No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT, INC., ET AL.,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, ET AL.,

Defendants-Appellants

On Appeal from the United States District Court for the
Northern District of Texas, Fort Worth Division

AMICI CURIAE BRIEF OF THE AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN KIDNEY FUND, ARTHRITIS FOUNDATION, CANCER*CARE*, CANCER SUPPORT COMMUNITY, CYSTIC FIBROSIS FOUNDATION, EPILEPSY FOUNDATION, HEMOPHILIA FEDERATION OF AMERICA, LEUKEMIA AND LYMPHOMA SOCIETY, NATIONAL MINORITY QUALITY FORUM, ,NATIONAL MULTIPLE SCLEROSIS SOCIETY, NATIONAL PATIENT ADVOCATE FOUNDATION, THE AIDS INSTITUTE, AND WOMENHEART SUPPORTING DEFENDANTS' MOTION FOR A PARTIAL STAY OF FINAL JUDGMENT PENDING APPEAL

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CERTIFICATION OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 29.2 and Federal Rule of Appellate Procedure 26.1, *amici curiae* American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund (AKF), Arthritis Foundation, Cancer*Care*, Cancer Support Community (CSC), Cystic Fibrosis Foundation, Epilepsy Foundation, Hemophilia Federation of America, Leukemia and Lymphoma Society (LLS), National Minority Quality Forum (NMQF), National Multiple Sclerosis Society, National Patient Advocate Foundation, The AIDS Institute, and WomenHeart submit this certificate of interested persons to fully disclose all those with an interest in this brief and provide the required information as to their corporate status and affiliations.

The undersigned counsel of record certifies that, in addition to the parties to this case, the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

a. Amicus Curiae **American Cancer Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

b. Amicus Curiae **American Cancer Society Cancer Action Network** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

c. Amicus Curiae **American Kidney Fund** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

d. Amicus Curiae **Arthritis Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

e. Amicus Curiae **Cancer*Care*** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

f. Amicus Curiae **Cancer Support Community** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

g. Amicus Curiae **Cystic Fibrosis Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

h. Amicus Curiae **Epilepsy Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

i. Amicus Curiae **Hemophilia Federation of America** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

j. Amicus Curiae **Leukemia and Lymphoma Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

k. Amicus Curiae **National Minority Quality Forum** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

l. Amicus Curiae **National Multiple Sclerosis Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

m. Amicus Curiae **National Patient Advocate Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

n. Amicus Curiae **The AIDS Institute** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

o. Amicus Curiae **WomanHeart** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

p. The above-listed amici curiae are represented by Beth Petronio, John Longstreath, Adam Cooper, Gretchen Mahoney, and Brian Hopkins of K&L Gates LLP and by Mary Rouvelas of American Cancer Society Cancer Action Network, Inc.

/s/ Beth Petronio
BETH PETRONIO

Counsel for Amici Curiae

INTEREST OF *AMICI*[1]

The American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund (AKF), Arthritis Foundation, Cancer*Care*, Cancer Support Community (CSC), Cystic Fibrosis Foundation, Epilepsy Foundation, Hemophilia Federation of America, Leukemia and Lymphoma Society (LLS), National Minority Quality Forum (NMQF), National Multiple Sclerosis Society, National Patient Advocate Foundation, The AIDS Institute, and WomenHeart, (collectively, "*amici*") are among the largest, most prominent organizations representing the interests of patients, survivors, and families affected by these chronic conditions. These conditions are frequently detected in early stages by preventive services, including those recommended by the U.S. Preventive Services Task Force (USPSTF) pursuant to the preventive care mandate of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 300gg-13.

Amici are dedicated to supporting patients and their families across the United States. Collectively, we represent millions of individuals who suffer from the respective diseases and conditions to which we dedicate our efforts. Amici's activities range from medical research to patient support and other services in

[1] Counsel for each of the parties have consented to the filing of this brief. *Amici* certify that this brief was authored in whole by counsel for *amici* and no part of the brief was authored by any attorney for a party. No party, nor any other person or entity, made any monetary contribution to the preparation or submission of this brief.

support of curing, lessening the burden of, or otherwise minimizing the effects of the various illnesses discussed herein. Collectively, amici bring decades of experience to fighting these illnesses and advocating on behalf of patients.

