IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

UNITED STATES ex rel. CHERYL TAYLOR, Plaintiff-Appellee,	)	No. 25-10842
HEALTHCARE ASSOCIATES OF TEXAS, LLC, Defendant-Appellant.	)	

UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF OF AMICI CURIAE

Pursuant to Federal Rules of Appellate Procedure 27 and 29 and Fifth Circuit Rules 27 and 29, Blood Cancer United, Cancer*Care*, Cancer Nation, Epilepsy Foundation of America, Muscular Dystrophy Association, and National Patient Advocate Foundation hereby seek leave to file a brief as amici curiae in support of Plaintiff-Appellee and affirmance of the judgment below. This motion is unopposed and is accompanied by the proposed brief.

Amici curiae are patient advocacy organizations that work to ensure access to quality and affordable health care for their patient communities. Because many of these patients receive care through federal healthcare programs such as Medicare and Medicaid, amici have an interest in supporting measures that reduce fraud, waste, and abuse in those government programs, which help to keep health

care costs in check and protect patients. *Qui tam* actions under the False Claims Act, such as the one brought by Plaintiff-Appellee here, are a critical mechanism in curbing unnecessary and harmful medical treatments, reducing wasteful spending, and returning much-needed funds to government health care programs. For that reason, amici have an interest in supporting the continued vitality and constitutionality of whistleblower suits under the False Claims Act.

Defendant-Appellant urges this Court, as an alternative ground for reversal, to hold the *qui tam* provisions of the False Claims Act unconstitutional. Amici seek leave to share their perspective on why the *qui tam* provisions are important to government healthcare beneficiaries and why Defendant-Appellant's requested ruling would adversely impact patient care. Because the views of amici are unique from the parties and other amici, amici believe that their brief will assist the Court in its disposition of this appeal.

Undersigned counsel has conferred with counsel for the parties and the United States Government, who have consented to the filing of amici's proposed brief.

Respectfully submitted,

Dated: March 30, 2026

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limitations of Fed. R. App. P. 27(d)(1)(2) because the motion contains 308 words.

2. This document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, font size 14.

Date: March 30, 2026

/s/ Catherine H. Dorsey
Catherine H. Dorsey

CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2026, I electronically filed the foregoing Unopposed Motion For Leave to File Brief of Amici Curiae with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

Date: March 30, 2026

/s/ Catherine H. Dorsey
Catherine H. Dorsey

No. 25-10842

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

UNITED STATES *ex rel.* CHERYL TAYLOR,
Plaintiff-Appellee/*Cross-Appellant*, and

v.

HEALTHCARE ASSOCIATES OF TEXAS, LLC,
Defendant-Appellant/*Cross-Appellee.*

On Appeal from the United States District Court for the Northern District of Texas, No. 3:19-cv-2486 (Hon. David C. Godbey)

BRIEF OF *AMICI CURIAE* BLOOD CANCER UNITED, CANCER*CARE*, CANCER NATION, EPILEPSY FOUNDATION OF AMERICA, MUSCULAR DYSTROPHY ASSOCIATION, AND NATIONAL PATIENT ADVOCATE FOUNDATION IN SUPPORT OF PLAINTIFF-APPELLEE AND AFFIRMANCE OF THE JUDGMENT BELOW

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SUPPLEMENTAL STATEMENT OF INTERESTED PERSONS

No. 25-10842, *United States ex rel. Cheryl Taylor v. Healthcare Associates of Texas, LLC*

Pursuant to Fifth Circuit Rules 26.1, 28.2.1, and 29.2, and Federal Rule of Appellate Procedure 26.1, counsel for amici curiae Blood Cancer United, Cancer*Care*, Cancer Nation, Epilepsy Foundation of America, Muscular Dystrophy Association, and National Patient Advocate Foundation certifies that the following listed persons and entities, in addition to those listed in the briefs of the parties and other amici curiae, may have an interest in the outcome of this appeal:

