IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT INC. et al. Plaintiffs, v. XAVIER BECERRA et al. Defendants.	)	Civil Action No. 4:20-cv-00283-O

UNOPPOSED MOTION OF THE AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN KIDNEY FUND, AMERICAN LUNG ASSOCIATION, ARTHRITIS FOUNDATION, CANCERCARE, 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 FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' RESPONSE

Movants, through undersigned counsel, and pursuant to Fed. R. Civ. P. 7 and Rule 7.2(b) of the local rules of this Court, move for leave to file the attached brief *amici curiae* in support of Defendants' Response.

Counsel for all parties have consented to this Motion and to the filing today of the attached brief *amici curiae*. This brief is being filed timely within seven days of Defendants' Response, the same amount of time allowed for an *amici curiae* brief under the Federal Rules of Appellate Procedure, Fed. R. App. P. 29(a)(6).

Movants The American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund, American Lung Association, Arthritis Foundation, CancerCare, 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 are the largest and most prominent nonpartisan, nonprofit organizations representing the interests of patients, survivors, and families affected by the widespread chronic conditions of cancer, diabetes, heart disease, stroke, lung disease, and Multiple Sclerosis (MS), respectively. These conditions result in a significant portion of the nation's health care spending. Movants are exempt from federal income taxation under 26 U.S.C. §§ 501(c)(3), 501(c)(4).

I. THE *AMICI CURIAE* BRIEF PROVIDES HELPFUL INFORMATION TO SUPPLEMENT DEFENDANTS' RESPONSE.

Movants' *amici curiae* brief, submitted with this Motion, supports the position of the Defendants. However, movants provide additional information and context to supplement Defendants' Response that they believe will be relevant and helpful to the court in making its decision. The brief discusses the essential role of preventive services in managing chronic diseases, including scientific data linking availability of preventive screenings with improvement in patient outcomes and decreased costs associated with patient care.

II. THE ACCEPTANCE OF BRIEFS *AMICUS CURIAE* HAS BEEN FOUND USEFUL IN CASES SUCH AS THIS.

District courts have broad discretion to accept *amicus* filings. *See Gudur v. Deloitte Consulting LLP*, 512 F. Supp. 2d 920, 927 (S.D. Tex. 2007). *Amicus* filings should be allowed when "the proffered information is timely and useful or otherwise necessary to the administration of justice." *United States ex rel. Long v. GSD & M Idea City LLC*, 2014 WL 11321670, at *4 (N.D. Tex. Aug. 8, 2014) (quoting *Does 1–7 v. Round Rock Indep. Sch. Dist.*, 540 F.Supp.2d 735, 738 n.2 (W.D.Tex.2007)). For the reasons stated above, particularly in bringing to the attention of the Court important principles and context surrounding the enactment of the ACA and the implications of its repeal, this *amici* brief will inform the Court's effort to resolve the question before it.

Given the nationwide significance of this case, and its profound implications for all Americans, movants respectfully request leave to file the accompanying brief *amici curiae* in support of Defendants' Response.

Respectfully submitted,

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November 30, 2022

CERTIFICATE OF CONFERENCE

Pursuant to Local Rule 7.1(b) I certify that counsel for *Amici* conferred with counsel for Plaintiffs' and Defendants regarding timing and filing this motion and attached *amici curiae* brief. Counsel for Plaintiffs and Defendants did not object.

/s/ Beth Bivans Petronio
BETH BIVANS PETRONIO

CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.1(d), I certify that all counsel of record who have appeared in this case received a copy of this document via the Court's CM/ECF system on November 30, 2022.

/s/ Beth Bivans Petronio
BETH BIVANS PETRONIO

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT INC. et al.	)	
Plaintiffs,	)	
v.	)	Civil Action No. 4:20-cv-00283-O
XAVIER BECERRA et al.	)	
Defendants.	)	

ORDER GRANTING UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' RESPONSE

On this date, the Court considered American Cancer Society, et al.'s Unopposed Motion for Leave to File Brief *Amici Curiae* in Support of Defendants' Response. The Court, having considered the Motion and lack of opposition, concludes that cause exists to grant the Motion. It is, therefore:

ORDERED that the Motion is **GRANTED** in all respects.

The Clerk is **DIRECTED** to file American Cancer Society, et al.'s Brief *Amici Curiae* as a separate docket entry.

SO ORDERED on this **__ day** of **_____, 2022**.

