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

TEXAS, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:18-cv-167-O
	)	
UNITED STATES OF AMERICA, et al.	)	
	)	
Defendants.	)	
	)	

UNOPPOSED MOTION OF AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN DIABETES ASSOCIATION, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AND NATIONAL MULTIPLE SCLEROSIS SOCIETY FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF INTERVENOR-DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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 Intervenor-Defendants' Brief in Opposition to Plaintiffs' Application for a Preliminary Injunction.

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 the Intervenor-Defendants' Brief in Opposition, 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), and consistent with the time period in which an *amicus* brief was filed in support of Plaintiffs' Application.

Movants American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Diabetes Association (ADA), American Heart Association

(AHA), and its division, the American Stroke Association (ASA), American Lung Association (ALA) and National Multiple Sclerosis Society (NMSS) 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 INTERVENOR-DEFENDANTS' RESPONSE.

Movants' *amici curiae* brief, submitted with this Motion, supports the position of the Intervenor-Defendants. However, movants provide additional information and context to supplement Intervenor-Defendants' Brief in Opposition to Plaintiffs' Application for a Preliminary Injunction that they believe will be relevant and helpful to the court in making its decision. The brief discusses the essential role of comprehensive health insurance in managing chronic diseases, including scientific data linking insurance status and health outcomes, and how this data informed Congress's decision to enact the ACA. The brief also address how the ACA has impacted insurance coverage of patients with chronic conditions.

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 Intervenor-Defendants' Brief in Opposition to Plaintiffs' Application for a Preliminary Injunction.

Respectfully submitted,

/s/ Beth Bivans Petronio

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June 14, 2018

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
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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 June 14, 2018.

/s/ Beth Bivans Petronio
BETH BIVANS PETRONIO

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AMICI CURIAE BRIEF OF THE AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN DIABETES ASSOCIATION, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, AND NATIONAL MULTIPLE SCLEROSIS SOCIETY SUPPORTING DEFENDANTS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

GLOSSARY

ACA or Act	Patient Protection and Affordable Care Act ("Affordable Care Act"), Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 11-152, 124 Stat. 1029
ACS	American Cancer Society
ACS CAN	American Cancer Society Cancer Action Network
ADA	American Diabetes Association
AHA or AHA/ASA	American Heart Association and American Stroke Association
ALA	American Lung Association
Amici	The parties filing this brief: American Cancer Society, American Cancer Society Cancer Action Network, American Diabetes Association, American Heart Association, American Lung Association and National Multiple Sclerosis Society
COPD	Chronic obstructive pulmonary disease
CVD	Cardiovascular disease
ED	Emergency Department
HPV	Human papillomavirus
MS	Multiple Sclerosis
NMSS	National Multiple Sclerosis Society

INTEREST OF *AMICI*[1]

The American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Diabetes Association (ADA), American Heart Association (AHA), and its division, the American Stroke Association (ASA), American Lung Association (ALA) and National Multiple Sclerosis Society (NMSS) (collectively, "*Amici*") are the largest and most prominent nonpartisan 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.

ACS is the nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem, with a global network of two million volunteers. ACS's extensive scientific findings have established that health insurance status is strongly linked to medical outcomes and that the lack of adequate insurance coverage is a major impediment to advancing the fight against cancer. Along with its nonpartisan advocacy affiliate, ACS CAN, which has over a million patient and survivor advocates nationwide, including thousands who participated in efforts supporting enactment of strong patient protections in the Patient Protection and Affordable Care Act (ACA), ACS strongly advocates guaranteeing all Americans affordable, adequate, accessible, health insurance that is easy to understand.

ALA is the nation's oldest voluntary health organization, representing the 33 million Americans with lung disease in all 50 states and the District of Columbia. Because people with or at risk for lung cancer and lung diseases—such as asthma, Chronic Obstructive Pulmonary

[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.

Disease (COPD) and pulmonary fibrosis—need quality and affordable health care to prevent or treat their disease, ALA strongly supports increasing access to health care.

ADA, a nationwide, nonprofit, voluntary health organization founded in 1940, has over 400,000 members, and approximately 14,000 health professional members. Its mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. ADA is the most authoritative source for clinical practice recommendations, guidelines, and standards for the treatment of diabetes. As part of its mission, ADA works to improve access to high quality medical care and treatment for all people with, and at risk for, diabetes. In seeking to prevent diabetes, protect the rights of patients, and improve access to affordable and adequate insurance for people with diabetes, and based on clear evidence that lack of health insurance leads to increased risk of diabetes complications, ADA supported provisions in the ACA that specifically impact all eligible people with diabetes, including the provisions making health care affordable.

AHA is a voluntary health organization that, since 1924, has been devoted to saving people from heart disease and stroke—the first and fifth leading causes of death in the United States. AHA and its more than 40 million volunteers work to fund innovative research, fight for stronger public health policies, and provide lifesaving tools and information to prevent and treat these diseases. Based on well-documented research that uninsured and under-insured Americans with heart disease and stroke experience higher mortality rates, poorer blood pressure control, greater neurological impairments and longer hospital stays after a stroke, AHA ASA has worked to represent the needs and interests of all eligible heart disease and stroke patients during the Congressional debates on health care reform and supported provisions of the Act making health care more affordable.

