No. 19-10011

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

TEXAS, ET AL.,

Plaintiffs-Appellees,

ν.

United States of America, et al.,

Defendants-Appellants,

STATE OF CALIFORNIA, ET AL.,

Intervenor Defendants-Appellants.

On Appeal from the United States District Court for the Northern District of Texas, Fort Worth Division (No. 4:18-cv-00167-O)

AMICI CURIAE BRIEF IN SUPPORT OF INTERVENOR DEFENDANTSAPPELLANTS AND REVERSAL BY THE AMERICAN CANCER SOCIETY,
AMERICAN CANCER SOCIETY CANCER ACTION NETWORK,
AMERICAN DIABETES ASSOCIATION, AMERICAN HEART ASSOCIATION,
AMERICAN LUNG ASSOCIATION, CROHN'S & COLITIS FOUNDATION,
CYSTIC FIBROSIS FOUNDATION, EPILEPSY FOUNDATION,
GLOBAL HEALTHY LIVING FOUNDATION, HEMOPHILIA FEDERATION OF
AMERICA, LEUKEMIA & LYMPHOMA SOCIETY, MARCH OF DIMES,
NATIONAL ALLIANCE ON MENTAL ILLNESS, NATIONAL COALITION FOR
CANCER SURVIVORSHIP, NATIONAL HEMOPHILIA FOUNDATION,
NATIONAL MULTIPLE SCLEROSIS SOCIETY, AND THE KENNEDY FORUM

John Longstreth K&L GATES LLP 1601 K Street, N.W. Washington, DC 20006 (202) 778-9000

John.Longstreth@klgates.com

Alexander J. Chern K&L GATES LLP 1717 Main Street, Suite 2800

Dallas, Texas 75201 (214) 939-5500

Beth W. Petronio

Adam S. Cooper

Beth.Petronio@klgates.com Adam.Cooper@klgates.com Alex.Chern@klgates.com Counsel for Amici Curiae

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TABLE OF AUTHORITIES

Page(s)
Cases
King v. Burwell, 135 S. Ct. 2480 (2015)
Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012)
Statutes
42 U.S.C. § 18091(2)(E)
Patient Protection and Affordable Care Act
Other Authorities
163 CONG. REC. S4227 (daily ed. July 26, 2017), https://www.congress.gov/crec/2017/07/26/CREC-2017-07-26-pt1-PgS4227-9.pdf
A National Poll: Facing Cancer in the Health Care System, Am. CANCER SOC'Y CANCER ACTION NETWORK (2010)
Adelle Simmons et al., <i>The Affordable Care Act: Promoting Better Health for Women</i> , ASPE ISSUE BRIEF, https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIs sueBrief.pdf (June 14, 2016)
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.pdf10, 16
Am. Diabetes Ass'n, <i>Economic Costs of Diabetes in the U.S. in 2012</i> , 36 DIABETES CARE 1033, 7-9 tbls.9 & 10 (Supp. 2013), http://care.diabetesjournals.org/content/suppl/2013/03/05/dc12-2625.DC1/DC122625SupplementaryData.pdf

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)	23
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)	10
Andrea S. Christopher et al., <i>Access to Care and Chronic Disease Outcomes Among Medicaid-Insured Persons Versus the Uninsured</i> , 106 Am. J. Pub. Health 63, 63-69 (2015), https://ajph.aphapublications.org/doi/10.2105/AJPH.2015.302925	22
Andrew P. Wilper et al., <i>Health Insurance and Mortality in US Adults</i> , 99 Am. J. Pub. Health 2289, 2292 (2009)	16, 20
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)	15
Benjamin D. Sommers et al., Early Changes in Health Insurance Coverage under the Trump Administration, 378 New Eng. J. Med. 1061 (2018)	21
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)	22
The Better Care Reconciliation Act of 2017, H.R. 1628, 115th Cong. (2017-2018)	3
Birth Data, CENTERS FOR DISEASE CONTROL AND PREVENTION: NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, https://www.cdc.gov/nchs/nvss/births.htm	7
(last updated Feb. 21, 2019)	/

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)	20
Bruce Cohen et al., MS Therapy Adherence & Relapse Risk, 80:7 NEUROLOGY (2013), http://n.neurology.org/content/80/7_Supplement/P01.193	17
Cancer Facts and Figures 2019, Am. CANCER SOC'Y, https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf;	5
Cancer Treatment & Survivorship, Facts & Figures, 2016-2017, AM. CANCER SOC'Y, 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	5
Charles U. Begley & Tracy L. Durgin, <i>The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates</i> , 56 EPILEPSY BEHAV. 1376 (2015), https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084	11
Christopher S. Lathan et al., Association of Financial Strain With Symptom Burden and Quality of Life for Patients With Lung or Colorectal Cancer, 34 J. CLINICAL ONCOLOGY 1732 (2016), http://ascopubs.org/doi/abs/10.1200/JCO.2015.63.2232?sid=8a09e 15b-fc58-45b6-9b35-b94c65d78437	13
Chronic Diseases in America, Centers for Disease Control and Prevention: National Center for Chronic Disease Prevention and Health Promotion, https://www.cdc.gov/chronicdisease/pdf/infographics/chronic-disease-H.pdf (last updated Mar. 18, 2019)	6
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	4, 26

Consensus Health Care Reform Principles, AM. CANCER SOC'Y CANCER ACTION NETWORK ET AL.,	
http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_492352.pdf (last visited Mar. 31, 2019)	2
Continuing Progress on the Opioid Epidemic: The Role of the Affordable Care Act, ASPE ISSUE BRIEF, https://aspe.hhs.gov/system/files/pdf/255456/ACAOpioid.pdf (Jan. 11, 2017)	24
Daniel M. Hartung, Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA, 14:4 NEUROTHERAPEUTICS 1018 (2017)	11
David J. Thurman et al., <i>Health-Care Access Among Adults with Epilepsy: The U.S. National Health Interview Survey, 2010 and 2013</i> , 55 EPILEPSY BEHAV. 184 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/	19
David T. Rubin et al., <i>The Crohn's and Colitis Foundation of America Survey of Inflammatory Bowel Disease Patient Health Care Access</i> , 23 INFLAMMATORY BOWEL DISEASES 224 (2017), https://www.ncbi.nlm.nih.gov/pubmed/27997434	19
David U. Himmelstein et al., <i>Medical Bankruptcy in the United States</i> , 2007: Results of a National Study, 122 Am. J. MED. 741, 745 (2009)	10
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)	14
Emelia J. Benjamin et al., <i>Heart Disease and Stroke Statistics</i> —2018 Update, A Report From the American Heart Association, AMERICAN HEART ASSOCIATION (2018)	20