The Honorable Reed O'Connor
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT INC. et al. Plaintiffs, v. XAVIER BECERRA et al. Defendants.	)	Civil Action No. 4:20-cv-00283-O

AMICI CURIAE BRIEF OF THE AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN KIDNEY FUND, AMERICAN LUNG ASSOCIATION, ARTHRITIS FOUNDATION, CANCERCARE, 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' RESPONSE

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF *AMICI*[1]

The American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund, American Lung Association, Arthritis Foundation, CancerCare, 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, (collectively, "*amici*") are the largest and most prominent organizations representing the interests of patients, survivors, and families affected by the widespread chronic conditions of cancer, kidney diseases, lung diseases, arthritis, cystic fibrosis, epilepsy, hemophilia, diabetes, multiple sclerosis, HIV/AIDS, and heart disease, respectively. These conditions result in a significant portion of the nation's health care spending, and are frequently detected in their 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.

The mission of the American Cancer Society (ACS) is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer. ACS's extensive scientific findings have established that (1) access to preventive care is strongly linked to early detection and successful treatment of many forms of cancer, and (2) inability to access such preventive screenings is a major impediment to advancing the fight against cancer. The American Cancer

[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.

Society Cancer Action Network (ACS CAN) is ACS's nonprofit, nonpartisan advocacy affiliate, making cancer a top priority for policymakers at every level of government. ACS CAN advocates for guaranteeing all Americans access to preventive care and affordable and adequate health insurance.

American Kidney Fund (AKF) fights kidney disease on all fronts. AKF assists the 37 million Americans living with or at risk for kidney disease with an unmatched scope of programs that support patients from prevention through transplant. An important tool in preventing kidney disease is patient access to preventive services, particularly screenings for diabetes and hypertension, the two leading causes of kidney disease.

American Lung Association is the nation's oldest voluntary health organization representing the 34 million Americans with lung disease in all 50 states and the District of Columbia.

Arthritis Foundation is championing the fight to conquer America's #1 cause of disability with life-changing science, resources, advocacy and community connections.

CancerCare is the leading national organization providing free, professional support services and information for managing cancer's emotional, practical and financial challenges.

Cancer Support Community (CSC) is dedicated to ensuring that all people affected by cancer are empowered by knowledge, strengthened by action, and sustained by community. CSC delivers more than $50 million in free support and navigation services to cancer patients, conducts research on the emotional, psychologic, and financial journeys of cancer patients, and advocates for policies to help individuals whose lives have been disrupted by cancer.

Cystic Fibrosis Foundation seeks to cure cystic fibrosis (CF) by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

Out-of-pocket expenses for treating CF can quickly add up. Reinstituting financial barriers to preventive services could prevent CF patients from accessing essential care, leading to costly hospitalizations and fatal lung infections.

Epilepsy Foundation is the leading national, voluntary health organization representing over 3.4 million Americans with epilepsy and seizures. Uncontrolled seizures can lead to disability, injury, and death. Epilepsy medications are the most common, cost-effective treatment for controlling and/or reducing seizures. Timely access to quality, affordable, physician-directed care and effective coverage for epilepsy medications is vital for epilepsy patients.

Hemophilia Federation of America is a community-based, grassroots advocacy organization that educates, assists, and advocates for people with hemophilia, von Willebrand disease, and other rare bleeding disorders.

Leukemia & Lymphoma Society (LLS) is the world's largest voluntary health agency dedicated to curing leukemia, lymphoma, Hodgkin's disease, and myeloma, and ensuring that the more than 1.3 million blood cancer patients and survivors in the United States have sustainable access to quality, affordable, coordinated healthcare regardless of their source of coverage.

National Minority Quality Forum (NMQF) is a national non-partisan, not-for-profit research and education organization. NMQF works to reduce patient risk, assure optimal care, and create an American health services, research, delivery, and financing system focused on reducing patient risk for amenable morbidity and mortality and improving quality of life.

National Multiple Sclerosis Society mobilizes people and resources so that the nearly one million people affected by multiple sclerosis (MS) can live their best lives while the Society works to stop MS in its tracks, restore what has been lost, and end MS forever.

National Patient Advocate Foundation is the advocacy affiliate of the Patient Advocate Foundation, which provides assistance and support services for families confronting complex, chronic and serious diseases.

The AIDS Institute is a leading national nonpartisan, nonprofit patient advocacy organization working to end the HIV and viral hepatitis epidemics by increasing access to health care for people living with and at risk for infectious disease and chronic illness. The Institute promotes action for social change through public policy, research, advocacy, and education.

WomenHeart is the nation's only patient-centered organization focused solely on providing support, education and advocacy to women living with or at risk for heart disease.

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 why the ACA's preventive care mandate, and the USPSTF's preventive care recommendations, are so important to millions of patients and survivors and their families across a wide range of diseases. The "universal" remedy Plaintiffs seek would lead to adverse consequences and preventable deaths for patients suffering from the serious diseases *amici* are battling to eradicate.