1. Baron & Budd, P.C. (law firm of counsel for amici curiae)
2. Blood Cancer United (amicus curiae)
3. Cancer*Care* (amicus curiae)
4. Cancer Nation (amicus curiae)
5. Capesius, Kenneth D. (counsel for amici curiae)
6. Cartner, Joel (Director, Access Policy, Muscular Dystrophy Association)
7. Czubaruk, Kim (Vice President of Policy, Cancer*Care*)
8. Dorsey, Catherine H. (counsel for amici curiae)
9. Epilepsy Foundation of America (amicus curiae)
10. Kirch, Rebecca A. (Executive Vice President of Policy and Programs, National Patient Advocate Foundation)

11. Muscular Dystrophy Association (amicus curiae)

12. Nasso, Shelley Fuld (Chief Executive Officer, Cancer Nation)

13. National Patient Advocate Foundation (amicus curiae)

14. Rich, Noah M. (counsel for amici curiae)

15. Yaghoubi, Roxanne (Senior Director, Federal Relations & Policy, Epilepsy Foundation of America)

16. Young, Kinika (Director of Legal Advocacy, Blood Cancer United)

Blood Cancer United is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in Blood Cancer United.

Cancer*Care* is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in Cancer*Care*.

Cancer Nation is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in Cancer Nation.

Epilepsy Foundation of America is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in the Epilepsy Foundation of America.

Muscular Dystrophy Association is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in the Muscular Dystrophy Association.

National Patient Advocate Foundation is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in National Patient Advocate Foundation.

These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

Date: March 30, 2026

s/ Catherine H. Dorsey
Catherine H. Dorsey

Counsel for Amici Curiae Blood Cancer United, CancerCare, Cancer Nation, Epilepsy Foundation of America, Muscular Dystrophy Association, and National Patient Advocate Foundation

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are Blood Cancer United, Cancer*Care*, Cancer Nation, Epilepsy Foundation of America, Muscular Dystrophy Association, and National Patient Advocate Foundation.

Blood Cancer United[2] is the world's largest voluntary health agency dedicated to fighting blood cancer and ensuring that the more than 1.6 million blood cancer patients and survivors in the United States have access to the care they need. Its mission is to cure blood cancer and to improve the quality of life of affected patients and their families. Blood Cancer United advances that mission by advocating for blood cancer patients to ensure that they have sustainable access to quality, affordable, and coordinated healthcare, regardless of their particular health insurance. Many of these patients receive care through federal healthcare programs such as Medicare, Medicare Advantage, and Medicaid.

For over 80 years, Cancer*Care* has empowered millions of people affected by cancer through free counseling, resource navigation, support groups, educational resources, advocacy, and direct financial assistance. Cancer*Care*'s oncology social

[1] All parties have consented to the filing of this brief.

[2] Under Federal Rule of Appellate Procedure 29(a)(4)(E), amici certify that no party's counsel authored this brief in whole or in part, that no party or party's counsel contributed money intended to fund the preparation or submission of the brief, and that no person (other than amici curiae, their members, and their counsel) contributed money intended to fund the preparation or submission of the brief.

workers improve the lives of people diagnosed with cancer, caregivers, survivors and the bereaved, by addressing their emotional, practical, and financial challenges.

Cancer Nation (formerly the National Coalition for Cancer Survivorship) is the voice of 18 million Americans living with, through, and beyond cancer, advocating for care that supports not just survival, but the ability to live and thrive. The organization advocates for policies that deliver whole person cancer care, survivorship care plans, and financial protections. Many of the survivors Cancer Nation represents are covered by federal insurance programs, and its interest in this case is grounded in the lived realities of survivors and its commitment to demanding a cure for care that is accountable, accessible, and just.

Epilepsy Foundation of America is the leading national, voluntary health organization representing over 3.4 million Americans with epilepsy and seizures. Approximately 1.1 million Medicare beneficiaries have epilepsy, and 40% of adults between the ages of 18-64 who live with epilepsy have Medicaid coverage. Medicaid and Medicare coverage is critical for people living with epilepsy who need timely access to quality, affordable, provider-directed care, including access to anti-seizure medications. Epilepsy medications are the most common, cost-effective treatment for controlling and/or reducing seizures. Uncontrolled seizures can lead to disability, injury, and death.