Case: 19-10011 Document: 00514896778 Page: 7 Date Filed: 04/01/2019

Examining Threats to Workers with Preexisting Conditions: Hearing Before The H. Educ. and Labor Comm., 116th Cong. 6 (2019) (statement of Rahul Gupta, Senior Vice President And Chief Medical And Health Officer, March Of Dimes), https://edlabor.house.gov/imo/media/doc/Testimony_Gupta020619.pdf	6, 7, 25
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	10
Gabriela Dieguez et al., <i>The Cost Burden of Blood Cancer Care</i> , MILLIMAN RESEARCH REPORT (Oct. 2018) https://www.lls.org/sites/default/files/Milliman%20study%20cost%20burden%20of%20blood%20cancer%20care.pdf	12
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)	24
Helen Yu et al., Market Share and Costs of Biologic Therapies for Inflammatory Bowel Disease in the United States, 47 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 364 (2018)	12
Hugo Torres et al., Coverage and Access for Americans with Chronic Disease under the Affordable Care Act: A Quasi-Experimental Study, 166 Annals Internal Med. 472, 472-79 (2017), https://annals.org/aim/article-abstract/2599147/coverage-access-americans-chronic-disease-under-affordable-care-act-quasi?doi=10.7326%2fM16-1256	22
Institute of Medicine, Insuring America's Health, Principles and Recommendations 43 (2004), https://www.nap.edu/catalog/10874/insuring-americas-health-principles-and-recommendations	28
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)	18

Jay J. Shen & Elmer Washington, Disparities in Outcomes Among Patients with Stroke Associated with Insurance Status, 38 STROKE 1010, 1013 (2007)	20
Joanne Volk, Affordable Care Act's Ban on Lifetime Limits Has Ended Martin Addie's Coverage Circus, Georgetown University Health Policy Institute, (Nov. 14, 2012) https://ccf.georgetown.edu/2012/11/14/affordable-care-acts-ban-on-lifetime-limits-has-ended-martin-addies-coverage-circus/	12
John T. Wilkins et al., Lifetime Risk and Years Lived Free of Total Cardiovascular Disease, 308 J. Am. Med. Ass'n 1795, 1798 (2012)	6
Jonaki Bose et al., Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health, Substance Abuse and Mental Health Services Administration (Sept. 2018), https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHFFR2017/NSDUHFFR2017.pdf	7
Kevin Griffith et al., <i>The Affordable Care Act Reduced Socioeconomic Disparities In Health Care Access</i> , 36:8 HEALTH AFF. 1503, 1507-08 (2017), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017.0083	21
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)	16
L.I. Ionezzi et al., <i>Health, Disability and Life Insurance Experiences of Working-Age Persons with Multiple Sclerosis</i> , 13 MULTIPLE SCLEROSIS J. 534, 538 (2008), https://journals.sagepub.com/doi/abs/10.1177/1352458507080466	17
Linda J. Blumberg et al., State-by-State Estimates of the Coverage and Funding Consequences of Full Repeal of the ACA, URBAN INSTITUTE: HEALTH POLICY CENTER 2 (Mar. 2019), https://www.urban.org/sites/default/files/publication/100000/repeal	2 -
_of_the_aca_by_state.pdf (reflecting data collected in 2019)	26

Matthew M. Zack & Rosemarie Kobau, National and State Estimates of the Numbers of Adults and Children with Active Epilepsy – United States, 2015, 66 MORBIDITY AND MORTALITY WEEKLY REPORT 821 (2017),	
https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a1.htm	6
Mitchell T. Wallin et al., <i>The Prevalence of MS in the United States: A Population-Based Estimate Using Health Claims Data</i> , 92 Neurology 1029, 1035 (2019), https://n.neurology.org/content/neurology/92/10/e1029.full.pdf	6
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	5
National Health Interview Survey, 2016, CENTERS FOR DISEASE CONTROL AND PREVENTION	6
Nina E. Flavin et al., Health Insurance and the Development of Diabetic Complications, 102 S. Med. J. 805, 807 (2009)	18
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)	20
Olga Khavjou et al., <i>Projections of Cardiovascular Disease and Costs:</i> 2015-2035, Am. HEART ASS'N (Nov. 2016), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491513.pdf	6
Priscilla Novak et al., Changes in Health Insurance Coverage and	
Barriers to Health Care Access Among Individuals with Serious	
Psychological Distress Following the Affordable Care Act, 45	
ADMIN. POL'Y MENTAL HEALTH AND MENTAL HEALTH SERVICES	2.4
RES. 924 (2018), https://doi.org/10.1007/s10488-018-0875-9	24

Recommendations of Congressman Patrick J. Kennedy to the President's Commission on Combating Drug Addiction and the Opioid Crisis, The Kennedy Forum, https://chp-wp-uploads.s3.amazonaws.com/www.thekennedyforum.org/uploads/2017/10/PJK-recommendations-to-Opioid-Commission.pdf (Oct. 2017)	25
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)	23
Sara R. Collins et al., <i>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</i> , 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	16
Sarah J. Tribble, <i>Several Probes Target Insulin Drug Pricing</i> , KAISER HEALTH NEWS (Oct. 28, 2017), https://www.nbcnews.com/health/health-news/several-probestarget-insulin-drug-pricing-n815141	19
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	15
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)	20
Wenya Yang, Economic Costs of Diabetes in the U.S. in 2017, 41 DIABETES CARE 917 (2018)	11
William T. Cefalu et al., Insulin Access and Affordability Working Group: Conclusions and Recommendations, 41 DIABETES CARE 1301 (2018)	11, 19