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 the early detection and treatment of many diseases. Early detection yields two primary benefits. First, and most importantly, early detection increases patients' chances of survival and extends life expectancies. Second, early detection decreases the overall costs of treating illnesses over patients' lifetimes. Unless it is of no effect at all, which Plaintiffs plainly do not intend, Plaintiffs' proposed "universal" remedy would reduce coverage

for the preventive services and screenings USPSTF has recommended by allowing health insurance providers to opt out of covering such care. Preventive care has saved countless lives and helped control the costs of treating the diseases and conditions *amici* are fighting. The "universal" remedy would also prevent USPSTF from making future preventive care recommendations, compounding the problem.

The ACA's preventive services mandate, and the USPSTF's recommendations, increase access to preventive services that can identify illnesses early, and therefore reduce the physical and financial burdens of treating severe illnesses like cancer, heart, kidney and lung diseases, arthritis, cystic fibrosis, hemophilia, diabetes, HIV/AIDS, and MS. Detecting severe diseases early allows for less invasive, more effective, and lower-cost treatment options, and substantially improves patient outcomes. Reducing insurance coverage of preventive services will lead to the opposite result, worsening patient outcomes, leading to preventable deaths, and creating higher long-term medical costs. By disrupting a status quo that has now been in place for over twelve years, the extraordinary relief plaintiffs seek would substantially harm the patients *amici* work to help, and the public interest at large.

ARGUMENT

I. THE PREVENTIVE SERVICE COVERAGE THE USPSTF RECOMMENDS INCREASES ACCESS TO CARE, IMPROVES TREATMENT OUTCOMES, AND SAVES LIVES

The need for health care is difficult to predict, but practically inevitable at some point in life. *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.

Studies relevant to the diseases that are the focus of *amici's* efforts show USPSTF-recommended preventive services improve health outcomes and save lives. These are summarized by disease below:

Cancer-Related Studies:

- The five-year survival rate when lung cancer cases are diagnosed at an early stage is 61%. Unfortunately, 44% of cases are not caught until a late stage when the survival rate is only 7%. American Lung Association, Lung Cancer Key Findings, American Lung Association (2022), https://www.lung.org/research/state-of-lung-cancer/key-findings.
- Colorectal cancer (CRC) screening can prevent the disease through the detection and removal of precancerous growths and detect cancer at an early stage, when treatment is usually more successful. As a result, screening reduces CRC mortality both by decreasing incidence and increasing survival. There are several USPSTF recommended CRC screening methods, all of which have a comparable ability to improve life expectancy when performed at the appropriate time intervals and with the recommended follow-up. American Cancer Society, Colorectal Cancer Facts & Figures 2020-2022, Atlanta: Am. Cancer Soc'y, Inc. (2020), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf.

- Screenings for Colorectal Cancer increased from 57.3% to 61.2% between 2008 and 2013, especially among low-income, lower-educated, and Medicare-insured patients. These results are likely associated with the ACA provisions removing cost-sharing for these screenings. Stacey A. Fedewa et al., Elimination of cost-sharing and receipt of screening for colorectal and breast cancer, Cancer (2015), https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.29494.
- In May 2021, the USPSTF revised its CRC screening recommendation and lowered the minimum age of screening to age 45 instead of 50. Colon cancer remains one of the leading causes of cancer deaths, and increased preventive screening has resulted in a decrease in colorectal cancer incidence. Office of Health Policy: Assistant Secretary for Planning and Evaluation, Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act, U.S. Dep't of Health and Hum. Serv., at 8 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.
- Improvement in screening rates for colorectal cancer in early Medicaid expansion states translated to an additional 236,573 low-income adults receiving screenings in 2016 and, if the same absolute increases were experienced in non-expansion states, 355,184 more low-income adults would have had CRC screening as of 2019. Colon cancer screenings in accordance with Task Force recommendations have reduced the incidence of colon cancer. Jeff Legasse, First states to expand Medicaid saw larger screening rate increases, Healthcare Finance, (May 24, 2019), https://www.healthcarefinancenews.com/news/first-states-expand-medicaid-saw-larger-screening-rate-increases (citing Fedewa et al., Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the

Affordable Care Act, Am. J. of Preventive Med., (July, 2019), https://www.sciencedirect.com/science/article/abs/pii/S0749379719301163.).