Muscular Dystrophy Association is the preeminent voluntary health organization in the United States for people living with muscular dystrophy, ALS, and over 300 other neuromuscular conditions. For over 75 years, Muscular Dystrophy Association has led the way in accelerating research, advancing care, and advocating for support and inclusion of families living with neuromuscular disease. Muscular Dystrophy Association's mission is to empower the people it serves to live longer, more independent lives.

National Patient Advocate Foundation is dedicated to improving access, affordability, experiences, and outcomes for patients and caregivers. As the advocacy affiliate of Patient Advocate Foundation, National Patient Advocate Foundation advances policies integrating physical, mental, and financial health holistically to make the healthcare system work for all.

All amici are committed to ensuring that all Americans have a high-quality healthcare system and access to comprehensive, affordable healthcare to prevent disease, manage health, and cure illness. Amici advocate to ensure that patients with chronic conditions, including cancer, muscular dystrophy, and epilepsy, have access to care and can afford the care they need to live longer, healthier lives. Understanding the serious burdens of these diseases, amici work to remove barriers that patients often face in obtaining healthcare. Limiting the cost of care across the healthcare system, including by reducing fraud that artificially inflates costs, is a priority to

improve access and affordability. Many patients rely on government healthcare programs, including Medicare and Medicaid, to obtain lifesaving care. Thus, the financial viability and integrity of government healthcare programs are important to patients.

Because the patients and consumers whom amici serve have a strong interest in the outcome of this case, amici submit this brief in support of Plaintiff–Appellee and affirmance of the district court's judgment, and to urge this Court to reject Defendant-Appellant's arguments challenging the constitutionality of the False Claims Act's *qui tam* provisions.

SUMMARY OF THE ARGUMENT

"The False Claims Act is the government's primary litigation tool for recovering losses sustained as the result of fraud."[3] Whistleblower suits are critical to enforcement of the False Claims Act, leading to nearly $11 billion dollars in direct recoveries—and perhaps $110 billion in deterrence value—in the last five years alone. These figures represent the large majority of the funds recovered under, and protected by, the False Claims Act.

Whistleblower lawsuits under the False Claims Act also benefit patient welfare. By curbing unnecessary and harmful medical treatments, reducing wasteful

[3] *U.S. ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 388 (5th Cir. 2008).

spending, and returning much-needed funds to government healthcare programs, whistleblower suits help protect patient health and lower the costs of healthcare.

Defendant-Appellant's constitutional challenges to the *qui tam* provisions of the False Claims Act threaten to significantly impair whistleblowers' critical role in punishing and deterring fraud on the government, including in government healthcare programs. This Court should reject those arguments as a basis for reversal of the judgment below.

ARGUMENT

I. Fraud Impairs the Integrity of Government Healthcare Programs and Substantially Increases the Cost of Healthcare

According to the Government Accountability Office, "each year as much as 10 percent of total health care costs are lost to fraud and abuse … [,] costing taxpayers and policyholders large sums of money."[4] Medicare is particularly "at high risk for fraud and abuse due to its size, complexity, scope, and decentralized administrative structure."[5] The estimated loss of taxpayer dollars in the Medicare and Medicaid programs "ranges from a staggering $126 [billion] to $420 billion dollars in one year alone."[6]

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[4] H.R. Rep. No. 104-497, at 48 (1996).

[5] Cliff Binder, Cong. Rsch. Serv., RL34217, *Medicare Program Integrity: Activities to Protect Medicare from Payment Errors, Fraud, and Abuse* 6–7 (2011).