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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)	18
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	23

INTEREST OF AMICI¹

The American Cancer Society, American Cancer Society Cancer Action Network, American Diabetes Association, American Heart Association, and its division, the American Stroke Association, American Lung Association, Crohn's & Colitis Foundation, Cystic Fibrosis Foundation, Epilepsy Foundation, Global Healthy Living Foundation, Hemophilia Federation of America, Leukemia & Lymphoma Society, March of Dimes, National Alliance on Mental Illness, National Coalition for Cancer Survivorship, National Hemophilia Foundation, National Multiple Sclerosis Society, and The Kennedy Forum (collectively, "Amici") represent millions of patients and consumers across the country facing serious, acute, chronic health conditions. As organizations that fight to prevent, treat, and cure some of the most deadly diseases, Amici and the millions of Americans they represent would be among those hit hardest if the lower court's invalidation of the ACA is allowed to stand—particularly because many of the individuals *Amici* represent have preexisting conditions and depend directly on the protections provided by the ACA.

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¹ In accordance with Fed. R. App. P. 29(a)(2), *Amici* received consent to file this brief from counsel for each of the parties. Per Fed. R. App. P. 29(a)(4)(E), *Amici* certify that this brief was authored in whole by counsel for *Amici* and that 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.

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Because extensive scientific research establishes a strong link between lack of health insurance and poorer medical outcomes, *Amici* advocate for affordable, adequate, and accessible health insurance that is easy to understand.² Many *Amici* were actively involved in Congress's enactment of the ACA in 2010 and opposed repeal efforts in subsequent years. *Amici* are uniquely able to assist the Court in understanding why the Act is crucial to millions of patients, survivors, and their families.

In this brief, *Amici* demonstrate how the ACA, and health insurance generally, are critical in addressing and defeating the diseases that *Amici*'s constituents fight every day. If the lower court's extraordinary decision to invalidate the ACA is allowed to stand, the forthcoming disruption to the status quo—a status quo in place and preserved by Congress—will substantially harm disease sufferers and the public interest.³

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 that *Amici* represent is high. Moreover, the costs of treating such serious conditions are often

² Consensus Health Care Reform Principles, Am. CANCER SOC'Y CANCER ACTION NETWORK ET AL., http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm 492352.pdf (last visited Mar. 31, 2019).

³ Additional information about each of the individual *Amici* and the specific interests and constituents they serve is included in the Addendum filed contemporaneously herewith.

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staggering and beyond the financial means of most individuals and families. The question is not *whether* individual Americans will incur health care expenses but *how* those expenses will be financed. Without the health care provided by the ACA, access to vital health-care services and the quality of health outcomes diminishes, making it more difficult to manage the myriad of chronic diseases that *Amici* help Americans fight every day. Not many Americans have the means to pay for adequate treatment of these diseases without insurance coverage—for most Americans, insurance is a not a luxury, but a prerequisite to obtaining treatment.

Not only are the financial burdens of medical care staggering to uninsured Americans, but uninsured status comes with a tragic consequence: many individuals choose to forgo screening and treatment rather than taking on the financial burden of paying out-of-pocket. Without early detection, serious diseases become more difficult and costly to treat and have poorer medical outcomes.

Congress is aware of this reality—it reviewed the scientific data when it passed the ACA in 2010. During 2017, amidst public outcry to protect the Act and data tying lack of affordable health insurance to more costly and longer-term treatment, Congress chose not to repeal the ACA despite lengthy consideration and debate.⁴

⁴ The Better Care Reconciliation Act failed 43-57 in the Senate. The Better Care Reconciliation

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Congress's choice to preserve the ACA was a decision that has proven critical to preserving insurance coverage for many Americans, including those living with chronic diseases: ACA repeal would have resulted in 17 million Americans losing their insurance in 2018, with the total reaching 27 million by 2020. CONGRESSIONAL BUDGET OFFICE COST ESTIMATE, H.R. 1628, Obamacare of Repeal Reconciliation Act 2017 (July 19, 2017), https://www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/52939hr1628amendment.pdf. Indeed, members of Congress on both sides of the aisle were emphatic that critical protections not be repealed without a replacement that would ensure patients had 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. And with good reason—as the data illustrates, the ACA has resulted in greatly improved access to affordable medical care for Americans dealing with chronic illnesses.

The lower court's ruling does precisely what Congress considered and chose not to do. Congress expressly rejected a "repeal-without-replace" scenario that would have left millions of Americans without adequate coverage—a policy decision properly in the province of the legislature, not the court. *See King v. Burwell*, 135 S. Ct. 2480, 2496 (2015) (stating that the power to make the laws rests with Congress, and because Congress passed the ACA to improve the health-

insurance market, courts must interpret the Act consistent with that goal). By invalidating the ACA over Congress's clear intent to the contrary, the lower court's decision will have life-altering implications for patients with chronic diseases.

ARGUMENT

I. AFFORDABLE, ACCESSIBLE HEALTH CARE IS ESSENTIAL IN MANAGING CHRONIC DISEASES

"Everyone will eventually need health care at a time and to an extent they cannot predict." *Nat'l Fed'n of Indep. Bus. v. Sebelius* ("*NFIB*"), 567 U.S. 519 (2012). There is also a pervasive need for health care in connection with the most serious diseases—diseases that are the focus of *Amici*'s efforts:

- An estimated 1.7 million Americans will be diagnosed with cancer in 2019, and more than 15.5 million Americans with a history of cancer were alive on January 1, 2016. Approximately four out of ten men and nearly four out of ten women in the U.S. will develop cancer in Cancer Facts and Figures 2019, Am. CANCER their lifetime. Soc'y, https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/annual-cancer-facts-andfigures/2019/cancer-facts-and-figures-2019.pdf; Cancer Treatment & Survivorship. **Facts** Figures, 2016-2017, Am. CANCER & Soc'y, https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/cancer-treatment-andsurvivorship-facts-and-figures/cancer-treatment-and-survivorshipfacts-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/nation al-diabetes-statistics-report.pdf.