The fight against all of these diseases requires access to affordable, quality health care and health insurance that includes preventive care. *Amici* desire to assist the Court in understanding (1) why the USPSTF's preventive care recommendations and the agency actions implementing them are crucial for patients battling a wide range of diseases, and (2) the immediate and devastating impact that impeding access to preventive care will have for patients.

SUMMARY OF ARGUMENT

All Americans use or will use health care services, and the lifetime risk that individual Americans will contract one of the diseases or conditions towards which *amici* direct our efforts is high. Preventive services can aid in prevention, early detection and treatment of many diseases, which increases patients' chances of survival and extends life expectancies. Preventive care also helps control patients' costs of treating these diseases and conditions.

The ACA's preventive services mandate, the USPSTF's recommendations, and the agency actions implementing those recommendations increase access to preventive services that can prevent disease outright, identify illnesses early, and reduce the physical and financial burdens of treating severe illnesses. Detecting

severe diseases early allows for less invasive, more effective, and lower-cost treatment options, and substantially improves patient outcomes.

The U.S. District Court's March 30 decision threatens to imminently and drastically reduce insurance coverage of preventive services, deter utilization of those services, and worsen patient outcomes. Without a stay, the District Court's order will substantially harm the patients *amici* serve and support.

ARGUMENT

I. ABSENT A STAY, THE DISTRICT COURT'S DECISION WILL IMMINENTLY HINDER PATIENT ACCESS TO CRITICAL PREVENTIVE CARE SERVICES

The need for health care is difficult to predict, but practically inevitable at some point in all Americans' lives. *See Nat. Fedn. of Indep. Business v. Sebelius*, 132 S. Ct. 2566, 2610 (2012) (Ginsburg, J., concurring) ("Virtually every person residing in the United States, sooner or later, will visit a doctor or other health-care professional."); *see also id*. at 2585 (Roberts, C.J.) ("Everyone will eventually need health care at a time and to an extent they cannot predict."). The ACA recognizes that for the vast majority of Americans, accessing such necessary care requires health insurance coverage.

Thus, the ACA provides a framework for coverage that has withstood three major legal challenges at the United States Supreme Court. This framework includes insurance coverage for preventive services without cost sharing so that Americans

will have greater access to such services, thereby preventing illnesses or catching them early to more successfully treat them. The District Court's ruling will have the opposite effect. Whether insurers and employers choose to implement cost sharing for preventive services or drop them altogether, many patients, especially low income patients, will be forced to utilize preventive services less frequently, or not at all. A review of 65 papers published from 2000-2017 found that "even relatively small levels of cost sharing in the range of $1 to $5 are associated with reduced use of care, including necessary services." Samantha Argita et al., The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings, Kaiser Family Foundation (2017) https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.

For example, even with insurance, Cystic Fibrosis, Multiple Sclerosis, and epilepsy patients have often experienced financial and emotional distress due to medical expenses. The Importance of Cost and Affordability for People with CF, Cystic Fibrosis Foundation (2022) https://www.cff.org/about-us/importance-cost-andaffordability-people-cf; Make MS Medications Accessible, National Multiple Sclerosis Society (2022) https://www.nationalmssociety.org/TreatingMS/Medications/Make-MS-Medications-Accessible; The U.S. National Health Interview Survey, 2010 and

2013, 55 Epilepsy & Behavior (Feb. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/. Accordingly, patients have resorted to foregoing tests, skipping medication doses, and delaying filling their prescriptions. Such actions cause breakdowns in treatment and open the door for disease progressions. In turn, patients face uncertain outcomes and experience heightened anxiety. *Id*. Coverage of USPSTF recommendations without cost-sharing means patients do not need to choose between paying for already-needed treatments and trying to prevent additional illnesses.

A survey conducted just before the District Court's decision revealed that three out of ten respondents had delayed or skipped healthcare within the last year, largely due to income constraints. Ricky Zipp, Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through, Moring Consult, (Mar. 8, 2023) https://morningconsult.com/2023/03/08/affordable-care-act-polling-data/. Two out of five respondents stated that they would not pay out of pocket for eleven out of twelve preventive services included in the survey. *Id*. This data underscores the damaging gap in patient care the District Court's decision will open if permitted to take effect.