The NMSS mobilizes people and resources so that everyone affected by MS can live their best lives as we stop MS in its tracks, restore what has been lost, and end MS forever. To fulfill this mission, the NMSS funds more MS research and provides more programs for people with MS and their families than any other voluntary health organization in the world. As part of its mission, the NMSS works to ensure that all people with MS have access to affordable high quality MS health care. To meet these goals, the NMSS supported provisions in the ACA that would make health insurance and health care more affordable and accessible for all eligible people with MS.

The fight against all of these diseases requires access to affordable, quality health care and health insurance. *Amici* desire to assist the Court in understanding why the Act is so important to millions of patients and survivors, as well as their families. Absent affordable health insurance, sufferers of the chronic diseases addressed by *Amici* have poorer health outcomes and require more costly care. In enacting the ACA, Congress intended to and did address these known problems. Congress has not repealed the ACA, despite lengthy consideration.[2] During the debates that have followed, members of Congress on both sides of the aisle have been emphatic that critical protections not be repealed without a replacement that would ensure patients can continue to have access to care. *See* 163 CONG. REC. S4227, S4227-96 (daily ed. July 26, 2017), https://www.congress.gov/crec/2017/07/26/CREC-2017-07-26-pt1-PgS4227-9.pdf. If the court strikes down the Act in full, or as the Justice Department proposes, strikes down the key protections of guaranteed issue and community rating, the "repeal without replace" scenario that Congress expressly sought to avoid will occur.

[2] The Better Care Reconciliation Act failed 57-43 in the Senate. The Better Care Reconciliation Act of 2017, H.R. 1628, 115th Cong. (2017-2018).

This result would be devastating for the millions of Americans who suffer from serious illness or have preexisting conditions and rely on those protections under current law to obtain life-saving health care. If either the plaintiffs' or the administration's position were adopted by the court, people with serious illness are likely to be denied coverage due to their preexisting conditions or charged such high premiums because of their health status that they will be unable to afford any coverage that may be offered. Without access to comprehensive coverage, patients will be forced to delay, skip, or forego care. Striking down these provisions would be catastrophic and have dire consequences for many patients with serious illnesses.

Many of the millions of people who would lose coverage if the ACA were invalidated, and who would thereby be unable to afford health care, suffer from the chronic diseases as to which *Amici* focus our efforts.

SUMMARY OF ARGUMENT

All Americans use or will use health care services, and the lifetime risk that individual Americans will acquire one of the diseases or conditions towards which *Amici* direct our efforts is high. Moreover, the costs of treating such serious conditions are often staggering and beyond the financial means of most individuals and families. The question is thus not *whether* individual Americans will incur health care expenses, but *how* those expenses will be financed. How care is financed, in turn, directly impacts access to vital health care services and the quality of health outcomes.

ACS CAN, ADA, AHA, ALA and NMSS were actively involved in the legislative process leading to enactment of the ACA in 2010. Because of the massive implications for patients with the diseases *Amici* seek to fight, each organization has continued to be involved in Congress's reconsideration of the ACA. Last year, *Amici* urged Congress to ensure that any

health care reform it enacted include three key elements: (1) affordability, providing for reasonable insurance premiums, cost-sharing, and co-pays; (2) accessibility, maintaining patient protections such as the bans on pre-existing condition exclusions and annual or lifetime limits regardless of geographic location or employment status; and (3) adequacy, in which plans are required to cover a full range of needed health benefits, including preventive services, and maintain an adequate network of providers.[3] In the face of a public outcry to protect the Act, Congress did not repeal the ACA.

The outcome of the debate was critical to many Americans, in particular those suffering from chronic illness. According to nonpartisan Congressional Budget Office estimates, ACA repeal would have caused 17 million Americans to lose their insurance in 2018, and 27 million by 2020. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE, H.R. 1628, Obamacare Repeal Reconciliation Act of 2017 (July 19, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/52939-hr1628amendment.pdf.

During consideration of the ACA, Congress was made aware of, and relied on, data establishing that people have poorer health outcomes and require more costly, long-term treatment without affordable health insurance. 42 U.S.C. § 18091(2)(E) ("The economy loses up to $207,000,000,000 a year because of the poorer health and shorter lifespan of the uninsured. By significantly reducing the number of the uninsured, the requirement, together with the other provisions of this Act, will significantly reduce this economic cost."). The Supreme Court has recognized that the broad policy goals of the Act were "to increase the number of Americans

[3] Consensus Health Care Reform Principles, American Cancer Society Cancer Action Network, American Diabetes Association, American Heart Association, American Lung Association, Cystic Fibrosis Foundation, JDRF, March of Dimes, Muscular Dystrophy Association, National Multiple Sclerosis Society, National Organization for Rare Disorders, and WomenHeart, the National Coalition for Women and Heart Disease, http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_492352.pdf

covered by health insurance and decrease the cost of health care." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 519 (2012) ("NFIB") (Roberts, C.J.). And in *King v. Burwell*, the Court emphasized that such policy goals are the province of the legislature, not the courts:

> In a democracy, the power to make the law rests with those chosen by the people. Our role is more confined —"to say what the law is." That is easier in some cases than in others. But in every case we must respect the role of the Legislature, and take care not to undo what it has done. A fair reading of legislation demands a fair understanding of the legislative plan. Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter.