- Researchers estimated that changes to Medicare made by the ACA increased the number of early-stage colorectal cancer diagnoses by 8 percent per year. Since there were 26,236 early-stage colorectal cancers diagnosed in the Surveillance Epidemiology and End Results (SEER) registry regions in the period 2011–13, and the SEER registry regions include about one-fourth of the US population, they inferred that ACA changes to Medicare led to roughly 8,400 additional early-stage colorectal cancer diagnoses among US seniors during 2011–13. Brett Lissenden and Nengliang "Aaron" Yao, Affordable Care Act Changes To Medicare Led To Increased Diagnoses Of Early-Stage Colorectal Cancer Among Seniors, Health Affairs, (Jan. 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0607.[2]
- Cervical cancer incidence and mortality rates have decreased by more than 50% over the past three decades and are attributed to screening, which can detect both cervical cancer at an early stage and precancerous lesions. American Cancer Society, Cancer Prevention & Early Detection Facts & Figures 2021-2022, at 33.
- The risk of breast cancer death has been shown to have been reduced due to early detection of breast cancer by mammography, which increases treatment options. American Cancer Society, Breast Cancer Facts & Figures 2022-2024, Atlanta: Am. Cancer Soc'y, Inc., (2022), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2022-2024-breast-cancer-fact-figures-acs.pdf.

[2] "In January 2022, the federal government issued a ruling that non-grandfathered group health plans and health insurance issuers are required to cover, without the imposition of any cost sharing, a follow-up colonoscopy conducted after a positive non-invasive stool-based screening test or direct visualization test (e.g., sigmoidoscopy, CT colonography)." Department of Labor, FAQs about Affordable Care Act implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation. Washington, D.C: Department of Labor, 2022:16.

- Compared with non-Medicaid expansion states, states that implemented expansion saw greater improvement in breast cancer screening rates among lower-income women. Stacey A. Fedewa et al., Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act, 57 Am. J. Preventive Med. 1, 3 (2019).
- The COVID-19 pandemic triggered substantial disruptions to health care delivery in the US due to stay-at-home orders and patient fears about visiting health care facilities. Thus, many forms of health care use, including cancer screenings, sharply decreased in early 2020. Boyce et al., Rates of Routine Cancer Screening and Diagnosis Before vs After the COVID-19 Pandemic, JAMA Oncology, (Nov. 17, 2022), https://jamanetwork.com/journals/jamaoncology/fullarticle/2798851?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top. The temporary pause in preventive screening was clinically reasonable and situationally appropriate; however, long-term delays or avoidance will have adverse implications for population-level cancer-related morbidity and mortality. *Id*.

The downturn in cancer screenings during the height of the COVID-19 pandemic will have adverse consequences for cancer patients. Continuing this downturn by reintroducing financial obstacles to cancer screenings only increases the likelihood of poorer health outcomes and increased deaths due to cancer diagnosed at later stages.

Studies Regarding Vaccinations, Blood Pressure Testing, and Cholesterol Testing:

- Use of blood pressure checks, cholesterol checks, and flu vaccinations increased significantly in the years after ACA passage. Gery P. Guy Jr., Xuesong Han, Ahmedin Jemal, K Robin Yabroff, Zhiyuan Zheng, Has recommended preventive service use

increased after elimination of cost-sharing as part of the Affordable Care Act in the United States?, Prev Med., (Jul. 23, 2015), https://pubmed.ncbi.nlm.nih.gov/26209914/.

- The ACA provision expanding dependent insurance coverage to young adults up to 26 was associated with a 3.67 percentage points increase in receipt of blood-pressure measurement among young adults aged 19-25 years. Dependent Coverage and Use of Preventive Care under the Affordable Care Act, New England Journal of Medicine (Dec 11, 2014), available at https://www.nejm.org/doi/pdf/10.1056/NEJMc1406586?articleTools=true.
- Childhood vaccines in accordance with expert recommendations have saved 732,000 lives. Whitney, C. G., Zhou, F., Singleton, J., & Schuchat, A., Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013, Morbidity and Mortality Weekly Report, 2014 Apr. 25; 63(16): 352, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584777/.
- Preventive services without cost sharing, in part, led to 854,000 young women completing the Human Papillomavirus (HPV) vaccine series from 2010-2012.[3] Office of Health Policy: Assistant Secretary for Planning and Evaluation at 8. Coverage without cost-sharing was associated with a 4.3 percentage point increase in HPV vaccine completion for females aged 9-26 who were privately insured and a 5.7 percentage point increase for Medicaid enrollees in three states. *Id*. at 8, 10.

[3] Although the issue of HPV vaccine coverage does not appear to be before the Court in the remedies phase, amici do note for the record that high-risk types of HPV cause the majority of throat, cervical, vaginal, vulvar, anal, and penile cancers, and they thus strongly support coverage of the HPV vaccine without cost sharing. *See* American Cancer Society, The Need for Increased HPV Vaccination, American Cancer Society, Inc., (2022), https://www.cancer.org/health-care-professionals/hpv-vaccination-information-for-health-professionals/the-need-for-increasing-hpv-vaccination.html. In the first 10 years after the vaccine was recommended in the United States in 2006, quadrivalent type HPV infections decreased by 86% in female teens 14 to 19 years old, and by 71% in women in their early 20s. Centers for Disease Control and Prevention (CDC), Vaccines and Preventable Diseases, CDC, U.S. Dep't of Health and Hum. Servs., (2022), https://www.cdc.gov/vaccines/vpd/hpv/hcp/safety-effectiveness.html#:~:text=The%20HPV%20vaccine%20works%20extremely,women%20in%20their%20early%2020s.