- In 2018, a projected 107.3 million Americans had cardiovascular disease ("CVD"). Olga Khavjou et al., *Projections of Cardiovascular Disease and Costs:* 2015-2035, Am. HEART ASS'N (Nov. 2016), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_491513.pdf. The lifetime risk of 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, 33.6 million Americans had some form of chronic lung disease, including an estimated 11.3 million adults with chronic obstructive pulmonary disease ("COPD") and 26.5 million with asthma. *National Health Interview Survey*, 2016, CENTERS FOR DISEASE CONTROL AND PREVENTION (analysis by the ALA Epidemiology and Statistics Unit using SPPS Software).
- In 2015, 3.4 million Americans reported active epilepsy. Matthew M. Zack & Rosemarie Kobau, *National and State Estimates of the Numbers of Adults and Children with Active Epilepsy United States*, 2015, 66 MORBIDITY AND MORTALITY WEEKLY REPORT 821 (2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a1.htm.
- The most recent data from statistically-based estimates indicates approximately 1 million individuals in the US have Multiple Sclerosis ("MS"). Mitchell T. Wallin et al., *The Prevalence of MS in the United States: A Population-Based Estimate Using Health Claims Data*, 92 Neurology 1029, 1035 (2019), https://n.neurology.org/content/neurology/92/10/e1029.full.pdf.
- 60 percent of adult Americans have a chronic disease, and 40 percent have two or more. *Examining Threats to Workers with Preexisting Conditions: Hearing Before The H. Educ. and Labor Comm.*, 116th Cong. 6 (2019) (statement of Rahul Gupta, Senior Vice President And Chief Medical And Health Officer, March Of Dimes), https://edlabor.house.gov/imo/media/doc/Testimony_Gupta020619.pdf (citing *Chronic Diseases in America*, CENTERS FOR DISEASE

CONTROL AND PREVENTION: NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, https://www.cdc.gov/chronicdisease/pdf/infographics/chronic-disease-H.pdf (last updated Mar. 18, 2019).

- Each year in the U.S., over 3 million women deliver about 4 million babies. Gupta, *Examining Threats to Workers*, *supra*, at 3 (citing *Birth Data*, CENTERS FOR DISEASE CONTROL AND PREVENTION: NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTIO N, https://www.cdc.gov/nchs/nvss/births.htm (last updated Feb. 21, 2019).
- In 2017, there were an estimated 46.6 million adults aged 18 or older in the United States with mental illness. This number represented 18.9% of all U.S. adults. Jonaki Bose et al., *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*, SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION (Sept. 2018), https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHFFR 2017/NSDUHFFR2017.pdf.

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

Good health and the chance for positive outcomes when dealing with illness should not be dependent upon a person's ability to pay for care. Patients with early-stage cancer should not forego potentially life-saving chemotherapy treatments because they cannot afford them. Americans with diabetes should not

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be forced to delay costly treatment or ration their life-saving insulin for so long that they lose a limb due to amputation. Americans experiencing heart-attack symptoms should not be reluctant to call 9-1-1 and lose access to quick diagnosis and treatment in a hospital out of concern that they cannot afford an emergency-department bill. Parents should not be forced to take children to the emergency department because they could not afford asthma medication that would have prevented an exacerbation. Patients with MS should not be financially unable to continue treatment, as lack of treatment increases the frequency and severity of relapses and disability and reduces years of survival. Americans are forced to make these financially motivated choices when insurance is unavailable, yet these choices can mean the difference between life and death.

Congress passed the ACA to improve Americans' access to health care. As nonpartisan organizations dedicated to studying and preventing the devastating impact of these diseases, *Amici* know firsthand that access to affordable, basic, preventive health care and life-saving treatments are fundamental to successful health outcomes.

II. THE ACA HAS IMPROVED ACCESS TO AFFORDABLE HEALTH CARE, REDUCING FINANCIAL BURDENS AND IMPROVING MEDICAL OUTCOMES FOR PATIENTS WITH LIFE-THREATENING AND CHRONIC DISEASES

Since its enactment, the ACA has been successful in reducing: (i) the financial burden of necessary medical expenses; (ii) the uninsured rates among

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adults; and (iii) the demonstrable gap between household income and insurance coverage. Congress's enactment of the ACA was spurred by the failures of our health-care system and the high costs of health insurance: these well-known failures hurt both the nation's economic well-being and the health and well-being of individual Americans. *See* 42 U.S.C. § 18091(2)(E) (explaining that the nation's economy "loses up to \$207,000,000,000 a year because of the poorer health and shorter lifespan of the uninsured."). Prior to Congressional enactment of the ACA, the mere prospect of the exorbitant cost of fighting chronic diseases frequently caused uninsured Americans to delay or forgo necessary screening and treatment at the expense of their well-being.

Improving access to health care by making coverage more affordable was a primary reason why Congress passed the ACA. *NFIB*, 567 U.S. at 538 ("The Act aims to increase the number of Americans covered by health insurance and decrease the cost of health care.") And the ACA has proven to be up to the challenge: the Act has made significant progress in reducing the problems faced by Americans dealing with chronic diseases.

A. The financial burden accompanying necessary medical care for uninsured Americans fighting chronic disease is staggering.

Prior to the enactment of the ACA, uninsured Americans with chronic diseases were often unable to receive necessary treatment or went into crushing debt to obtain medical care.

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For example, the high cost of treating CVD has been a leading cause of medical bankruptcy. 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 who suffered a stroke averaged out-of-pocket medical costs of \$23,380, and those with heart disease averaged medical costs of \$21,955. *Id.* 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 more than half cited cost as the reason they lacked coverage. See FACTS: Breaking Down the Barriers: The Uninsured with Heart Disease and Stroke, AM. **HEART** Ass'n (2013),http://www.heart.org/idc/groups/heartpublic/@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/g roups/heart-public/@wcm/@adv/documents/downloadable/ucm 432322.pdf.

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MS patients also suffer substantial financial 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).

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).