567 U.S. ___, 135 S. Ct. 2480, 2496 (2015) (citation omitted).

Plaintiffs here ignore both Congressional intent and these Supreme Court precedents in seeking to impose their own apparent policy preference that the ACA be entirely repealed. The ACA framework, which included the individual mandate, Medicaid expansion, tax credits, and patient protection provisions so critical to those who suffer from chronic illnesses, has been providing greater access to insurance coverage since its implementation, and Congress has stated no intent to retreat from this goal.

Amici seek in this brief to demonstrate the criticality of health insurance in addressing and defeating the diseases that our constituents fight every day. This data confirms that by disrupting a status quo now in place for over seven years, the extraordinary relief sought by plaintiffs would substantially harm sufferers of these diseases and the public interest.

ARGUMENT

I. ACCESS TO AFFORDABLE HEALTH CARE IS ESSENTIAL IN MANAGING CHRONIC DISEASES

The need for health care is difficult to predict, but practically inevitable at some point in life. *See NFIB*, 132 S. Ct. at 2610 (Ginsburg, J., concurring) ("Virtually every person residing in

the United States, sooner or later, will visit a doctor or other health-care professional.") (citing statistics); *see also id*. at 2585 (Roberts, C.J.) ("Everyone will eventually need health care at a time and to an extent they cannot predict."). Looking solely at the diseases that are the focus of *Amici's* efforts:

- An estimated 1.7 million Americans will be diagnosed with cancer in 2018, and more than 15.5 million Americans with a history of cancer were alive on January 1, 2016. In the US, approximately four out of ten men and nearly four out of ten women will develop cancer in their lifetime. *Cancer Facts and Figures 2018*, AMERICAN CANCER SOCIETY, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf; *Cancer Treatment & Survivorship, Facts & Figures, 2016-2017*, AMERICAN CANCER SOCIETY, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/cancer-treatment-and-survivorship-facts-and-figures-2016-2017.pdf.

- An estimated 30.3 million Americans have diabetes and 84 million American adults (about one third) have prediabetes. *National Diabetes Statistics Report, 2017, Estimates of Diabetes and Its Burden in the United States*, CENTERS FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.

- In 2018, a projected 107.3 million Americans had CVD. Olga Khavjou et al., *Projections of Cardiovascular Disease and Costs: 2015-2035*, AM. HEART ASS'N (November 2016), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491513.pdf. The lifetime risk for developing CVD among those free of known disease at age 45 is almost two in three for men and greater than one in two for women. *Id.* at 116 (citing John T. Wilkins et al., *Lifetime Risk and Years Lived Free of Total Cardiovascular Disease*, 308 J. AM. MED. ASS'N 1795, 1798 (2012)). By 2035, over 45% of the US population is projected to have some form of CVD, with total costs expected to reach $1.1 trillion. *Id*.

- In 2016, an estimated 11.3 million adults had COPD, and 26.5 million people currently have asthma, including 6.1 million children. Overall, 33.6 million Americans have some form of chronic lung disease. *National Health Interview Survey, 2016*, CENTERS FOR DISEASE CONTROL AND PREVENTION (analysis by the ALA Epidemiology and Statistics Unit using SPPS Software). During 2018, an estimated 234,030 new cases of lung cancer are expected to be diagnosed. Rebecca L. Siegel et al., *Cancer Statistics*, 68 CA CANCER J. CLIN 7 (2018).

- Although MS incidence and prevalence are not reported consistently, the most recent data from statistically-based estimates indicates approximately 1 million individuals in the US have the disease. *MS Prevelance*, NAT'L MULTIPLE SCLEROSIS SOCIETY, http://www.nationalmssociety.org/About-the-Society/MS-Prevalence.

These statistics confirm the virtual certainty that all Americans will need health care at some point in their lives to combat these serious chronic diseases or a myriad of other health conditions. Without affordable health insurance, patients and their families will continue to bear the burden of substantial health care costs and later stage diagnosis, as well as the risk of being denied the life-saving care they need.

Good health and the chance for positive outcomes from illness should not be dependent upon a person's ability to pay for care. *Amici* abhor when patients who cannot afford to seek care when a cancer is at an early stage forego potentially life-saving chemotherapy treatments, and are left helpless as their condition worsens. We find it tragic when high costs force people with diabetes to delay treatment or ration their life-saving insulin for so long that they lose a limb due to amputation. We are frustrated by the reluctance of people experiencing heart attack symptoms to call 9-1-1 out of concern that they cannot afford a large medical bill, thereby losing access to quick diagnosis and treatment in a hospital Emergency Department (ED) that can mean the difference between life and death. We ache for parents who must take their child to the ED because they cannot afford asthma medication that would have prevented an exacerbation. We are saddened when MS patients stop treatment due to cost, and therefore are likely to increase the frequency and severity of relapses and disability, as well as reduce their years of survival.

