IN THE

Supreme Court of the United States

California, et al., *Petitioners*, v.
Texas, et al., *Respondents*.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

AMICI CURIAE BRIEF IN SUPPORT OF PETITIONERS AND REVERSAL BY THE AMERICAN CANCER SOCIETY ET AL.

BETH W. PETRONIO
ADAM S. COOPER
CLAIRE PIEPENBURG
K&L GATES LLP
1717 Main Street, Suite 2800
Dallas, Texas 75201
(214) 939-5500
Beth.Petronio@klgates.com
Adam.Cooper@klgates.com
Claire.Piepenburg@klgates.com

Counsel of Record
K&L GATES LLP
1601 K Street, N.W.
Washington, DC 20006
(202) 778-9000
John.Longstreth@klgates.com

JOHN LONGSTRETH

MARY ROUVELAS
AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK
555 11th Street, N.W.
Suite 300
Washington, DC 20004
(202) 661-5707
Mary.Rouvelas@cancer.org

Counsel for Amici Curiae

Additional Counsel Listed On Signature Page

TABLE OF CONTENTS

STAT	'EMEN	T OF INTEREST 1
SUM	MARY	OF ARGUMENT 6
ARGU	JMEN'	Γ10
I.	HEAI	ORDABLE, ACCESSIBLE LTH CARE IS ESSENTIAL IN AGING CHRONIC DISEASES10
II.	TO A REDU AND OUTO LIFE	ACA HAS IMPROVED ACCESS AFFORDABLE HEALTH CARE, JCING FINANCIAL BURDENS IMPROVING MEDICAL COMES FOR PATIENTS WITH THREATENING AND CHRONIC ASES
	В.	Prior to enactment of the ACA, uninsured Americans often delayed treatment due to the costs of medical care
	С.	Congress's enactment and preservation of the ACA has significantly reduced Americans'

	financial burden and allowed Americans who need treatment the most to receive it27
III.	INVALIDATION OF THE ACA WOULD IGNORE CONGRESS'S POLICY-BASED DECISION TO PRESERVE THE ACA BECAUSE IT HAS IMPROVED ACCESS TO MUCHNEEDED, AFFORDABLE INSURANCE
CON	CLUSION

TABLE OF AUTHORITIES

Page(s)
Cases
King v. Burwell, 135 S. Ct. 2480 (2015)
Nat'l Fed'n of Indep. Bus. v. Sebelius ("NFIB"), 567 U.S. 519 (2012)
<u>Statutes</u>
42 U.S.C. § 18091(2)(E)
Patient Protection and Affordable Care Act $passim$
Other Authorities
156 Cong. Rec. E618-04 (daily ed. Apr. 22, 2010)
163 Cong. Rec. S4227–96 (daily ed. July 26, 2017)
A National Poll: Facing Cancer in the Health Care System, Am. Cancer Soc'y Cancer Action Network, 17 (2010), https://www.acscan.org/sites/default/files/ National%20Documents/ACS_CAN_Pollin g_Report_7.27.10.pdf
Adelle Simmons et al., The Affordable Care Act: Promoting Better Health for Women, ASPE ISSUE BRIEF (June 14, 2016)

Affordable Access to Health Care: Top Priorities of Heart Disease & Stroke Patients: Results from an Am. Heart Ass'n Patient Survey, Am. Heart Ass'n (2010), https://www.heart.org/idc/groups/heart- public/@wcm/@adv/documents/downloada ble/ucm_432322.pdf	https://aspe.hhs.gov/system/files/pdf/ 205066/ACAWomenHealthIssueBrief.pdf	33
and Chronic Disease Outcomes Among Medicaid-Insured Persons Versus the Uninsured, 106 Am. J. Pub. Health 63 (2015), https://ajph.aphapublications.org/doi/10.2 105/AJPH.2015.302925	Priorities of Heart Disease & Stroke Patients: Results from an Am. Heart Ass'n Patient Survey, Am. HEART ASS'N (2010), https://www.heart.org/idc/groups/heart- public/@wcm/@adv/documents/downloada	17, 22
and Mortality in US Adults, 99 Am. J. Pub. HEALTH 2289 (2009)	and Chronic Disease Outcomes Among Medicaid-Insured Persons Versus the Uninsured, 106 Am. J. Pub. Health 63 (2015), https://ajph.aphapublications.org/doi/10.2	29
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 J. 1212 (2014)	and Mortality in US Adults, 99 Am. J. Pub.	22, 26
in Health Insurance Coverage Under the Trump Administration, 378 NEW ENG. J. MED. 1061 (2018), https://www.ncbi.nlm.nih.gov/pubmed/295	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,	21
	in Health Insurance Coverage Under the Trump Administration, 378 NEW ENG. J. MED. 1061 (2018), https://www.ncbi.nlm.nih.gov/pubmed/295	27