Studies Related to Diabetes:

- Type 1 diabetes is an autoimmune disease that has distinct metabolic stages. Screening can identify people at risk of developing T1D before they become symptomatic, reducing their risk of developing diabetic ketoacidosis, which can be fatal. Screening in pediatric populations also showed lower HbA1cs and shorter hospital stays at diagnosis. Anne Peters, Screening for Autoantibodies in Type 1 Diabetes: A Call to Action, The J. of Family Practice (2021), https://cdn.mdedge.com/files/s3fs-public/jfp_hot_topics2021_0722_v3.pdf; Parth Narendran, Screening for type 1 diabetes: are we nearly there yet?, Diabetologia (13 November 2018), https://link.springer.com/article/10.1007/s00125-018-4774-0.

Studies Related to Smoking Cessation:

- ACA-covered cessation assistance via USPSTF-recommended smoking cessation resources result in a decrease in smoking. American Cancer Society, Cancer Prevention & Early Detection Facts & Figures 2021-2022 at 12 (citing US Preventive Services Task Force et al., Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement, J. of the Am. Med'l Ass'n, (Jan. 19, 2021), https://pubmed.ncbi.nlm.nih.gov/33464343/).
- Smoking cessation reduces the risks of 12 different cancers and can help improve health outcomes after a cancer diagnosis. Smoking cessation also reduced risk and improved health outcomes after a diagnosis as to cardiovascular diseases, strokes, aneurisms, respiratory diseases, asthma, pregnancy and reproductive health. United States Public Health Service Office of the Surgeon General, National Center for Chronic Disease Prevention and Health Promotion, U.S. Office on Smoking and Health, Smoking

Cessation: A Report of the Surgeon General, Ch. 4: the Health Benefits of Smoking Cessation, U.S. Dep't of Health and Hum. Serv., (2020), https://www.ncbi.nlm.nih.gov/books/NBK555590/.

Studies Related to Cardiovascular Diseases:

- It is widely known that many types of cardiovascular disease are preventable. It is critical that people have access to screenings so they can understand their own risk factors and make lifestyle and treatment decisions that are effective at reducing their risk and preventing disease. There are several preventive care benefits related to prevention and screening for risk of cardiovascular disease in adults that, under current law, must be covered without copay or coinsurance. HealthCare.gov, Preventive care benefits for adults, Dept of Health and Hum. Servs. U.S. Center for Medicare & Medicaid Servs., (2022), https://www.healthcare.gov/preventive-care-adults/. These include blood pressure screening, cholesterol screening, Type 2 diabetes screening, obesity screening, and others. *Id*. These are important because, for example, there is a strong link between uncontrolled blood pressure and ischemic heart and peripheral vascular disease, heart failure, stroke, kidney disease, and complications of pregnancy. William J. Oetgen and Janet S. Wright, Controlling Hypertension: Our Cardiology Practices Can Do a Better Job, J. of the Am. College of Cardiology, (June 15, 2021), https://www.sciencedirect.com/science/article/pii/S0735109721047902?via%3Dihub#bib4.
- While high cholesterol has no apparent symptoms, having high blood cholesterol raises the risk for heart disease. Centers for Disease Control and Prevention, High Cholesterol Facts,

Centers for Disease Control and Prevention, (2022), https://www.cdc.gov/cholesterol/facts.htm.

- Obesity increases the risk for high blood pressure and high cholesterol which are risk factors for heart disease. Centers for Disease Control and Prevention, Consequences of Obesity, Centers for Disease Control and Prevention, (2022), https://www.cdc.gov/obesity/basics/consequences.html.

Eliminating mandatory coverage without cost sharing for the above services would reduce patient access to them, meaning risk factors for heart disease would increasingly go undetected. Such circumstances would prevent patients from managing their risk factors and reducing their risk of developing heart disease.