These natural, indeed nearly universal, human responses are why hundreds of thousands of members and millions of volunteers and donors support *Amici* efforts to help increase access to affordable and quality health care for those with debilitating or life-threatening diseases, and

why Congress acted to improve access to health care. As nonpartisan organizations dedicated to addressing the devastating impact of these diseases, *Amici* know that access to affordable basic, preventive health care and life-saving treatments are fundamental to successful health outcomes.

II. CONGRESS KNEW THAT HEALTH INSURANCE MUST BE AVAILABLE TO MAKE HEALTH CARE AFFORDABLE AS IT INTENDED UNDER THE ACA

The debates over health care reform and Congress's enactment of the ACA were spurred by the failures of our health care system and high costs of health insurance. These known failures hurt not only the nation's economic well-being, but also the health and well-being of individual Americans. Improving access to health care by making coverage more affordable was thus a primary Congressional focus. *See NFIB*, 132 S. Ct. at 2580.

A. The Act addresses and has made significant progress in reducing the problems of cancer, diabetes, heart disease, stroke, lung disease, and MS patients and survivors who want and need health insurance but often could not afford it.

The cost of services to treat cancer, diabetes, heart disease, stroke, lung disease and MS is beyond the reach of all but the wealthiest individuals absent insurance. These chronic conditions thus can have significant financial implications for patients, survivors, and their families unless addressed by insurance. For example, in 2014, $87.8 billion was spent in the U.S. on cancer-related health care. *Total Expenses and Percent Distribution for Selected Conditions by Source of Payment: United States, 2014, Medical Expenditure Panel Survey Household Component Data*, AGENCY FOR HEALTH CARE RES. & QUALITY, Generated interactively (December 13, 2016). Individuals bore many of these costs. A 2013 study found that cancer patients were more than two and a half times as likely to file for bankruptcy as people who do not have cancer. Scott Ramsey et al., *Washington State Cancer Patients Found to be at Greater Risk for Bankruptcy than People Without a Cancer Diagnosis*, 32:6 HEALTH AFF. 1143, 1147-48 (June 2013), http://content.healthaffairs.org/content/early/2013/05/14/hlthaff.2012.1263.full.pdf+html.

This financial distress can cause poorer health outcomes: in interviews with lung and colorectal cancer patients, 33 to 40 percent of the patients reported having limited financial reserves. These patients with limited financial reserves reported significantly increased pain, greater symptom burden, and poorer quality of life. Christopher S. Lathan et al., *Association of Financial Strain With Symptom Burden and Quality of Life for Patients With Lung or Colorectal Cancer*, JOURNAL OF CLINICAL ONCOLOGY, Vol. 34, No. 15 (May 20, 2016), http://ascopubs.org/doi/abs/10.1200/JCO.2015.63.2232?sid=8a09e15b-fc58-45b6-9b35-b94c65d78437.

The high cost of treating CVD has also been a leading cause of medical bankruptcy. *See* David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741, 745 (2009). Among families with high levels of medical debt resulting in bankruptcy, those with stroke had average out-of-pocket medical costs of $23,380, and those with heart disease had average medical costs of $21,955. *Id*.

MS patients can also suffer substantial burdens. The cost of disease-modifying treatment is extremely high, averaging $81,731 per MS patient per year in 2017. Daniel M. Hartung, *Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA*, 14:4 NEUROTHERAPEUTICS 1018 (2017). In a survey of MS patients prior to the ACA, 27.4 percent had put off or postponed seeking the health care they needed because of the expense, and 22.3 percent delayed filling prescriptions, skipped doses of medications, or split pills because of costs. L.I. Ionezzi and L. Ngo, *Health, disability and life insurance experiences of working-age persons with multiple sclerosis*, MULTIPLE SCLEROSIS 13:534, 538 (May 2007). Similarly, 36 percent indicated spending less on such basic needs as food or heat to pay for health-related expenses. *Id*. at 544.

Patients with CVD faced similar dilemmas. Prior to the ACA, approximately 7.3 million (or 15 percent of) adults who reported having CVD were uninsured, and nearly one of four cardiovascular disease patients and one of three stroke patients had gone without coverage at some point since their diagnosis. *See FACTS: Breaking Down the Barriers: The Uninsured with Heart Disease and Stroke*, AM. HEART ASS'N (2013), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_304486.pdf (citing Analysis of 2006-10 NHIS Data Conducted by The George Washington University Center for Health Policy Research for the American Heart Association (Aug. 2011) (on file with the American Heart Association)); *Affordable Access to Health Care: Top Priorities of Heart Disease and Stroke Patients: Results from an American Heart Association Patient Survey*, AM. HEART ASS'N (2010), https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_432322.pdf. Four years before the ACA was passed, more than half of uninsured patients who suffered from CVD cited cost as the reason they lacked coverage. *FACTS: Breaking Down the Barriers: The Uninsured with Heart Disease and Stroke*, AM. HEART ASS'N (2013).

