 418.21(a), 418.22(a)(1). And CMS, the relevant part of HHS, has even gone so far as to assure hospices that they will *not* "be penalized if a patient lives longer than six months." Letter from Min DeParle, *supra*, at 1; *see also* CMS, *End of Life Care Enhances Dignity and Peace as Life Nears Its End*, 28 Physician Exec., no. 2, Mar./Apr. 2002, at 35 ("[T]here is no reason for a physician to be concerned about certifying an individual for hospice care that he or she believes to be terminally ill.");[7] Letter from Thomas A. Scully, Adm'r, CMS, to Jonathan Keyserling,

[7] *Available at* http://www.medicareadvocacy.org/old-site/News/Archives/

NHPCO (May 24, 2002) ("[I]t is entirely possible for hospice services to be needed for more than a 6-month period.").[8]

Third, information gleaned from face-to-face consultations with a patient can be especially important when judging how long that patient will live. By examining a patient in person, certifying physicians can gain important insights into the patient's condition, both physical and emotional. *See* 42 C.F.R. § 418.22(a)(4) (requiring a hospice physician or nurse practitioner to have "a face-to-face encounter with each hospice patient whose total stay across all hospices is anticipated to" exceed 180 days). And even if they themselves do not examine the patient, certifying physicians will have the benefit of input regarding in-person examinations conducted by other hospice physicians, nurse practitioners, and clinical professionals. *See* 42 U.S.C. § 1395x(dd)(2)(B) (listing the required members of the interdisciplinary hospice team); 42 C.F.R. § 418.22(b)(4) (requiring the "physician or nurse practitioner who performs the face-to-face encounter" to "state that the clinical findings of that visit were provided to the certifying physician"). After all, members of the interdisciplinary hospice team are in frequent personal contact with the patient, and the team, as a whole, confers regularly regarding each patient. *See* 42 C.F.R. § 418.56(d) (requiring the

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Hospice_CMSconfirmsCoverage.htm.

[8] *Available at* http://www.medicareadvocacy.org/old-site/News/Archives/Hospice_CMSconfirmsCoverage.htm.

interdisciplinary team to "review, revise and document" the patient's individualized plan of care "as frequently as the patient's condition requires, but no less frequently than every 15 calendar days"). By consulting with those team members, a certifying physician can learn what *they* learned through meeting with the patient face-to-face.

It is unrealistic, though, to expect certifying physicians to be able to capture in writing every facet of what they and other team members glean through personal contact with the patient. As a result, certifying physicians often have information that the written record does not fully convey. *Cf. Christopher v. Florida*, 449 F.3d 1360, 1368 (11th Cir. 2006) ("[W]e know that review of the cold record on appeal is not the same thing as being at the trial and observing the subtleties of tone and of demeanor for not just the speaker, but the listeners."). Conversely, physicians who, years later, review only the record have the benefit of hindsight: They *know* whether the patient lived longer than six months. *See Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1335 (11th Cir. 2014) (per curiam) ("Hindsight bias is a common-sense concept—everyone knows that 'hindsight is 20/20.' "). It should come as no surprise, then, that two physicians—one who actually saw the patient or consulted with other team members who did, and another who read only the medical record afterward—might come to different conclusions about the course and rate of the patient's terminal illness.

HHS recognizes that the written record does not always capture everything. Indeed, HHS expressly declined to require that each certification be accompanied by "specific . . . findings," after various commenters raised concerns that such a requirement would be too burdensome and force patients to undergo diagnostic tests and procedures to prove their eligibility. 70 Fed. Reg. at 70,537. Instead, HHS requires only that each certification be accompanied by "[c]linical information and other documentation that *support* the medical prognosis." 42 C.F.R. § 418.22(b)(2) (emphasis added); *see also id.* § 418.22(b)(3) (requiring only "a brief narrative explanation of the clinical findings that *supports* [the prognosis]" (emphasis added)). That is a low bar. Documentation can *support* a certification while not necessarily *compelling* one. The word "support" thus embodies a degree of deference to the certifying physician, requiring only that there be "*a* basis" in the record for the prognosis. 70 Fed. Reg. at 70,534 (emphasis added).

In short, a patient's life expectancy can be the subject of broad, yet reasonable, disagreement. That is so because of the nature of prognoses, the nature of death, and the limitations of medical records in capturing all of the considerations that accompany a prognosis of impending death. And it was in recognition of this fact that Congress and HHS chose to use words such as "normal course," "clinical judgment," and "support" throughout the regulatory scheme.

C. The Government Failed To Create A Genuine Issue As To Whether The Medical Prognoses In This Case Were Unreasonable.

To prove that the medical prognoses in this case were false, the Government had to show that they fell beyond the range of reasonableness. It had to show, in other words, that *no* reasonable physician would have certified the patients as terminally ill. *See* Mem. Op., Doc. 497, at 2, 7; Appellees' Br. 51.