Studies Related to Preventive Services Generally:

- Analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated that approximately 137 million Americans with private insurance had access to preventive services without cost sharing in 2015, which increased to 151.6 million by 2020. ASPE attributed the increase to growth in the number of people enrolled in private healthcare coverage subject to USPSTF recommendations, and a decrease in the share of such people enrolled in plans not subject to USPSTF recommendations. Office of Health Policy: Assistant Secretary for Planning and Evaluation, at p. 6. A majority of recent studies have showed increases in use when there is no cost sharing, and the findings suggest that low-socioeconomic status groups, and those who experience the greatest financial barriers to care, appear to benefit the most from cost-sharing elimination. Kara Gavin, What happens when preventive care becomes free to patients?, Univ. of Michigan Health

Lab, (June 28, 2021), https://labblog.uofmhealth.org/industry-dx/what-happens-when-preventive-care-becomes-free-to-patients.

These studies confirm that access to preventive services, facilitated by insurance coverage, increases the likelihood that healthcare providers will diagnose diseases earlier than they could without such services. The data also illustrate that when providers can catch these diseases early, the likelihood of successfully treating patients and extending their lives increases. As organizations dedicated to addressing the devastating impact of these diseases, *amici* know that access to affordable preventive health care is fundamental to successful health outcomes.

II. USPSTF'S PREVENTIVE SERVICE COVERAGE RECOMMENDATIONS REDUCE COST BURDENS FOR INDIVIDUALS AND THE NATIONAL HEALTHCARE SYSTEM

Congress enacted the ACA, including its preventive care mandate, in response to our health care system's failures and the high costs of health insurance. Because these known failures impeded the nation's economic wellbeing, one of Congress's primary aims for the ACA was improving access to health care by making coverage more affordable. *See NFIB*, 132 S. Ct. at 2580. Congress extended this coverage to preventive services recommended by the USPSTF. Affordable coverage increases access to screenings and preventive treatments, which makes diagnosing serious illnesses at early stages more likely, improving patient outcomes. Identifying serious illnesses in early stages narrows the scope and invasiveness of successful treatment, reducing the costs of treating serious illnesses over patients' lifetimes. Long term cost savings reduce the strain our healthcare system places on U.S. economic wellbeing.

Reducing health care costs for individuals is also crucial. For example, while the vast majority of people with cystic fibrosis (CF) are insured, this insurance does not shield them from burdensome out-of-pocket costs. Even when individual co-payments or cost-sharing are relatively modest for any single drug or service, the multitude of out-of-pocket expenses people with CF

incur can quickly add up. According to a 2020 Health Insurance study by the George Washington University, 71 percent of people with CF have experienced financial hardship due to medical expenses. Cystic Fibrosis Foundation, The Importance of Cost and Affordability for People with CF, Cystic Fibrosis Foundation, (2022), https://www.cff.org/about-us/importance-cost-and-affordability-people-cf. Furthermore, 45 percent of people with CF delayed their care in some way due to cost (including skipping medication doses, taking less medicine than prescribed, delayed filling a prescription, or did not get a provider-recommended treatment or test). *Id*. Reinstituting financial barriers to preventive services could force people with CF to forego essential care, jeopardizing their health and leading to costly hospitalizations and fatal lung infections. *Id*.

Similarly, individuals with MS struggle with the cost of care even with insurance. In one survey, 40 percent of respondents altered their use of a disease-modifying therapy (DMT) due to cost, including skipping or delaying treatment. National Multiple Sclerosis Society, Make MS Medications Accessible, (2022), https://www.nationalmssociety.org/Treating-MS/Medications/Make-MS-Medications-Accessible. 40 percent also said they experience stress or other emotional impact due to high out-of-pocket costs and are making lifestyle sacrifices to be able to pay for their DMT. *Id*. More than half are concerned about being able to afford their DMT over the next few years. *Id*. These challenges can cause delays in starting a medication or changing medications when a treatment is no longer working. *Id*. Delays may result in new MS activity (risking disease progression without recovery) and cause even more stress and anxiety about the future for people already living with the complex challenges and unpredictability of MS. *Id*.

In addition, twenty-one percent of adults with epilepsy reported not being able to afford prescription medications within the last year. David J. Thurman et al., Health-care access among

adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013, 55 Epilepsy & Behavior (Feb. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/.

Thus, adding costs to routine preventive services – the outcome that will result if plaintiffs prevail – would cause patients to choose between treating a current illness or trying to prevent new ones.

Studies relevant to the diseases that are the focus of *amici's* efforts show USPSTF-recommended preventive services also reduce costs for individuals and the U.S. health system:

Cancer-Related Studies:

- Lung cancer screening is cost-effective. Mehrad Bastani, Pianpian Cao, Steven Criss, Kevin ten Haaf, et al., Cost-Effectiveness Analysis of Lung Cancer Screening in the United States, Annals of Internal Med., (Dec. 3, 2019), https://www.acpjournals.org/doi/10.7326/M19-0322?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
- Screening for colorectal cancer is cost-effective, particularly compared with no screening. Jason A. Dominitz et al., Strategies for Colorectal Cancer Screening, Gastroenterology, (Jan. 2020), https://www.sciencedirect.com/science/article/abs/pii/S0016508519411852.