For the one-in-twenty-six Americans who develop epilepsy in their lifetimes, the annual cost of epilepsy-specific health care can approach \$20,000. Charles U. Begley & Tracy L. Durgin, *The Direct Cost of Epilepsy to the United States: A Systematic Review of the Estimates*, 56 EPILEPSY BEHAV. 1376 (2015), https://onlinelibrary.wiley.com/doi/full/10.1111/epi.13084. When Americans with epilepsy cannot get the correct treatment, it places a high financial strain on the system: epilepsy-related medical costs associated with uncontrolled epilepsy are two to ten times higher than costs associated with controlled epilepsy. *Id*.

Likewise, in the treatment of inflammatory bowel disease, corticosteroid-sparing therapy (such as biologics) has proven necessary in order to optimize long-term health outcomes for patients and maximize their quality of life. The cost of this treatment, however, is around \$36,051 per year. Helen Yu et al., *Market Share and Costs of Biologic Therapies for Inflammatory Bowel Disease in the United States*, 47 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 364 (2018).

For patients with hemophilia, the cost of routine treatment is enormous: depending on the severity of the disease, treatment for hemophilia can approach \$60,000 per month. Joanne Volk, *Affordable Care Act's Ban on Lifetime Limits Has Ended Martin Addie's Coverage Circus*, Georgetown University Health Policy Institute, (Nov. 14, 2012) https://ccf.georgetown.edu/2012/11/14/afforda ble-care-acts-ban-on-lifetime-limits-has-ended-martin-addies-coverage-circus/.

Similarly, treatment for blood-cancer patients averages \$156,000 in the year following diagnosis, with the cost of treatment for certain blood-cancer subtypes averaging as high as \$800,000 in the first year. Gabriela Dieguez et al., *The Cost Burden of Blood Cancer Care*, MILLIMAN RESEARCH REPORT (Oct. 2018) https://www.lls.org/sites/default/files/Milliman%20study%20cost%20burden%20of%20blood%20cancer%20care.pdf.

The data above represents a microcosm of the financial burden that uninsured Americans seeking treatment for chronic conditions often face.

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Potentially more worrisome is the fact that without insurance, many patients are unwilling to incur these costs, putting their well-being—and often, their lives—at risk.

B. Prior to Congressional enactment of the ACA, uninsured Americans often delayed treatment due to the costs of medical care.

Prior to the ACA, uninsured Americans often chose to delay or forgo treatment altogether—shortening their own lives or worsening their conditions—rather than incur the financial strain associated with receiving care. Even without the obvious, negative medical consequences of forgoing treatment, uninsured Americans fighting chronic conditions without financial reserves were often at risk of exacerbating their poor-health outcomes due to their financial condition alone. 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*, 567 U.S. at 594 (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.").

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⁵ In interviews with lung and colorectal cancer patients, 33 to 40 percent of the patients reported having limited financial reserves: these patients also 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*, 34 J. CLINICAL ONCOLOGY 1732 (2016), http://ascopubs.org/doi/abs/10.1200/JCO.2015.63.2232?sid=8a09e15b-fc58-45b6-9b35-b94c65d78437.

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Prior to the enactment of the ACA, 34 percent of individuals under age 65 who had cancer or a history of cancer reported delaying care in the preceding twelve months because of cost. *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_Pol ling_Report_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.

Being uninsured affects health outcomes for cancer patients at every step of treatment: patients delay preventive screenings due to cost; the cancer is not discovered until it has developed to an advanced stage as a result; or those individuals who actually receive treatment are subject to more invasive and aggressive medical interventions.

In a study that included nearly 850,000 patients with malignant tumors, uninsured patients were more than four times as 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 five-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).

Similarly, a 2014 study showed that adolescents and young adults without insurance 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.

A patient's inability to get screenings and treatment comes at a cost. 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_20 15/browse csr.php?sectionSEL=15&pageSEL=sect_15_table.12.html.

Furthermore, a 2009 Harvard Medical School study found approximately 45,000 deaths annually could be attributed to lack of health insurance among

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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.

With respect to heart disease, an American Heart Association survey found that more than half of the cardiovascular patients responding reported difficulty paying for medical care. Am. HEART ASS'N, Affordable Access to Health Care, supra. Consequently, 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.commonweal thfund.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 because of the financial implications. Kim G. Smolderen et

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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).

MS patients are no different. A 2007 survey concluded that 27.4 percent had postponed seeking needed health care because of the expense, and 22.3 percent delayed filling prescriptions, skipped doses of medications, or split pills because of costs. L.I. Ionezzi et al., Health, Disability and Life Insurance Experiences of Working-Age Persons with Multiple Sclerosis, 13 Multiple Sclerosis J. 534, 538 (2008),https://journals.sagepub.com/doi/abs/10.1177/1352458507080466. Similarly, 36 percent indicated spending less on basic needs such as food or heat to pay for their MS-related expenses. *Id.* at 544. Stopping treatment—which can occur when financial pressures mount—has been shown to have a negative impact on MS patients, including 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/conten t/80/7_Supplement/P01.193. Without health insurance to defray the costs of MS treatment, most patients living with the disease are not able to access their prescribed medicines, therapies, supportive services and equipment.

Uninsured individuals with diabetes show the same patterns. "Among persons aged 18 to 64 with diabetes mellitus, those who had no health insurance

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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/DC122625SupplementaryData.pdf. Those without insurance are more than 30 percent more likely to visit emergency departments than those with private insurance. *Id.* Diabetes patients with no health insurance were twice as likely to have complications 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).

Lack of health insurance also delays diagnosis and treatment, increasing the risks of complications. Diabetes went 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).

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Similarly, the cost of insulin has caused patients with diabetes to ration insulin or skip doses because they simply cannot afford it, even though this practice can lead to serious and even deadly complications. Cefalu et al., *supra*, at 1306. Patients may need several vials of insulin a month. With the list price of a single vial of insulin over \$300, lack of insurance for a person with diabetes can be devastating. Sarah J. Tribble, *Several Probes Target Insulin Drug Pricing*, KAISER HEALTH NEWS (Oct. 28, 2017), https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141.