[6] Alanna M. Lavelle & Timothy L. Helms, *How Healthcare Fraud and Abuse Perpetuate Health Disparities in the U.S.* 1 (2022),

The "[s]ignificant, ongoing fraud and abuse within Medicare may threaten the program's viability."[7] Medicare spending is expected to double between 2022 and 2031, and government officials expect the Medicare Part A Trust Fund to become insolvent between 2031 and 2035.[8] These expectations likely would be notably more dire if this Court were to hold the *qui tam* provisions of the False Claims Act unconstitutional, as billions of dollars in anticipated recoveries attributable to *qui tam* actions would no longer be deposited in the Medicare Trust Fund. *See infra* Section III. Such a result would be cataclysmic:

> The stakes are so high, and numbers in the Medicare program so large, they can sometimes begin to seem more technical than human. But Medicare's insolvency would touch the lives of almost every American, potentially transforming the country's health, welfare, and governance. The program is the linchpin of our health care system, and of many communities. Its roughly sixty million beneficiaries depend on it for medical care. The nation's 6,023 hospitals, fifteen thousand nursing homes, and nearly five thousand hospice facilities depend on it to remain afloat. Finally, the communities they serve depend on it for the jobs and economic lifeline that Medicare providers bring. Medicare insolvency would eventually impact all those who rely on Medicare.[9]

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https://www.mitre.org/sites/default/files/2022-02/pr-21-3650-how-healthcare-fraud-abuse-perpetuate-health-disparities.pdf.

[7] Sarah Clemente *et al.*, *Medicare and the Affordable Care Act: Fraud Control Efforts and Results*, 11 Int'l J. of Healthcare Mgmt. 356, 360 (2017).

[8] MedPAC, *Report to the Congress: Medicare Payment Policy* 361 (2024), https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-3.pdf, at 13, 16–17.

[9] Matthew B. Lawrence, *Medicare "Bankruptcy,"* 63 B.C. L. Rev. 1657, 1664 (2022).

To maintain the financial viability of Medicare, experts suggest that the government would need to significantly raise taxes, reduce Medicare spending, or siphon funds from other programs, meaning "fewer government resources will be available for other priorities, such as deficit reduction or investments that could expand future economic output."[10] If anticipated *qui tam* recoveries were eliminated, the government would need to provide even greater resources to shore up the Medicare system.

These increased costs also have serious deleterious effects on individual "beneficiaries' ability to afford health care by raising their premiums and cost sharing."[11] "The typical Medicare beneficiary has relatively modest resources to draw on when paying for premiums and cost sharing: Researchers estimate that the median Medicare beneficiary had an annual income in 2019 of $29,650 and savings of $73,800."[12] According to a recent survey, "[n]early one-fourth of enrollees … reported an affordability issue, including 15 percent who did not take their medicine as prescribed because of cost."[13] One study found that, among Medicare beneficiaries whose incomes and assets were too high to qualify for a low-income

[10] MedPAC, *supra* note 8, at 17.

[11] *Id.* at 19.

[12] *Id.* at 20.

[13] *Id.* at 343.

subsidy, "one in three did not fill prescriptions for anticancer drugs, one in five did not fill prescriptions for hepatitis C curative therapies, and well over half did not fill prescriptions for drugs for immune system disorders and high cholesterol."[14]

In short, fraud on the Medicare program harms all Americans. Every dollar that is misspent represents a dollar that could have gone to pay for necessary medical care, to reduce the costs for Medicare beneficiaries, or even to preserve the very survival of the Medicare program. If this Court were to reverse the judgment below on the grounds that the *qui tam* provisions of the False Claims Act are unconstitutional, that holding would eliminate *qui tam* actions in this Circuit, which serve as a vital mechanism for recovering some of these costs due to fraud.

II. Fraud on Government Healthcare Programs Harms Patients and Reduces Access to Care

In addition to the increased economic costs, healthcare fraud has serious adverse consequences on patient health and access to care. "[T]here is a critical interrelationship between healthcare fraud and health disparities, as vulnerable and medically underserved beneficiaries are routinely targeted, and often receive substandard, medically unnecessary, and even harmful care."[15]

[14] *Id.* at 21.

[15] Lavelle & Helms, *supra* note 6, at 1.