Diabetes poses a substantial financial burden on the 30 million people who live with the disease. People with diagnosed diabetes incur average medical expenditures of $16,750 per year. Wenya Yang, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917 (2018). And for millions of people with diabetes, including all people with type 1 diabetes, access to insulin is a matter of life and death. Yet the cost of insulin nearly tripled between 2002 and 2013. William T. Cefalu et al., *Insulin Access and Affordability Working Group: Conclusions and Recommendations*, 41 DIABETES CARE 1301 (2018). The cost of insulin has caused many patients to ration insulin or skip doses because they simply cannot afford it, even though this practice can lead to serious and even deadly complications. *Id.* at 1306. Patients may need

several vials of insulin a month—so with the list price of a single vial of insulin over $300, loss of insurance for a person with diabetes is devastating. Sarah J. Tribble, *Several Proves Target Insulin Drug Pricing*, Kaiser Health News, Oct. 28, 2017, https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141.

The ACA has significantly improved this situation, with uninsured rates among nonelderly adults decreasing by 6.3 percentage points between the fourth quarter of 2013 and the fourth quarter of 2016. Benjamin D. Sommers et al., *Early Changes in Health Insurance Coverage under the Trump Administration*, NEW ENG. J. MED. 378:1061-1063 (March 15, 2018). The data is even more striking when factoring in household income. The absolute gap in insurance coverage in households with annual income below $25,000 and those above $75,000 fell from 31 percent to 17 percent (a relative reduction of 46 percent) in Medicaid expansion states, and from 36 percent to 28 percent in non-expansion states. Kevin Griffith et al., *The Affordable Care Act Reduced Socioeconomic Disparities In Health Care Access*, 36:8 HEALTH AFF. 1503, 1507-08 (August 2017), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.0083.

Data from cancer patients provides an example of the ACA's impact. Before the ACA was enacted, one out of every three people diagnosed with cancer under age 65 was uninsured or had been uninsured at some point since diagnosis. *See A National Poll: Facing Cancer in the Health Care System,* AM. CANCER SOC'Y CANCER ACTION NETWORK (2010), at 4, https://www.acscan.org/sites/default/files/National%20Documents/ACS_CAN_Polling_Report_7.27.10.pdf. Of the cancer patients under 65 who reported being uninsured, 37 percent attributed their lack of health insurance to not being able to find an affordable plan. *Id*. at 11. However,

the ACA greatly improved this situation. *See* Amy J. Davidoff et al., *Changes in Health Insurance Coverage Associated With the Affordable Care Act Among Adults With and Without a Cancer History: Population-based National Estimates*, 56 J. MED. CARE AM. PUB. HEALTH ASS'N 220, 220-27 (2018). After the ACA was enacted, the uninsured rate among nonelderly patients with newly diagnosed cancer declined substantially, especially among low-income people who resided in Medicaid expansion states—where it decreased 6 percent. Ahmedin Jemal et al., *Changes in Insurance Coverage and Stage at Diagnosis Among Nonelderly Patients With Cancer After the Affordable Care Act*, 35 J. CLINICAL ONCOLOGY 3906 (2017).

This increase in coverage affects health outcomes—a small but statistically significant shift was found toward early-stage diagnosis for colorectal, lung, female breast, and pancreatic cancer and melanoma in patients in expansion states. Similarly, the ACA coverage expansion for dependent children up to age 26 has increased the insurance coverage rate among that population, had positive effect on initiation and completion of the human papillomavirus (HPV) vaccination, early diagnosis and receipt of fertility-sparing treatments for cervical cancer, and increased early-stage diagnosis for total cancer and osseous and chondromatous neoplasms among young adults 19 to 25 years old. Xuesong Han & Ahmedin Jemal, *The Affordable Care Act and Cancer Care for Young Adults*, 20:3 J. CANCER 194 (2017), https://www.ncbi.nlm.nih.gov/pubmed/28537966. The proportion of cancer survivors reporting delayed or forgone care and inability to afford health care services also significantly decreased during implementation of the ACA from 2010 to 2016. Ryan D. Nipp et al., *Patterns in Health Care Access and Affordability Among Cancer Survivors During Implementation of the Affordable Care Act*, JAMA ONCOLOGY (Mar. 29, 2018). Overall, the uninsured rate for cancer survivors decreased from 12.4 percent (pre-full ACA implementation, 2012) to 7.7 percent (post-

full ACA implementation, 2015). Amy J. Davidoff et al., *Changes in Health Insurance Coverage Associated With the Affordable Care Act Among Adults With and Without a Cancer History: Population-based National Estimates*, 56 J. MED. CARE AM. PUB. HEALTH ASS'N 220, 220-27 (2018).

B. Congress knew that, without affordable health insurance, people have poorer health outcomes and require more costly and longer-term treatment.

