**No. 24-13581**

**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE ELEVENTH CIRCUIT**

UNITED STATES *ex rel.* CLARISSA ZAFIROV,
*Plaintiff-Appellant,* and

UNITED STATES OF AMERICA,
*Intervenor-Appellant,*

v.

FLORIDA MEDICAL ASSOCIATES, LLC, *et al.*,
*Defendants-Appellees.*

On Appeal from the United States District Court
for the Middle District of Florida

# BRIEF OF THE LEUKEMIA & LYMPHOMA SOCIETY AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF-APPELLANT AND IN SUPPORT OF REVERSAL OF THE DISTRICT COURT'S DECISION

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## CERTIFICATE OF INTERESTED PERSONS

Pursuant to Eleventh Circuit Rule 26.1-1 and Federal Rule of Appellate Procedure 26.1, counsel for *Amicus Curiae* The Leukemia & Lymphoma Society 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.
2. Capesius, Kenneth D.
3. Connell, Brian
4. Dorsey, Catherine H.
5. The Leukemia & Lymphoma Society
6. Rich, Noah M.
7. Young, Kinika

*Amicus Curiae* The Leukemia & Lymphoma Society is a non-profit organization that has no parent corporation. No publicly traded corporation has any ownership interest in The Leukemia & Lymphoma Society.

Date: January 15, 2025

s/ Catherine H. Dorsey
Catherine H. Dorsey

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## INTEREST OF *AMICUS CURIAE*[1]

*Amicus Curiae* The Leukemia & Lymphoma Society ("LLS")[2] is the world's largest voluntary health agency dedicated to fighting blood cancer and ensuring that the more than 1.3 million blood cancer patients and survivors in the United States have access to the care they need. LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and to improve the quality of life of affected patients and their families. LLS 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.

LLS is 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. LLS advocates to ensure that blood cancer patients have access to care and can afford the care they need to live longer, healthier lives. Understanding the serious burdens of these diseases, LLS works to remove

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

[2] Under Federal Rule of Appellate Procedure 29(a)(4)(E), *Amicus Curiae* LLS certifies 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 LLS, their members, and their counsel) contributed money intended to fund the preparation or submission of the brief.

barriers that patients often face in obtaining healthcare. Reigning in the cost of cancer 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 Medicare Advantage, to obtain lifesaving care. Thus, the financial viability and integrity of government healthcare programs are important to blood cancer patients.

Because the patients and consumers whom LLS serves have a strong interest in the outcome of this case, LLS submits this brief in support of Plaintiff–Appellant and reversal of the district court's decision holding unconstitutional 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 more than $8 billion dollars in direct recoveries—and perhaps more than $80 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.

The district court's decision holding the *qui tam* provisions of the False Claims Act unconstitutional threatens to significantly impair whistleblowers' critical role in punishing and deterring fraud on the government, including in government healthcare programs. The district court's decision should be reversed.

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

The Medicare Advantage program, which is the subject of the instant case, is uniquely susceptible to fraud. Medicare Advantage is a public-private partnership in which the government pays private insurers, who, in turn, provide healthcare benefits to enrollees. The Medicare Advantage "payment system uses diagnostic information to assign a risk score to each beneficiary," and plan sponsors are paid according to each beneficiary's risk score.[7] Since risk scores are based on diagnostic data provided by plan sponsors, there are "strong incentives for plans to increase the reported morbidity of enrollees,"[8] including through fraudulent means. This is precisely what Appellant, as a *qui tam* relator, alleges here: Defendants brazenly carried out a fraudulent scheme to systematically inflate Medicare Advantage reimbursements by submitting false diagnosis codes, costing the government millions of dollars.[9]

The Medicare Payment Advisory Commission ("MedPAC"), an independent legislative agency that advises Congress on the Medicare program, estimates that inflated risk scores would lead to an additional $50 billion in spending on Medicare

[7] Richard Kronick & W. Pete Welch, *Measuring Coding Intensity in the Medicare Advantage Program*, 4 Medicare & Medicaid Res. Rev., no. 2, 2014, at E1, E3. For instance, if a Medicare Advantage "plan bids $1,000/month for an enrollee with a risk score of 1.0, and then enrolls a beneficiary with a risk score of 1.2, the plan gets paid $1,200/month for that enrollee (1.2 * $1,000/month)." *Id.*

[8] *Id.*

[9] *See* Plaintiff-Appellant's Opening Br. 5–6, ECF No. 41.

Advantage enrollees compared with traditional Medicare plans in 2024.[10] This increased spending is "subsidized by the taxpayers" and by traditional Medicare enrollees.[11]

The "[s]ignificant, ongoing fraud and abuse within Medicare may threaten the program's viability."[12] 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.[13] These expectations likely would be notably more dire if the district court's ruling is upheld, 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

[10] 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.

[11] *Id.* at 358.

[12] 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).

[13] MedPAC, *supra* note 10, at 13, 16–17.

> jobs and economic lifeline that Medicare providers bring. Medicare insolvency would eventually impact all those who rely on Medicare.[14]

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."[15] If anticipated *qui tam* recoveries were eliminated by virtue of the district court's decision, 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."[16] "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."[17] According to a recent survey, "[n]early one-fourth of enrollees … reported an affordability issue, including 15 percent who did not take their medicine

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

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

[16] *Id.* at 19.