In the inflammatory-bowel-disease community, 66.3 percent of surveyed patients reported health-care related financial worry prior to 2014, and 25.4 percent of patients reported delaying medical care with cost concerns cited as a major factor. David T. Rubin et al., *The Crohn's and Colitis Foundation of America Survey of Inflammatory Bowel Disease Patient Health Care Access*, 23 INFLAMMATORY BOWEL DISEASES 224 (2017), https://www.ncbi.nlm.nih.gov/pub med/27997434.

Twenty-one percent of adults with epilepsy reported not being able to afford their 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 BEHAV. 184 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/.

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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); 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"); Wilper et al., Health Insurance, supra, at 2292; 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).

Those who suffer an ischemic stroke⁶ 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).

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⁶ 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).

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Prior to the enactment of the ACA, uninsured Americans were left with an impossible choice—place themselves and their families in financial peril or forgo getting the treatment they needed. Congress passed the ACA to eliminate this untenable choice, and the ACA has largely risen to the occasion.

C. Congress's enactment and preservation of the ACA has significantly reduced Americans' financial burden and allowed Americans who need treatment the most to receive it.

Since Congress enacted the ACA, the Act has significantly improved circumstances for individuals with chronic diseases. Uninsured rates among nonelderly adults decreased by 6.3 percent 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*, 378 NEW ENG. J. MED. 1061 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29539288.

The data is even more striking when factoring in household income. The gap in insurance coverage between households with an 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 (2017), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2017. 0083.

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The ACA has had a direct benefit on Americans living with chronic conditions including arthritis, migraine, cardiovascular disease, psoriasis, inflammatory bowel disease, and osteoporosis. Over 606,277 adults aged 18 to 64 suffering from these chronic conditions received increased coverage and medical access due to the ACA. Hugo Torres et al., Coverage and Access for Americans with Chronic Disease under the Affordable Care Act: A Quasi-Experimental Study, 166 ANNALS INTERNAL MED. 472, 472-79 (2017), https://annals.org/aim/articleabstract/2599147/coverage-access-americans-chronic-disease-under-affordablecare-act-quasi?doi=10.7326%2fM16-1256. Detailed studies conducted from 1999 through 2012 confirm that individuals with Medicaid coverage were more likely than uninsured individuals to have at least one outpatient physician visit annually. Andrea S. Christopher et al., Access to Care and Chronic Disease Outcomes Among Medicaid-Insured Persons Versus the Uninsured, 106 Am. J. Pub. Health 63, 63-69 (2015), https://ajph.aphapublications.org/doi/10.2105/AJPH.2015.30292 5.

A survey of the impact of Medicaid expansion—which compared Kentucky and Arkansas with Texas, a non-expansion state—also showed that gaining coverage under the ACA was associated with a \$337 reduction in annual out-of-pocket spending and a 25 percent increase in blood glucose screening. Benjamin D. Sommers et al., *Three-Year Impacts of the Affordable Care Act: Improved*

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Medical Care and Health among Low-Income Adults, 36:6 HEALTH AFF. 1119 (2017).

This increase in coverage tangibly affects health outcomes—a small but statistically significant shift was found toward early-stage diagnosis for colorectal, lung, female breast, pancreatic cancer, and melanoma in patients in Medicaid-expansion states. Similarly, the ACA's coverage expansion for dependent children up to age 26 has: (i) increased the insurance-coverage rate among that population; (ii) had a positive effect on initiation and completion of the human papillomavirus (HPV) vaccination; (iii) resulted in more early diagnosis and receipt of fertility-sparing treatments for cervical cancer; and (iv) increased early-stage diagnosis for cancer 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 after the ACA was passed 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 in 2012 to 7.7 percent in 2015. Amy J. Davidoff et al., *Changes in Health Insurance Coverage Associated*

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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).

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 have not expanded, which show only 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). Patients in Medicaid-expansion states are being treated earlier and could experience better long-term outcomes. *Id.* at 835.

Patients with mental illnesses have also been greatly benefited by ACA coverage. "In states that expanded Medicaid under the ACA, the uninsured share of substance use or mental health disorder hospitalizations fell from about 20 percent in the fourth quarter of 2013 to about 5 percent by mid-2015." *Continuing Progress on the Opioid Epidemic: The Role of the Affordable Care Act*, ASPE ISSUE BRIEF, https://aspe.hhs.gov/system/files/pdf/255456/ACAOpioid.pdf (Jan. 11, 2017). The ACA has increased the rate of health-insurance coverage among nonelderly adults with serious psychological distress and has resulted in a reduction of patients choosing to delay or forgo treatment due to the cost of health care. Priscilla Novak et al., *Changes in Health Insurance Coverage and Barriers*

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to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act, 45 Admin. Pol'y Mental Health And Mental Health Services Res. 924 (2018), https://doi.org/10.1007/s10488-018-0875-9.

Notably, the ACA has proved valuable in addressing the ongoing drug-addiction and opioid crises—without the ACA, many of the recommendations for solving the crises that were included in the President's Commission on Combating Drug Addiction and the Opioid Crisis would be nullified. *See generally Recommendations of Congressman Patrick J. Kennedy to the President's Commission on Combating Drug Addiction and the Opioid Crisis*, THE KENNEDY FORUM, https://chp-wp-uploads.s3.amazonaws.com/www.thekennedyforum.org/uploads/2017/10/PJK-recommendations-to-Opioid-Commission.pdf (Oct. 2017).

Between the summer of 2013 and the winter of 2014-15, the uninsured rate among women of childbearing age decreased from 19.6 percent to 13.3 percent. Gupta, *Examining Threats to Workers*, *supra*, at 6. This improvement resulted in 5.5 million women being able to access health care to "help them get healthy before they got pregnant, and to protect their health during and after pregnancy and childbirth." *Id.* The proportion of young women who reported delaying or forgoing care due to cost concerns dropped by 3.4 percentage points. Adelle Simmons et al., *The Affordable Care Act: Promoting Better Health for Women*,

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ASPE ISSUE BRIEF, https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHeal thIssueBrief.pdf (June 14, 2016).

Congress's policy-based decision to pass and preserve the ACA has resulted in both the reduction of financial burdens on Americans and the improvement of medical outcomes for patients with chronic diseases.