Individuals without health insurance are less likely to receive preventive treatment or early detection screenings and are more likely to delay treatment. *See, e.g., NFIB*, 132 S. Ct. at 2611-12 (Ginsburg, J., concurring) ("Because those without insurance generally lack access to preventative care, they do not receive treatment for conditions—like hypertension and diabetes—that can be successfully and affordably treated if diagnosed early on.")(citing Institute of Medicine, INSURING AMERICA'S HEALTH, PRINCIPLES AND RECOMMENDATIONS 43 (2004), https://www.nap.edu/catalog/10874/insuring-americas-health-principles-and-recommendations). A 2009 Harvard Medical School study found approximately 45,000 deaths annually could be attributed to lack of health insurance among working-age Americans. These uninsured Americans had a 40 percent higher risk of death than their privately insured counterparts. Andrew P. Wilper et al., *Health Insurance and Mortality in US Adults*, 99 AM. J. PUB. HEALTH 2289, 2292 (2009). Not having access to insurance is associated with mortality despite advances in medical therapeutics. *See id*. at 2294.

An American Cancer Society Cancer Action Network poll conducted before the ACA determined that 34 percent of individuals under age 65 who have cancer or a history of cancer reported delaying care because of cost in the preceding twelve months. *A National Poll: Facing Cancer in the Health Care System*, AM. CANCER SOC'Y CANCER ACTION NETWORK (2010), at 17, https://www.acscan.org/sites/default/files/National%20Documents/ACS_CAN_Polling_Rep

ort_7.27.10.pdf. More specifically, 29 percent delayed needed health care, 19 percent delayed getting a recommended cancer test or treatment, and 22 percent delayed a routine cancer check-up. *Id.* at 18.

At every level of education, individuals with health insurance are about twice as likely as those without it to have access to critical cancer early detection procedures, such as mammography or colorectal screenings. Elizabeth Ward et al., *Association of Insurance with Cancer Care Utilization and Outcomes*, 58 CANCER J. FOR CLINICIANS 9, 21 (2008). In addition, a 2014 study showed that uninsured adolescents and young adults are at higher risk of advanced stage cancer diagnosis. *See* Anthony Robbins et al., *Insurance Status and Distant-Stage Disease at Diagnosis Among Adolescent and Young Adult Patients with Cancer Aged 15 to 39 Years: National Cancer Data Base, 2004 Through 2010*, 120 CANCER 1212 (2014). Uninsured females aged 15 to 39 were nearly twice as likely as those with private insurance to be diagnosed with cancer that has metastasized; uninsured males in that age group were 1.5 times as likely as those with private insurance to be diagnosed with metastatic cancer. *Id.* at 1214. Strikingly, the five-year lung cancer survival rate is only five percent for those diagnosed at a late stage after the tumor has spread, but increases to 56 percent for those diagnosed at an early stage before the tumor has spread. *See SEER Cancer Statistics Review 1975–2015*, NATIONAL CANCER INSTITUTE, SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS PROGRAM, https://seer.cancer.gov/csr/1975_2015/browse_csr.php?sectionSEL=15&pageSEL=sect_15_table.12.html.

With respect to heart disease, an AHA survey conducted before the ACA found that more than half of the cardiovascular patients responding reported difficulty paying for medical care. *Affordable Access to Health Care: Top Priorities of Heart Disease and Stroke Patients: Results from an American Heart Association Patient Survey*, AM. HEART ASS'N (2010),

https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_432322.pdf. Further, 46 percent of chronically ill patients said they had delayed getting needed medical care, 28 percent who took regular medication had not filled a prescription, and nearly 30 percent had delayed a screening test prior to diagnosis. *Id.* Fewer than half of uninsured adults had their cholesterol checked within the recommended timeframe. Sara R. Collins et al., *Insuring the Future: Current Trends in Health Coverage and the Effects of Implementing the Affordable Care Act: Findings from the Commonwealth Fund Biennial Health Insurance Survey, 2012*, THE COMMONWEALTH FUND (2013), at 12, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2013/apr/1681_collins_insuring_future_biennial_survey_2012_final.pdf. Even during a heart attack, uninsured patients are more likely to delay seeking medical care. Kim G. Smolderen et al., *Health Care Insurance, Financial Concerns in Accessing Care, and Delays to Hospital Presentation in Acute Myocardial Infarction*, 303 J. AM. MED. ASS'N 1392, 1395-99 (2010).

Uninsured individuals with diabetes show the same patterns. "Among persons aged 18 to 64 with diabetes mellitus, those who had no health insurance during the preceding year were six times as likely to forgo needed medical care as those who were continuously insured." J.B. Fox et al., *Vital Signs: Health Insurance Coverage and Health Care Utilization—United States, 2006-2009 and January-March 2010*, 59 MORBIDITY & MORTALITY WKLY. REP. 1448, 1448 (2010). Individuals with diabetes who have private health insurance see a doctor over four times as often as those who do not have insurance. Am. Diabetes Ass'n, *Economic Costs of Diabetes in the U.S. in 2012*, 36 DIABETES CARE 1033, 7-9 tbls.9 & 10 (Supp. 2013), http://care.diabetesjournals.org/content/suppl/2013/03/05/dc12-2625.DC1/DC122625Suppleme

ntaryData.pdf. Those without insurance are more than 30 percent more likely to visit EDs than those with private insurance. *Id.*