The Government fell far short of that burden. Its evidence consisted entirely of the testimony of a single expert, Dr. Solomon Liao, who opined, after reviewing the written medical records with the benefit of hindsight, that the patients were not terminally ill. Mem. Op., Doc. 497, at 3. But as the District Court correctly held, "[a] mere difference of opinion between physicians, *without more*, is not enough to show falsity." *Id.* at 2. After all, there can be a broad range of reasonable disagreement over how long a patient is expected to live. And the mere fact of disagreement here says nothing about whether the prognoses at issue fell beyond that range. *See* Appellees' Br. 42 ("Dr. Liao did *not* testify that no reasonable doctor could have concluded that the patients were terminally ill based upon a review of the records." (emphasis added)). Because the Government failed to create a genuine issue as to whether those prognoses were false, appellees were entitled to summary judgment.

III. THE GOVERNMENT'S CONTRARY RULE WOULD SERVE ONLY TO DENY MEDICARE HOSPICE BENEFITS TO THOSE WHO NEED THEM.

On appeal, the Government does not dispute that the medical prognoses in this case were reasonable. Instead, it contends that whether they were reasonable has no bearing on whether they were false. U.S. Br. 22, 32-33. In the Government's view, a physician's judgment regarding a patient's life expectancy can be false, even if that judgment was "reasonable." *Id.* at 28 (internal quotation marks omitted). A mere disagreement between physicians, the Government says, is enough to send the issue to the jury. *See id.* at 28-29.

That is a remarkable contention, and this Court should reject it. If accepted, the Government's position would render meaningless all of the efforts of the past 30 years to assure physicians that a certification of terminal illness does not require "certainty." 55 Fed. Reg. at 50,832. When HHS and then Congress inserted the words "normal course" into the certification statement, they did so out of recognition that "the establishment of long term prognoses always involves some uncertainty." *Id.* And when Congress and HHS added the words "clinical judgment," they did so precisely because "making medical prognostications of life expectancy is not always exact." 70 Fed. Reg. at 70,534. The Government's brief inhabits an altogether different reality, where predicting the end of someone's life is always black and white: If two physicians disagree, one of them must be right,

while the other wrong; one physician's prognosis must be true, while the other false. And in that alternate reality, it would not even matter which physician actually examined the patient, because that physician would not be entitled to any deference anyway. That world would be unrecognizable to both Congress and the agency that issued the regulations in effect still today.

Worse still, the practical effect of the Government's position would be to hurt the very people the Medicare hospice benefit was intended to help. If treble-damages liability under the False Claims Act could rest on mere disagreements about how long a patient is expected to live, physicians may understandably opt to refrain from making certifications except in the most obvious of cases. *See Bishop v. Wells Fargo & Co.*, 823 F.3d 35, 46 (2d Cir. 2016) (describing a similar chilling effect from potential False Claims Act liability). Instead of exercising their "best clinical judgment," physicians will simply decline to certify a patient as terminally ill—unless the patient is certain to die within six months. 79 Fed. Reg. at 50,470; *see also* 55 Fed. Reg. at 50,831-32 (describing how physicians were "discourage[d] . . . from certifying terminal illness" when the law "seemed to require certainty of prognosis"). And that will mean that many deserving patients—patients whom physicians would otherwise certify in their best judgment—will be denied the Medicare hospice benefit merely out of a fear of litigation. Even today, too many patients are referred to hospice programs too late:

Half of patients pass away within only 17.4 days of entering a hospice program, *Facts and Figures*, *supra*, at 5, a period far shorter than what is enough for patients and their families to benefit fully from hospice services. *See* Joan M. Teno et al., *Timing of Referral to Hospice and Quality of Care: Length of Stay and Bereaved Family Members' Perceptions of the Timing of Hospice Referral*, 34 J. of Pain & Symptom Mgmt. 120, 121 (2007). If the Court adopts the Government's reading of the False Claims Act, this problem will get even worse, as physicians wary of having their prognoses second-guessed in court hold off even longer in making certifications. The result will be an overall decline in use of a benefit Congress and HHS have so long sought to encourage.

And as those denied the hospice benefit are forced to turn to other Medicare benefits, the Government's position will harm another set of Americans: federal taxpayers. Medicare costs for patients enrolled in hospice are significantly lower than those for non-hospice enrollees. *See* Amy S. Kelley et al., *Hospice Enrollment Saves Money for Medicare and Improves Care Quality Across a Number of Different Lengths-of-Stay*, 32 Health Affairs 552, 555 (2013). So by discouraging "hospice enrollment," the Government's position may "actually *increase* . . . spending overall." *Id.* at 557 (emphasis added). Because that would be "precisely the opposite" of what Congress intended, *Bishop*, 823 F.3d at 46, the Government's position should be rejected.

CONCLUSION

For all of the foregoing reasons and those set forth in appellees' brief, the judgment of the District Court should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 5,750 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the typestyle requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

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CERTIFICATE OF SERVICE

I certify that, on October 24, 2016, I electronically filed the foregoing through the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ Catherine E. Stetson
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