III. THE LOWER COURT'S DECISION TO INVALIDATE THE ACA IGNORES CONGRESS'S POLICY-BASED DECISION TO PRESERVE THE ACA BECAUSE THE ACA HAS IMPROVED ACCESS TO MUCH-NEEDED, AFFORDABLE INSURANCE

Congress's conscious choice to preserve the ACA after lengthy debate was meant to ensure that the significant progress made in reducing the medical and financial problems faced by individuals with chronic diseases was not lost. If the ACA were eliminated in its entirety, the number of uninsured Americans would increase by 19.9 million or 65 percent. Linda J. Blumberg et al., State-by-State Estimates of the Coverage and Funding Consequences of Full Repeal of the ACA, Urban INSTITUTE: HEALTH **POLICY** CENTER 2 (Mar. 2019), https://www.urban.org/sites/default/files/publication/100000/repeal_of_the_ aca_by_state.pdf (reflecting data collected in 2019); see also CONGRESSIONAL BUDGET OFFICE COST ESTIMATE, supra (contemplating that 17 million Americans would lose their insurance in 2018 if the ACA were repealed, without the benefit of 2019 data).

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Congress was explicitly unwilling to leave millions without coverage in a "repeal-without-replace" scenario. *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. By invalidating the ACA in its entirety, the lower court substituted its own judgment for Congress's policy-based decision, threatening the significant progress the ACA has made in getting patients the medical care they need.

In enacting 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 covered by health insurance and decrease the cost of health care." *NFIB*, 567 U.S. at 519. In *King v. Burwell*, the Court emphasized that such policy goals are the province of the legislature, not the courts. 135 S. Ct. at 2496. And, as discussed above and recognized by the Supreme Court, individuals without health insurance are less likely to receive

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preventive treatment or early detection screenings and are more likely to delay treatment. *See*, *e.g.*, *NFIB*, 567 U.S. at 594 (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).

Congress passed the ACA to address the known failures of the health-insurance market and the tragic consequences those failures have on patients and their families. By making health insurance available to all eligible individuals regardless of financial status, the ACA helps protect patients from the negative financial and medical outcomes of being uninsured or underinsured. Congress decided that preserving the ACA was the best way to continue improving access to much-needed, affordable insurance—a worthy policy goal that falls squarely on Congress.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request that the Court reverse the lower court's ruling. Congress, in repealing only one, discrete provision of the ACA, did not repeal the whole Act or its important provisions designed to provide

access to health care. On the contrary, the ACA has operated, and should continue to operate, to help patients and survivors of chronic disease—exactly as Congress intended.

Respectfully submitted,

/s/	Beth	W.	Peti	ronic

John Longstreth K&L GATES LLP 1601 K Street, N.W. Washington, DC 20006 (202) 778-9000 John.Longstreth@klgates.com Beth W. Petronio Adam S. Cooper Alexander J. Chern K&L GATES LLP 1717 Main Street, Suite 2800

Dallas, Texas 75201 (214) 939-5500

Beth.Petronio@klgates.com Adam.Cooper@klgates.com Alex.Chern@klgates.com Counsel for All Amici Curiae

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Additional Counsel on Next Page

Mary P. Rouvelas
Senior Counsel
AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK
555 11th Street NW, Suite 300
Washington, DC 20004
(202) 661-5707
Mary.Rouvelas@cancer.org
Co-Counsel for Amici ACS and ACS
CAN

Timothy Phillips

General Counsel

AMERICAN CANCER SOCIETY

250 Williams St.

Atlanta, GA 30303

(404) 327-6423

Timothy.Phillips@cancer.org

Co-Counsel for Amici ACS and ACS

CAN

Sarah Fech-Baughman
Director of Litigation
AMERICAN DIABETES ASSOCIATION
2451 Crystal Drive Suite 900
Arlington, VA 22202
(703) 253-4823
Sfech@diabetes.org
Co-Counsel for Amici ADA

Lewis Kinard
General Counsel
AMERICAN HEART ASSOCIATION
7272 Greenville Avenue
Dallas, TX 75231
(214) 706-1246
Lewis.Kinard@heart.org
Co-Counsel for Amici AHA

Chris Gegelys
Senior Vice President & Chief Legal
Officer
CYSTIC FIBROSIS FOUNDATION
4550 Montgomery Ave., Suite 1100 N
Bethesda, MD 20814
(301) 841-2627
cgegelys@cff.org
Co-Counsel for Amici CFF

Steven R. Newmark

General Counsel

GLOBAL HEALTHY LIVING FOUNDATION
515 N. Midland Ave.

Upper Nyack, NY 10960
(646) 715-2138

snewmark@ghlf.org

Co-Counsel for Amici GHLF

Deborah Matz

Senior Vice President, Legal &
Enterprise Risk Management
THE LEUKEMIA & LYMPHOMA SOCIETY
3 International Drive
Rye Brook, NY 10573
(914) 821-8824
Deborah.Matz@lls.org

Co-Counsel for Amici LLS

Bari Talente

Executive Vice President, Advocacy
NAT'L MULTIPLE SCLEROSIS SOC'Y
733 3rd Ave.
New York, NY 10017
(212) 463-7787
Bari.Talente@nmss.org
Co-Counsel for Amici National MS
Society

Adrian Mollo
Sr. VP & General Counsel
MARCH OF DIMES
1550 Crystal Drive, Suite 1300
Arlington, VA 22202
(571) 257-1043
AMollo@marchofdimes.org
Co-Counsel for Amici March of
Dimes

Eric Hilty

Chief Legal Officer

NAT'L MULTIPLE SCLEROSIS SOC'Y

900 S. Broadway, 2nd Floor

Denver, CO 80209

(303) 698-6100

Eric.Hilty@nmss.org

Co-Counsel for Amici National MS

Society

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CERTIFICATE OF COMPLIANCE

This document complies with Fed. R. App. P. 29(a)(5) and the word limit of

Fed. R. App. P. 32(a)(7)(B). Excluding the Addendum and other parts of the

document exempted by Fed. R. App. P. 32(f), this document contains 6,071 words.

This document complies with the typeface requirements of Fed. R. App. P.