Examples of the potential harm caused by healthcare fraud abound. According to a recent study from researchers with Johns Hopkins University, patients treated by individuals or entities that had been disbarred from participation in Medicare and Medicaid for engaging in fraud were "approximately 14% to 17% more likely to die than those who were treated by their law-abiding counterparts."[16] *Qui tam* actions that help alert the government to potential healthcare fraud, therefore, play an important role in protecting patient health and safety.

As a further example, off-label marketing schemes can often lead to patient harm. The U.S. Food and Drug Administration ("FDA") "is responsible for the approval of drugs and medical devices for commercial marketing and distribution in the United States."[17] Once the FDA grants such approval, a manufacturer may market the drug "only for the purposes and manners of use that were studied, because safety and efficacy for any other uses or methods have not been shown."[18] Medicare will reimburse for a drug only if it is used for an approved ("on-label") purpose or if such use is otherwise "medically accepted."[19] These restrictions are well founded;

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[16] *Id.* at 2.

[17] Gail A. Van Norman, *Off Label Use vs Off-Label Marketing of Drugs*, 8 J. Am. Coll. Cardiology: Basic to Translational Science 224, 225 (2023).

[18] *Id.*

[19] *U.S. ex rel. Marchese v. Cell Therapeutics, Inc.*, No. CV06-0168MJP, 2007 WL 4410255, at *1 (W.D. Wash. Dec. 14, 2007).

the use of off-label prescriptions can "facilitate[] patient exposure to treatments that are of unproven and possibly no benefit, while elevating the risks of unknown adverse consequences of the off-label uses when underlying medical evidence supporting the use is scant."[20] Nevertheless, "[m]otivated to increase sales and prescriptions, and subsequent profits, manufacturing companies frequently encourage expanded use" through off-label marketing schemes.[21] As a result, government healthcare programs such as Medicare are often improperly billed for these off-label and unapproved uses that may endanger patients.

"An excellent illustration of the dangers of off-label use is Fen-Phen, a combination prescription of fenfluramine hydrocholoride plus phentermine," each of which had been approved only individually.[22] When taken together, one-third of patients "suffered significant damage to the lungs and heart," leading to surgical treatment, disability, and death.[23] Other "examples of serious harms from off-label use include" Gabitril, "which was approved for use to prevent partial seizures, but then was used off-label to treat pain, and caused new-onset seizures," Qualaquin, which "resulted in life-threatening bleeding" after being used off-label for leg

[20] Van Norman, *supra* note 17, at 226.

[21] *Id.* at 224.

[22] *Id.* at 226.

[23] *Id.*

cramps, and NovoSeven, which was approved to treat hemophilia and caused "acute heart attacks, strokes, paralysis, and death" in non-hemophiliac patients to whom the drug was prescribed.[24] In 2019, a pharmaceutical manufacturer agreed to pay more than $116 million in civil and criminal penalties to resolve allegations that it had fraudulently marketed Nuedexta—which was FDA approved only for a rare condition called pseudobulbar affect—as a way to "control[] the behavior of [elderly nursing home] patients prone to disruptive outbursts."[25] According to a CNN investigation, Nuedexta had the potential to cause harm "ranging from rashes, dizziness and falls to comas and death."[26]

Healthcare fraud can also reduce access to care, as "[h]ealthcare professionals ordering or providing medically unnecessary treatments take valuable and limited health resources away from those individuals who truly need the services and often have the most difficulty accessing those services."[27] For example, the state of Florida suspended the medical license of Dr. Ishrat Sohail, a pediatrician who "was found to

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[24] *Id.* at 22–27.

[25] Blake Ellis & Melanie Hicken, *Cashing in on Dementia Patients: Drugmaker to Pay $116 Million in Fraud Settlement*, CNN (Sept. 26, 2019, 9:37 p.m. EDT), https://www.cnn.com/2019/09/26/health/nuedexta-avanir-doj-settlement-invs/index.html.

[26] Blake Ellis & Melanie Hicken, *The Little Red Pill Being Pushed on the Elderly*, CNN (Oct. 12, 2017, 5:51 p.m. EDT), https://www.cnn.com/2017/10/12/health/nuedexta-nursing-homes-invs/index.html.