Studies Related to Smoking Cessation:

- Smoking cessation interventions reduce the likelihood that individuals will develop smoking-related diseases and conditions, which ultimately cuts healthcare costs on a system-wide basis. United States Public Health Service Office of the Surgeon General, National Center for Chronic Disease Prevention and Health Promotion, U.S. Office on Smoking and Health, Smoking Cessation: A Report of the Surgeon General, Ch. 5: the

Health Benefits of Smoking Cessation, U.S. Dep't of Health and Hum. Serv., (2020), https://www.ncbi.nlm.nih.gov/books/NBK555593/.

Studies Related to Kidney Disease:

- Type 2 diabetes (T2D) is the leading cause of chronic kidney disease (CKD) and end-stage kidney disease (ESKD). More than one-third of people with T2D also have CKD, and this population is associated with a 10-fold or greater increase in all-cause mortality compared with T2D alone. Furthermore, CKD progression leads to ESKD, which is irreversible and fatal in the absence of kidney replacement therapy. CKD and ESKD are associated with high economic burden, accounting for 22.3% (US$81.8 billion) and 7.2% (US$36.6 billion), respectively, of all Medicare fee-for-service spending in 2018. Medicare expenditures for people with CKD have risen at a rate higher than expenditures for the general Medicare population and have been found costlier for people with CKD and comorbid heart failure or diabetes (type 1 or 2), highlighting clear clinical and economic rationales for early identification and treatment intervention to limit CKD progression in all populations, particularly in people with T2D and cardiovascular risk factors. McGill et al., Making an impact on kidney disease in people with type 3 diabetes: the importance of screening for albuminuria, BMJ Open Diabetes Research & Care (9 May 2022), https://drc.bmj.com/content/10/4/e002806.

Studies Related to Preventive Services Generally:

- Cost sharing reduces the use of both low- and high-value care, including preventive care. Because preventive care services do not address acute health problems, some people may skip such care if cost sharing is required. Rajender Agarwal, Olena Mazurenko, Nir Menachemi, High-Deductible Health Plans Reduce Health Care Cost And Utilization,

Including Use of Needed Preventive Services, Health Aff., (Oct. 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0610?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

- Research shows that required cost sharing, including co-pays, co-insurance and deductibles, can be a significant barrier for patients who need preventive services. This finding is especially true for lower-income patients and patients on a fixed income, for whom these payments can represent a significant percentage of their income. Removing cost-sharing for preventive services has proven to increase the use of those services. American Cancer Society Cancer Action Network, Strong Prevention Policies Will Reduce the Cancer Burden, Atlanta: Am. Cancer Soc'y, Inc., (Jan. 9, 2017), https://www.fightcancer.org/sites/default/files/Prevention%20Factsheet%2001-05-17.pdf.
- Removal of coverage for preventive care would have minimal impact on employers' cost of providing health care coverage. The costs of covering select preventive services are very low. Reintroduction of patient cost sharing will make little difference on overall employer health care spending. If employers imposed 20 percent cost sharing on all medications recommended by USPSTF, employer spending would fall by 0.3 percent." Employee Benefit Research Institute, EBRI Fast Facts: The Impact of Covering Select Preventive Services on Employer Health Care Spending, Emp. Benefit Rsch. Inst., at p. 2 (Oct. 20, 2022), https://www.ebri.org/docs/default-source/fast-facts/ff-444-preventiveservices-20oct22.pdf?sfvrsn=8efb382f_2.
- Much of the health care that 35.3 million privately insured children receive falls under the ACA's preventive care provision, including well-child visits, immunizations, screenings, and important dental services like oral health assessments and fluoride

treatments. Jessica Banthin, Laura Skopec, Free Preventive Services Improve Access to Care, Urban Inst., (July 2022), at 1, https://www.urban.org/sites/default/files/2022-07/Free%20Preventive%20Services%20Improve%20Access%20to%20Care.pdf.

Preventive care is also critical for 132.2 million privately insured adults, and the preventive services requirement covers the following services for adults without cost sharing: cancer screenings, immunizations like flu vaccines and shingles vaccine, and preventive medications like PrEP to prevent HIV and statins and aspirin to prevent cardiovascular disease. The 67.7 million adult women with private insurance can receive a range of care without cost sharing, including well-woman visits, prenatal screenings, birth control, and cancer screenings. *Id*. at 2.