Lack of health insurance also leads to cases of diabetes going undiagnosed, delaying the start of needed treatment, and increasing the risks of complications. Diabetes was undiagnosed in 42.2 percent of individuals without health insurance, compared to 25.9 percent of those with insurance. Xuanping Zhang et al., *The Missed Patient with Diabetes: How Access to Health Care Affects the Detection of Diabetes*, 31 DIABETES CARE 1748, 1749 (2008). And, unfortunately, lack of preventive care and delayed treatment result in uninsured patients with poorer health outcomes who require more costly long-term and invasive treatment than individuals with insurance. *See, e.g., NFIB*, 132 S. Ct. at 2612 (Ginsburg, J., concurring) ("When sickness finally drives the uninsured to seek care, once treatable conditions have escalated into grave health problems, requiring more costly and extensive intervention.").

Insurance status affects health outcomes for cancer patients at every level: they delay preventive screenings due to cost; the cancer is not discovered until it has developed to an advanced stage as a result, and those individuals who actually receive treatment are subject to more invasive and aggressive medical interventions. For example, aside from age, health insurance status was found to be the strongest predictor of cervical cancer stage at diagnosis. Uninsured patients were 1.4 times more likely to be diagnosed with advanced-stage cervical cancer than those with insurance. Stacy A. Fedewa et al., *Association of Insurance Status and Age with Cervical Cancer Stage at Diagnosis: National Cancer Database, 2000-2007*, 102 AM. J. PUB. HEALTH 1782, 1784-85 (2012).

In a study that included a cohort of nearly 850,000 patients with malignant tumors, uninsured patients were over four times more likely to be diagnosed with advanced-stage breast

cancer, and 1.4 times more likely to be diagnosed with colorectal cancer. In all cases, the 5-year survival rate for patients with advanced cancer was significantly smaller than that of patients with less advanced cancer. Elizabeth M. Ward et al., *The Association of Insurance and Stage at Diagnosis Among Patients Aged 55 to 74 Years in the National Cancer Database*, 16 CANCER J. 614, 619 (2010).

Women who are diagnosed at more advanced stages of breast cancer experience lower survival, more debilitating and invasive treatment, and greater long-term treatment-related morbidity, if they are treated at all. Michael T. Halpern et al., *Insurance Status and Stage of Cancer at Diagnosis Among Women with Breast Cancer*, 110 CANCER 403, 408 (2007). Additionally, uninsured patients diagnosed with stage IV colorectal cancer are almost four times as likely to receive no treatment for their cancer compared to patients with private insurance. Anthony S. Robbins et al., *Insurance Status and Survival Disparities Among Nonelderly Rectal Cancer Patients in the National Cancer Data Base*, 116 CANCER 4178, 4180 (2010).

Likewise, uninsured patients with CVD experience higher mortality rates and poorer blood pressure control than their insured counterparts. *See* Tefera Gezmu et al., *Disparities in Acute Stroke Severity, Outcomes, and Care Relative to Health Insurance Status*, 23 J. STROKE & CEREBROVASCULAR DISEASE 93, 95-97 (2014) (demonstrating that multiple factors lead to higher mortality rates for the uninsured including delaying seeking medical attention, lack of a regular primary care physician to monitor common risk factors, and lengthier hospital stays due to the inability to be transferred to a rehabilitation facility); Brent M. Egan et al., *The Growing Gap in Hypertension Control Between Insured and Uninsured Adults: National Health and Nutrition Examination Surveys 1988-2010*, 8 J. AM. SOC'Y HYPERTENSION 7, 7-8 (Supp. 2014) ("By 2010, hypertension was controlled in 29.8 percent of uninsured and 52.5 percent of insured adults . . .

[a difference of] 22.7 percent"); Andrew P. Wilper et al., *Health Insurance and Mortality in US Adults*, 99 AM. J. PUB. HEALTH 2289, 2292 (2009); O. Kenrik Duru et al., *Health Insurance Status and Hypertension Monitoring and Control in the United States*, 20 AM. J. HYPERTENSION 348, 350-52 (2007).

Similarly, those who suffer an ischemic stroke[4] and are uninsured experience greater neurological impairments, longer hospital stays, and up to a 56 percent higher risk of death than the insured. Jay J. Shen & Elmer Washington, *Disparities in Outcomes Among Patients with Stroke Associated with Insurance Status*, 38 STROKE 1010, 1013 (2007).

People with diabetes who are insured have more than double the office visits than the uninsured, while the uninsured have significantly more ED visits than the insured. Wenya Yang, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917 (2018). Additionally, people with insurance have over twice as many prescriptions than the insured. *Id*. at 924-25 (demonstrating that individuals without insurance are getting less necessary care than those individuals who have insurance).