The ACA's framework sought to increase use of preventive care by requiring health insurers to cover USPSTF-recommended services with "A" and "B" grades without cost sharing. Congress's goal was to allow individuals greater access to

evidence-based care as science evolves. Numerous USPSTF recommendations have changed since the March 2010 cut-off designated by the District Court. For example, before March 2010, the USPSTF recommended colorectal cancer screenings for adults 50 and older. Final Recommendation Statement: Colorectal Cancer: Screening, U.S. Preventive Services Task Force (2008) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-2008. The current colorectal cancer screening recommendation has reduced the screening age to 45 and added screening modalities not present in and/or not yet developed at the time of the original recommendation. Final Recommendation Statement: Colorectal Cancer: Screening, U.S. Preventive Services Task Force (2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.

The USPSTF recommended lung cancer screenings in 2013 and updated its recommendation in 2021. Final Recommendation Statement: Lung Cancer: Screening, U.S. Preventive Services Task Force (2021) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening. The USPSTF developed its new recommendation based, in part, on data from the National Lung Cancer Screening Trial (NLST). The NLST provided direct evidence of moderate certainty that lung cancer screening in high-

risk populations was effective in reducing lung cancer deaths. The National Lung Screening Trial Research Team, Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening, N. Engl. J. of Med. (August 4, 2011) https://www.nejm.org/doi/full/10.1056/nejmoa1102873. These screenings are essential to catching lung cancer early, when it is more treatable. The five-year survival rate when lung cancer is diagnosed at an early stage is 61%, a stark contrast to the 7% survival rate for late-stage diagnoses. Lung Cancer Key Findings, American Lung Association (2022), https://www.lung.org/research/state-of-lung-cancer/key-findings.

Additionally, in February 2019, the USPSTF recommended counseling interventions for pregnant and post-partum individuals at increased risk of perinatal depression. U.S. Preventive Services Task Force, A & B Recommendations, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations. This care is crucial, as one in seven post-partum individuals experience postpartum depression and anxiety disorders. Nellie Garlow et al., Issue Brief: Societal Costs of Untreated Perinatal Mood and Anxiety Disorders in the United States, Mathmateica (2019) https://www.mathematica.org/publications/societal-costs-of-untreated-perinatal-mood-and-anxiety-disorders-in-the-united-states.

In 2019, over eight million American children aged 3-17 had a current, diagnosed mental or behavioral health condition, the most common of which were anxiety and depression. NSCH Data Brief: Mental and Behavioral Health, Health Resources and Services Administration (2020) https://mchb.hrsa.gov/sites/default/files/mchb/data-research/nsch-data-brief-2019-mental-bh.pdf. In that year, over half of those children received treatment or counseling from a mental health professional. *Id*. In October 2022, the USPSTF recommended screenings for anxiety in children and adolescents aged 8-18. U.S. Preventive Services Task Force, A & B Recommendations.

Further, in July 2019, the USPSTF recommended Hepatitis B Virus (HBV) screenings for pregnant individuals at their first prenatal visit, and HBV screening for adolescents and adults at increased risk for infection in December 2020. U.S. Preventive Services Task Force, A & B Recommendations. These screenings are crucial because chronic HBV has been shown to cause liver cancer and increase risk of non-Hodgkin lymphoma. American Cancer Society, Cancer Prevention & Early Detection Facts & Figures, Atlanta: American Cancer Society (2022) https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/2021-cancer-prevention-and-early-detection.pdf.

There are additional examples of the USPSTF has updating recommendations made prior to March 23, 2010. Notably, in August 2022, the USPSTF recommended use of statins for adults aged 40-75 with one or more risk factors for cardiovascular disease. *Id*. In August 2018, the USPSTF recommended cervical cancer screening, at either three or five-year intervals, for women aged 21-65. Final Recommendation Statement: Cervical Cancer: Screening, U.S. Preventive Task Force (2018) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening. This update to the 2003 recommendation added the option for HPV testing and information regarding specific testing modalities and intervals. *Id*.

In March 2020, the USPSTF updated its Hepatitis C Virus screening recommendation. Final Recommendation Statement: Hepatitis C Virus Infection in Adolescents and Adults: Screening, U.S. Preventive Services Task Force (2020) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening. The new version "incorporates new evidence" and "expands the ages for screening to all adults from 18-79 years." *Id*. In June 2019, the USPSTF added HIV screening and treatment recommendations, leading to an extension of mandatory screening coverage to adolescents and adults aged 15-65, adolescents and adults at increased risk of infection, and pregnant individuals. Final Recommendation Statement: Human Immunodeficiency Virus (HIV) Infection: Screening, U.S. Preventive Services Task Force (2019)

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening. It simultaneously extended PrEP coverage to individuals at high risk of HIV acquisition. Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis, U.S. Preventive Services Task Force (2019) https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. These recommendations are especially important because many people experience no symptoms of HIV infection, meaning the only way to identify an infection and prevent the spread of HIV is to test/screen. About HIV, Centers for Disease Control and Prevention (2022) https://www.cdc.gov/hiv/basics/whatishiv.html.