III. PLAINTIFFS' PROPOSED REMEDY WOULD BE HIGHLY DISRUPTIVE TO THE HEALTH CARE SYSTEM AND PATIENT CARE

Plaintiffs concede that the Court cannot award broad nationwide relief under the Declaratory Judgment Act, stating after a lengthy discussion criticizing nationwide injunctions that "[d]eclaratory relief is necessarily litigant-specific, because 28 U.S.C. § 2201 allows an 'interested party' to obtain a declaration of its *own* 'rights' and 'legal relations' (but no one else's)." Pl. Supp. Br. at 6. They nonetheless assert that "there is no need for angst over the issuance of a 'nationwide' or 'universal' injunction" because Plaintiffs seek injunctive relief solely "concomitant to the [Administrative Procedure Act] remedy" of vacating or setting aside an unlawful agency action under 5 U.S.C. § 706(2). *Id*., at 10. However, as the Fifth Circuit has recognized, courts have regularly declined to vacate agency actions where doing so would be "disruptive." *See Central and South West Services, Inc. v. U.S. E.P.A*., 220 F.3d 683, 692 (5th Cir. 2000)(citing to decisions applying the D.C. Circuit's decision to that effect in *Allied Signal, Inc. v. United States Nuclear Regulatory Comm'n*, 988 F.2d 146 (D.C. Cir. 1993)). *See also, e.g., Am. Great Lakes Ports Ass'n*

v. Schultz, 962 F.3d 510, 520-21 (D.C. Cir. 2020)(denying vacatur where the disruption would be significant, even though the agency's error was also significant); *Basinkeeper v. United States Army Corps of Engineers*, 715 Fed. Appx. 399, 401 (5th Cir. 2018) (Owen, J., concurring)(applying the *Allied-Signal* standard); *Texas v. United States*, 2022 WL 2109204, at *44 (S.D. Tex. June 10, 2022) (denying vacatur and citing *Schultz*).

The use of APA vacatur as an end run around the limitations on nationwide injunctions has been criticized both by judges, *see Arizona v. Biden*, 31 F. 4th 469, 484 (6th Cir. 2022)(Sutton, C.J., concurring)(expressing doubt that "Congress meant to upset the bedrock practice of case-by-case judgments with respect to the parties in each case or create a new and far-reaching power through [the] unremarkable language" of § 706(2)), and by commentators. *See* John Harrison, Section 706 of the Administrative Procedure Act Does Not Call for Universal Injunctions or Other Universal Remedies, 37 Yale J. Reg. Bull. 37, 41–47 (2020). The Court should decline Plaintiffs' invitation to make such an end run here. In any case, the significant resulting disruption to the health care system precludes Plaintiffs' requested "universal" remedy preventing the defendants from enforcing the disputed coverage mandates against anyone anywhere. The USPSTF's preventive care recommendations have been adopted and relied on by patients and providers in the health care system for over 12 years. The ACA's coverage rule for preventive services applies to private plans in the individual and group markets, which cover more than 171.6 million Americans, and to Medicaid expansion plans. It is a popular provision of the law favored by 62% of Americans. Office of Health Policy: Assistant Secretary for Planning and Evaluation, Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act, U.S. Dep't of Health and Hum. Serv., at 8 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.

Plaintiffs' proposed remedy would call into immediate question ACA coverage for these services. Unless it were to be of no effect at all, the remedy would result in losses of coverage for preventive services that have been vital tools in diagnosing the illnesses *amici* are committed to fight, leading to poorer patient outcomes and preventable deaths.

Plaintiffs' suggestion that this relief is mandatory, despite not requesting it in their complaint, Pl. Supp. Mem. at 9 n.6, is inconsistent with the law in this and other circuits. None of the cases Plaintiffs cite on the point suggest that the remedy should be imposed in circumstances where, as here, significant disruption would result. To the contrary, the law of this Circuit and others cited above provides that agency action should not be vacated where such disruption would occur. The studies cited above showing the use and benefits of USPSTF-recommended preventive services confirm the significant disruption and harm Plaintiffs' proposed remedy would cause. *See also* Banthin et al., supra, at 1- 2 ("Overturning the preventive services requirement could reduce access to life-saving care for the 167.5 million Americans covered under ACA-compliant private health plans. . . . Much of the health care that 35.3 million privately insured children receive falls under this benefit, including well-child visits, immunizations, screenings, and important dental services. . .").

CONCLUSION

For the foregoing reasons, *amici* respectfully submit that the Court should reject the Plaintiffs' request for a universal remedy that would set aside currently-implemented USPSTF recommendations and hamstring future USPSTF recommendations. The ACA's preventive care mandate and the USPSTF have helped patients and survivors of cancer, hemophilia, kidney and lung and heart diseases, arthritis, epilepsy, cystic fibrosis, HIV/AIDS, diabetes and MS as Congress intended, and should continue to do so.

Respectfully submitted,

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