Patients with no health insurance were twice as likely to have a diabetes complication as patients with health insurance. Nina E. Flavin et al., *Health Insurance and the Development of Diabetic Complications*, 102 S. MED. J. 805, 807 (2009). However, in states that have expanded Medicaid under the ACA, a surge of individuals have been screened for and diagnosed with diabetes, compared with states that haven't expanded, which show a minimal increase. Harvey W. Kaufman*, Surge in Newly Identified Diabetes Among Medicaid Patients in 2014 Within Medicaid Expansion States Under the Affordable Care Act*, 38 DIABETES CARE 833 (2015).

[4] Ischemic strokes account for 87 percent of all stroke incidents and are by far the most common type. Emelia J. Benjamin et al., *Heart Disease and Stroke Statistics—2018 Update, A Report From the American Heart Association*, AMERICAN HEART ASSOCIATION (2018).

Consequently, patients in Medicaid expansion states are being treated earlier and could experience better long-term outcomes. *Id*. at 835. These facts are consistent with the insight in the Supreme Court decisions above that many health care costs are ultimately imposed somewhere in the absence of insurance.

A survey of the impact of Medicaid expansion in three states—Kentucky, Arkansas, and Texas—also showed that gaining coverage under the ACA was associated with a $337 reduction in annual out-of-pocket spending for uninsured individuals gaining coverage and a 25 percent increase in blood glucose screening. Benjamin D. Sommers et al., *Three-Year Impacts Of The Affordable Care Act: Improved Medical Care And Health Among Low-Income Adults*, 36:6 HEALTH AFF. 1119 (2017).

Lung patients fare better with health insurance as well. Access to health insurance improves numerous health outcomes for children with asthma, including reductions in the number of asthma-related attacks and hospitalizations. Szilagyi PG et al., *Improved Asthma Care After Enrollment in the State Children's Health Insurance Program in New York*, 117:2 PEDIATRICS 486-96 (2006). Disease management programs based on guideline-based care for children with asthma reduced hospitalizations, ED visits, and outpatient visits also increase. Cloutier MM et al., *Use of Asthma Guidelines By Primary Care Providers to Reduce Hospitalizations and Emergency Department Visits in Poor, Minority, Urban Children*, 146:5 J. PEDIATRICS 591-7 (2005). Moreover, access to COPD management programs reduces hospital readmissions. *See* Ko, Fanny W.S. et al., *COPD Care Programme Can Reduce Readmissions and In-Patient Bed Days*, 108:12 RESPIRATORY MEDICINE 1771-8 (2014).

Early treatment is also critical for MS patients. Strong evidence suggests that disease-modifying treatment should be given as soon as possible following a diagnosis of relapsing-

remitting MS, and be ongoing for benefits to persist. Stopping treatment has been shown to have a negative impact, which may include an increase in the frequency and severity of relapses, or worsening symptoms. Bruce Cohen et al., *MS Therapy Adherence & Relapse Risk*, 80:7 NEUROLOGY (2013), http://n.neurology.org/content/80/7_Supplement/P01.193. In addition, registry studies specific to MS and large population cohort studies of patients untreated with a disease-modifying therapy have demonstrated a reduction in survival of eight to 12 years. Multiple Sclerosis Coalition, *The Use of Disease Modifying Therapies in MS: Principles and Current Evidence* (2014), at 5, n.12, 15, n.123, http://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color. The best chance for reducing long-term disability caused by MS is early treatment, with the goal being to slow the accumulation of lesions, decrease the number of relapses, and prevent disease progression. *Id.* at 11, n.50.

Without health insurance to defray most of the costs of MS treatment, it is highly unlikely that most patients now living with the disease would be able to access their prescribed medicines, therapies, supportive services and equipment. Lack of treatment means the disabling consequences of MS would advance at their fastest pace, forcing patients out of the workforce and into lives of physical, financial, and emotional dependence.

Congress enacted the ACA to address these known failures of the health insurance market and the tragic consequences those failures have for individuals. By making health insurance available to all eligible individuals regardless of financial status, the ACA protects patients from the negative health and financial outcomes that accompany being uninsured or underinsured. Without the ACA, patients and survivors of chronic illness who cannot afford

health insurance will continue to be plagued by the serious financial and health consequences associated with a lack of insurance.

CONCLUSION

For the foregoing reasons, *Amici* respectfully submit that the court should reject the plaintiffs' argument that Congress, in repealing one provision of the ACA but leaving the rest in place, intended that the whole Act, or important provisions of it, should be repealed. The ACA, has operated, and should not be prevented from continuing to operate, to help patients and survivors of cancer, diabetes, heart disease, stroke, lung disease, and MS, as Congress intended.

Respectfully submitted,

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

TEXAS, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Case No. 4:18-cv-167-O
	)	
UNITED STATES OF AMERICA, et al.	)	
	)	
Defendants.	)	
	)	

ORDER GRANTING UNOPPOSED MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE* IN SUPPORT OF INTERVENOR-DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

On this date, the Court considered American Cancer Society, et al.'s Unopposed Motion for Leave to File Brief *Amici Curiae* in Support of Intervenor-Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction (the "Motion"). 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 **_____, 2018**.

The Honorable Reed O'Connor
UNITED STATES DISTRICT JUDGE