[27] Lavelle & Helms, *supra* note 6, at 2.

be improperly administering vaccines from the federal Vaccines for Children Program to children with private insurance. The vaccines were intended for children with Medicaid or who were uninsured."[28]

Healthcare fraud can also reduce patients' trust in providers and in the larger healthcare system. "Trust matters in health care because it encourage[s] patients to volunteer intimate facts about their lives, cooperate with diagnosis and treatment, draw reassurance from medical explanations, and experience the doctor-patient relationship itself as empowering and comforting."[29] Indeed, "[s]tudies have shown that trust in the health care system is a top determinant of good health behaviors."[30] Unfortunately, "[a]s patients become aware of fraudulent … schemes through media reports or other means, their institutional trust declines because the fraud demonstrates a lack of fidelity on the part of providers."[31] By alerting the government to potential fraud, and helping to punish and deter wrongdoers through False Claims Act litigation, whistleblowers play a vital role in ensuring the integrity of government healthcare programs—which, in turn, promotes trust in the healthcare

[28] *Id.* at 7.

[29] Katrice Bridges Copeland, *Health Care Fraud and the Erosion of Trust*, 118 Nw. U. L. Rev. 89, 94 (2023) (internal quotation marks and footnote omitted).

[30] *Id.* at 95.

[31] *Id.* at 108; *see* Dhruv Khullar, *Building Trust in Health Care—Why, Where, and How*, 322 JAMA 507, 507 (2019).

system so that patients will seek the care they need. A ruling holding the *qui tam* provisions unconstitutional, however, would threaten to eliminate whistleblowers as watchdogs of fraud against the government, leaving a healthcare system plagued with fraud and wary patients.

III. Whistleblowers and the FCA's *Qui Tam* Mechanism are Integral to Protecting Government Healthcare Programs and Taxpayer Dollars

Despite the enormous amount of money lost to healthcare fraud, the Government Accountability Office "has concluded that only a small fraction of this fraud and abuse is detected."[32] Lawmakers have long recognized that whistleblowers are essential partners in the fight against fraud. For instance, during the debate prior to the passage of the False Claims Act, Michigan Senator Jacob Howard remarked on the "crying evil[] … that our Treasury is plundered from day to day by bands of conspirators."[33] The "safest and most expeditious way" to combat these fraudsters, said Senator Howard, was to employ the assistance of whistleblowers.[34] Likewise, when Congress amended and reinvigorated the False Claims Act in 1986, the Senate Judiciary Committee agreed that "only a coordinated effort of both the Government and the citizenry" could effectively combat the "wave of defrauding public funds."[35]

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[32] H.R. Rep. No. 104-497, at 48.

[33] Cong. Globe, 37th Cong., 3d Sess. 955 (1863).

[34] *Id.* at 956.

[35] S. Rep. No. 99-345, at 2 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5267.

As the healthcare industry itself has grown, so too has the importance of whistleblowers in the healthcare context.

Whistleblower suits under the False Claims Act have been extraordinarily successful. In fiscal year 2025 alone, settlements and judgments recovered by the United States under the False Claims Act exceeded $6.8 billion—the highest recovery in a single year in the history of the statute—with over $5.7 billion of that amount related to matters involving the health care industry.[36] These recoveries were attributable in large part to the efforts of whistleblowers, whose cases accounted for almost $4.5 billion—or over 78 %—of the Government's total healthcare recoveries under the False Claims Act.[37] And in fiscal year 2023, "civil health care fraud settlements and judgments under the False Claims Act exceeded $1.8 billion," and the government "attained additional administrative impositions in health care fraud cases and proceedings," for a total of $3.4 billion in recoveries.[38] Of this amount,

[36] Press Release, U.S. Dep't of Justice, *False Claims Act Settlements and Judgments Exceed $6.8B in Fiscal Year 2025* (Jan. 16, 2026), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-68b-fiscal-year-2025.

[37] Civil Division, U.S. Dep't of Justice, *Fraud Statistics* 7 (2025), https://www.justice.gov/opa/media/1424121/dl.