[17] *Id.* at 20.

as prescribed because of cost."[18] One study found that, among Medicare beneficiaries whose incomes and assets were too high to qualify for a low-income 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."[19]

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 affirmed, the district court's holding will 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."[20]

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[18] *Id.* at 343.

[19] *Id.* at 21.

[20] 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."[21] *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."[22] 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."[23] 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."[24] These restrictions are well founded;

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[21] *Id.* at 2.

[22] 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).

[23] *Id.*

[24] *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."[25] Nevertheless, "[m]otivated to increase sales and prescriptions, and subsequent profits, manufacturing companies frequently encourage expanded use" through off-label marketing schemes.[26] 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.[27] When taken together, one-third of patients "suffered significant damage to the lungs and heart," leading to surgical treatment, disability, and death.[28] 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

[25] Van Norman, *supra* note 22, at 226.

[26] *Id.* at 224.

[27] *Id.* at 226.

[28] *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.[29] 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."[30] According to a CNN investigation, Nuedexta had the potential to cause harm "ranging from rashes, dizziness and falls to comas and death."[31]

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."[32] For example, the state of Florida suspended the medical license of Dr. Ishrat Sohail, a pediatrician who "was found to

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[29] *Id.* at 22–27.

[30] 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.

[31] Blake Ellis & Melanie Hicken, *The Little Red Pull 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.

[32] 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."[33]

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."[34] Indeed, "[s]tudies have shown that trust in the health care system is a top determinant of good health behaviors."[35] 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."[36] 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

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[33] *Id.* at 7.

[34] 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).

[35] *Id.* at 95.

[36] *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. The district court's decision, however, effectively eliminates 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."[37] 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."[38] The "safest and most expeditious way" to combat these fraudsters, said Senator Howard, was to employ the assistance of whistleblowers.[39] 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."[40]

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

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

[39] *Id.* at 956.

[40] 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 2023 alone, "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.[41] Of this amount, $978 million was deposited in the Medicare Trust Fund,[42] providing crucial support for the ongoing viability of the Medicare program. These recoveries were attributable in large part to the efforts of whistleblowers, whose cases accounted for nearly $1.6 billion—or 87%—of the government's healthcare recoveries under the False Claims Act.[43] Two *qui tam* cases alleging fraud related to Medicare Advantage resulted in nearly $200 million in recoveries.[44]

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[41] 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.

[42] *Id.*

[43] Civil Division, U.S. Dep't of Justice, *Fraud Statistics* 5 (2024), https://www.justice.gov/opa/media/1339306/dl?inline.

[44] Press Release, U.S. Dep't of Justice, *Cigna Group to Pay $172 Million to Resolve False Claims Act Allegations* (Sept. 30, 2023), https://www.justice.gov/opa/pr/cigna-group-pay-172-million-resolve-false-claims-act-allegations; Press Release, U.S. Dep't of Justice, *Martin's Point Health Care Inc. to Pay $22,485,000 to Resolve*

Whistleblower suits under the False Claims Act have directly impacted the lives of the patients whose interests LLS represents. For example, Cell Therapeutics, Inc. manufactured a drug called Trisenox, which was FDA approved only for the treatment of acute promyelocytic leukemia.[45] Seeking additional revenue from Medicare, Cell Therapeutics fraudulently promoted Trisenox for additional conditions, including multiple myeloma, myelodysplastic syndrome, and chronic myeloid leukemia.[46] 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,"[47] a "life-threatening complication" that causes "acute end-organ damage."[48] Cell Therapeutics settled the action for $10.5 million.[49] Similar suits involving alleged off-label marketing of the cancer drugs Thalomid and Rituxan were resolved for hundreds of millions of dollars.[50]

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*False Claims Act Allegations* (July 31, 2023), https://www.justice.gov/opa/pr/martins-point-health-care-inc-pay-22485000-resolve-false-claims-act-allegations.

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

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

[47] *Id.* at *5.

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

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

[50] 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-

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."[51] Thus, with nearly $8.2 billion in recoveries from *qui tam* cases over the past five fiscal years,[52] whistleblowers may have prevented another *$82 billion* in further fraud.

* * *

If affirmed, the district court's decision holding the *qui tam* provisions of the False Claims Act unconstitutional would eliminate in this Circuit the essential role that whistleblowers serve in rooting out fraud against the government and in recovering taxpayer funds lost to fraud. Both functions are critical to protecting the viability of 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. The district court's decision imperils these important goals.

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agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs; *U.S. ex rel. Tra v. Fesen*, No. 2:14-cv-2249 (D. Kan.).

[51] 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.

[52] U.S. Dep't of Justice, *Fraud Statistics*, *supra* note 43, at 5.

## CONCLUSION

For the forgoing reasons, as well as those stated by the Plaintiff-Appellant and the United States in their opening briefs, the district court's decision should be reversed.

Date: January 15, 2025

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) and Eleventh Circuit Rule 32-4, this document contains 3,361 words.

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Date: January 15, 2025

/s/ Catherine H. Dorsey
Catherine H. Dorsey

**CERTIFICATE OF SERVICE**

I hereby certify that on January 15, 2025, I electronically filed the foregoing Brief of The Leukemia & Lymphoma Society as *Amicus Curiae* in Support of Plaintiff-Appellant with the Clerk of the Court for the United States Court of Appeals for the Eleventh 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: January 15, 2025

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