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Respectfully submitted,

/s/ Beth W. Petronio

Beth W. Petronio

April 1, 2019

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CERTIFICATE OF SERVICE

I certify that on April 1, 2019, the forgoing document was filed with the Clerk of the Court, using the CM/ECF system, causing it to be served on all

counsel of record.

Respectfully submitted,

/s/ Beth W. Petronio

Beth W. Petronio

April 1, 2019

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ADDENDUM

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American Cancer Society ("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 Cancer Action Network ("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 ACA, ACS strongly advocates guaranteeing all Americans affordable, adequate, accessible, health insurance that is easy to understand.

American Diabetes Association ("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,

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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.

American Heart Association ("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.

American Lung Association ("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 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.

The Crohn's & Colitis Foundation is dedicated to finding the cures for Crohn's disease and ulcerative colitis and to improve the quality of life of children and adults affected by these diseases, collectively known as inflammatory bowel disease (IBD). For over 50 years, the Crohn's & Colitis Foundation has been the leading non-profit organization focused on both research and patient support for IBD. Treatment for the 3.1 million Americans who are affected by IBD is highly individualized, and studies show that better health outcomes are associated with consistent and timely access to care. Further, IBD treatments are expensive and costs are rising, and most Americans with IBD cannot afford their care without insurance coverage. The Foundation supports provisions in the Affordable Care Act that protect and enable the ability of persons with pre-existing conditions to purchase and afford insurance coverage.

The Cystic Fibrosis Foundation's ("CFF") mission is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care. The CFF

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advocates for policies that promote affordable, adequate, and available health care coverage for people with cystic fibrosis.

The Epilepsy Foundation is the leading national voluntary health organization that speaks on behalf of more than 3.4 million Americans with epilepsy and seizures. Uncontrolled seizures can lead to disability, injury, and even death. Epilepsy medications are the most common and most cost-effective treatment for controlling and/or reducing seizures—making timely and consistent access to quality, affordable, physician-directed and person-centered health insurance coverage and care critically vital for people living with epilepsy.

Global Healthy Living Foundation ("GHLF"), and its arthritis community CreakyJoints®, is a non-profit foundation representing people with chronic disease, including arthritis, migraine, cardiovascular disease, psoriasis, inflammatory bowel disease and osteoporosis. GHLF advocates for improved access to care at the community, state, and federal levels, and amplifies its education and support services through its popular CreakyChats Twitter with an average of 6 million impressions and CreakyJoints Facebook feeds. GHLF is also a staunch advocate for vaccines. The organization further represents patients through its ArthritisPower patient-reported outcomes research registry, and its 50-State Network of patient advocates.

Hemophilia Federation of America ("HFA") is a community-based, grassroots advocacy organization that assists, educates, and advocates for people with hemophilia, von Willebrand disease, and other rare bleeding disorders. HFA works for patient access to quality and affordable care and coverage—priorities that reflect the nature of bleeding disorders as serious, life-long, and expensive health conditions. Quality and affordable healthcare coverage is indispensable for people living with bleeding disorders.

Leukemia & Lymphoma Society ("LLS") is the world's largest voluntary health agency dedicated to fighting blood cancer and ensuring that the more than 1.3 million blood cancer patients and survivors in the United States have access to the care they need. The significant costs associated with essential blood cancer treatments—particularly hospitalization, stem cell transplantation, and anti-cancer drug therapies—put even routine cancer care out of reach for those patients without comprehensive and stable health insurance. LLS and its network of more than 100,000 advocacy volunteers promote policies that ensure access to quality insurance coverage and reduce barriers to vital cancer care.

March of Dimes is a nonprofit organization that leads the fight for the health of all moms and babies. March of Dimes educates medical professionals and the public about best practices, supports lifesaving research, provides comfort and support to families in neonatal intensive care units, and advocates for moms and

babies. Ensuring that pregnant women and their children have access to timely, affordable, and high-quality healthcare is essential to achieving its goals.

National Alliance on Mental Illness ("NAMI") is the nation's largest grassroots organization dedicated to building better lives for the millions of Americans affected by mental illness. NAMI advocates for access to services, treatment, support, and research, and is steadfast in its commitment to raising awareness and building a community of hope for individuals living with mental illness across the lifespan. NAMI has a strong interest in ensuring that people with mental health conditions as well as people with other medical conditions and disabilities have full access to services and support in the community, in accordance with their individual needs and preferences.

National Coalition for Cancer Survivorship ("NCCS") is a national organization that advocates for access to quality care for survivors of all forms of cancer. The cancer survivors represented by NCCS have a pre-existing condition from the day of diagnosis and rely on affordable and adequate health insurance.

The National Hemophilia Foundation ("NHF") is the nation's leading advocacy organization working to ensure that individuals affected by hemophilia and related bleeding disorders have timely access to high quality medical care and services, regardless of financial circumstances or place of residence. Patients with bleeding disorders have complex, lifelong medical needs and depend on

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prescription medications (clotting factor or other new therapies) to treat or avoid painful bleeding episodes that can lead to advanced medical issues. Hemophilia treatment is extremely expensive, costing anywhere from \$250,000 to \$1 million or more annually, depending on the severity of the disorder and whether complications such as an inhibitor are present. Access to specialized high quality care is critical to managing the health and well-being of people living with these disorders.

The National Multiple Sclerosis Society ("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 Kennedy Forum as a 501(c)(3) is organized to drive real, lasting, meaningful policy change to fulfill our vision. Today, The Kennedy Forum's work is not singular in its focus. It promotes mental health coverage through a series of initiatives, which include: ensuring health plan accountability and compliance with

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the letter and spirit of the parity law by educating consumers, providers, and regulators, so that each group holds themselves and others accountable for proper enforcement; establishing ways to promote provider accountability through evidence-based outcomes measures that are validated and quantifiable; implementing proven collaborative practice models that promote the integration of mental health and substance use disorder services into mainstream health care; using technology to optimize electronic/digital communications and enhance assessment/treatment tools; and promoting brain fitness and wellness, which includes identifying opportunities to translate neuroscience research findings into preventive and treatment interventions.