Over 150 million individuals in the U.S. have health insurance coverage subject to the ACA's preventive services requirement and receive preventive services recommended by the USPSTF cost-free. Office of Health Policy: Assistant Secretary for Planning and Evaluation, Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act, 8. A recent study found that six out of eight privately insured American adults, roughly 100 million people, received some form of ACA preventive healthcare in 2018. Krutika Amin, et al., Preventive Services Use Among People with Private Insurance Coverage, Kaiser Family Foundation (Mar. 20, 2023) https://www.healthsystemtracker.org/brief/preventive-

services-use-among-people-with-private-insurance-coverage/?utm_campaign=KFF-2022-Private-Insurance&utm_medium=email&_hsmi=250924771&_hsenc=p2ANqtz--ROq45DUlI7CpvgjC-QUCn4x8usGAaEZCvk8cxtaPCIqrIyQabI4_uqxOuWl-CE1Q3eOYnq8VzmiL-sKcTJsgcmszcW8IRxe9JM3DpwmolsApHdNc&utm_content=250924771&utm_source=hs_email#Share%20of%20privately%20insured%20enrollees%20receiving%20preventive%20care,%202018.

In 2018, 61% of individuals covered by large employers, 57% of those covered by small employers, and 55% of those in the individual insurance market received ACA preventive care. Further, seven out of ten American children received ACA preventive services in 2018. *Id*. Among the most utilized services were screenings for heart disease, cervical cancer, and diabetes, all of which the USPSTF updated recommendations for after March 23, 2010. Krutika Amin et al., Preventive Services Use Among People with Private Insurance Coverage; U.S. Preventive Services Task Force, A & B Recommendations.

The District Court's decision to vacate all agency actions taken to implement the USPSTF's recommendations since the enactment of the ACA, and to enjoin enforcement of all future recommendations will allow insurers to either drop preventive care coverage altogether or to re-introduce cost sharing for all preventive

services. Group and individual health plans typically operate on a calendar year basis, but a significant minority operate on academic or fiscal years. This variety, and some insurers' ability to change services covered mid-year, means that patients' loss of cost-free preventive care coverage is imminent. Furthermore, based on the District Court's decision, certain employers are likely to drop some of the more costly preventive services or impose cost sharing on such services in the near future.

Since March 23, 2010, the USPSTF has recommended lifesaving "A" and "B" screenings and treatments for a wide array of diseases and conditions, including those which *amici* seek to eradicate. These recommendations and their implementation have reduced financial barriers to preventive care services, increased utilization of those services, and saved and prolonged lives. The District Court's decision threatens to erect formidable financial barriers to these critical services and reverse over a decade's worth of progress in improving health outcomes. Without a stay, millions of Americans, including those *amici* serve and support, will imminently struggle to access current, evidence-based preventive care services.

CONCLUSION

For the foregoing reasons, *amici* respectfully submit that this Court should grant the Appellants' Motion for Partial Stay of Judgment Pending Appeal. The

ACA's preventive care mandate and the USPSTF's recommendations have saved lives and should continue to do so.

Respectfully submitted,

/s/ Beth Petronio

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May 2, 2023

CERTIFICATE OF COMPLIANCE

This document complies with the word limit established by Fed. R. App. P. 27(d)(2) because, excluding portions of the brief exempted by Federal Rule of Appellate Procedure 32(f) and the Rules of this Court, this document contains 2,220 words.

In accordance with Fed. R. App. P. 27(d)(1)(E), this document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6). This motion has been prepared in a proportionally spaced typeface using Microsoft Word in 14 point, Times New Roman.

/s/ Beth Petronio
BETH PETRONIO

CERTIFICATE OF SERVICE

I certify that a copy of this brief was served, via the Court's CVM/ECF Document Filing System, on all counsel of record who have appeared in this case on May 2, 2023. I further certify that a copy of this brief was served on Christopher M. Lynch, counsel for U.S. Department of Justice, via United States mail.

/s/ Beth Petronio
BETH PETRONIO