[38] U.S. Dep't of Health & Human Servs. & U.S. Dep't of Justice, *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2023* at 8 (2024), https://oig.hhs.gov/documents/hcfac/10087/HHS%20OIG%20FY%202023%20HCFAC.pdf.

$978 million was deposited in the Medicare Trust Fund,[39] providing crucial support for the ongoing viability of the Medicare program.

Whistleblower suits under the False Claims Act have directly impacted the lives of the patients whose interests amici curiae represent. For example, Cell Therapeutics, Inc. manufactured a drug called Trisenox, which was FDA-approved only for the treatment of acute promyelocytic leukemia.[40] Seeking additional revenue from Medicare, Cell Therapeutics fraudulently promoted Trisenox for additional conditions, including multiple myeloma, myelodysplastic syndrome, and chronic myeloid leukemia.[41] Although Cell Therapeutics had originally planned to seek FDA approval for these additional uses, the company halted the necessary clinical trials when it learned that off-label use of Trisenox was "causing a side-effect in patients called APL-like Differentiation Syndrome,"[42] a "life-threatening complication" that causes "acute end-organ damage."[43] Cell Therapeutics settled the action for $10.5 million.[44] Similar suits involving alleged off-label marketing of the

[39] *Id.*

[40] *Marchese*, 2007 WL 4410255, at *1.

[41] *Id.* at *3-4.

[42] *Id.* at *5.

[43] Gizem Reyhanoglu *et al.*, *Differentiation Syndrome, a Side Effect from the Therapy of Acute Promyelocytic Leukemia*, 12 Cureus e12042, at 1 (2020).

[44] *Marchese*, 2007 WL 4410255, at *7.

cancer drugs Thalomid and Rituxan were resolved for hundreds of millions of dollars.[45]

In addition to the direct monetary contributions to Medicare attributable to *qui tam* actions, whistleblowers play a critical role in preventing fraud. Researchers have estimated that the value of deterrence from whistleblower suits "was nearly 10 times the amount of recovery over the first five years following each lawsuit."[46] Thus, with nearly $11 billion in recoveries from *qui tam* cases involving health care over the past five fiscal years,[47] whistleblowers may have prevented another *$110 billion* in further fraud.

* * *

A holding by this Court that the *qui tam* provisions of the False Claims Act are unconstitutional would eliminate in this Circuit the essential role that whistleblowers play in rooting out fraud against the government and in recovering taxpayer funds lost to fraud. Both functions are critical to protecting the viability of

[45] Press Release, U.S. Dep't of Justice, *Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs for Uses Not Approved by FDA* (July 24, 2017), https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs; *U.S. ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949 (D. Kan. 2019).

[46] Jetson Leder-Luis *et al.*, *Measuring the Value of Healthcare Anti-Fraud Efforts* 4, 11-14 (2024), https://www.cms.gov/files/document/measuring-value-healthcare-anti-fraud-efforts.pdf.

[47] U.S. Dep't of Justice, *Fraud Statistics*, *supra* note 37 at 6-7.

government healthcare programs, to keeping healthcare affordable for patients, to ensuring access to quality care, and to promoting patient trust in the government healthcare system. For those reasons, amici urge this Court to reject Defendant-Appellant's alternative ground for reversal.

CONCLUSION

For the forgoing reasons, this Court should reject Defendant-Appellant's constitutional challenge to the False Claims Act and affirm the district court's decision.

Date: March 30, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(a)(7)(B)(i) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 3,528 words.

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Date: March 30, 2026

/s/ Catherine H. Dorsey
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CERTIFICATE OF SERVICE

I hereby certify that on March 30, 2026, I electronically filed the foregoing Brief of *Amici Curiae* Blood Cancer United, Cancer*Care*, Cancer Nation, Epilepsy Foundation of America, Muscular Dystrophy Association, and National Patient Advocate Foundation in Support of Plaintiff-Appellee and Affirmance of the Judgment Below with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

Date: March 30, 2026

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