Benjamin D. Sommers et al., Three-Year Impact of the Affordable Care Act: Improved Medical Care and Health among	
Low-Income Adults, 36 Health Aff. 1119 (2017)	29
Better Care Reconciliation Act, H.R. 1628, 115th Cong. (2017)	7
Breaking Down the Barriers: The Uninsured With Heart Disease & Stroke, Am. HEART ASS'N (2013), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloada ble/ucm_304486.pdf	17
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 (Supp. 2014)	26
Bruce Cohen et al., MS Therapy Adherence & Relapse Risk, 80 NEUROLOGY (7 Supplement) (2013), http://n.neurology.org/content/80/7_Supplement/P01.193	23
Cancer Facts and Figures 2020, AM. CANCER SOC'Y (2020), https://www.cancer.org/content/dam/cance r-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf.	9

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.1308418
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/downloada
ble/ucm_492352.pdf (last visited Mar. 31, 2019)
Continuing Progress on the Opioid Epidemic: The Role of the Affordable Care Act, ASPE ISSUE BRIEF (Jan. 11, 2017) https://aspe.hhs.gov/system/files/pdf/2554 56/ACAOpioid.pdf
Cost Estimate of H.R. 1628 Obamacare Repeal Reconciliation Act of 2017, CONG. BUDGET OFF. (July 19, 2017), https://www.cbo.gov/system/files?file=115t h-congress-2017-2018/costestimate/52939- hr1628amendment.pdf
Dan Dalton, Hemophilia in the Managed Care Setting, 21 Am. J. OF MANAGED CARE S123 (Apr. 1, 2015), https://www.ajmc.com/journals/supplemen t/2015/ace0024_mar15_hemophiliace/ace0 024 mar15 hemophilia dalton?p=3

Daniel M. Hartung, Economics and Cost- Effectiveness of Multiple Sclerosis Therapies in the USA, 14:4 NEUROTHERAPEUTICS 1018 (2017)	17
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	26
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/pubmed/279 97434.	27
Economic Costs of Diabetes in U.S. in 2012, AM. DIABETES ASS'N, 36 DIABETES CARE 1033 (Supp. 2013), http://care.diabetesjournals.org/content/su ppl/2013/03/05/dc12- 2625.DC1/DC122625SupplementaryData. pdf	
Elizabeth M. Ward et al., The Association of Insurance and Stage at Diagnosis Among Patients Aged 55 to 74 in the National Cancer Database, 16 CANCER J. 614 (2010)	20
Emelia J. Benjamin et al., Heart Disease and Stroke Statistics—2018 Update. A Report	

from the American Heart Association, Am. Heart Ass'n (2018)	26
Gabriela Dieguez et al., The Cost Burden of Blood Cancer Care, MILLIMAN RESEARCH REP., 2 (Oct. 2018) https://www.lls.org/sites/default/files/Milliman%20study%20cost%20burden%20of% 20blood%20cancer%20care.pdf	19
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)	31
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)	18
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 (2017), https://annals.org/aim/article-abstract/2599147/coverage-access-americans-chronic-disease-under-affordable-care-act-quasi?doi=10.7326%2fM16-1256	29
J.B. Fox et al., Vital Signs: Health Insurance Coverage and Health Care Utilization— United States, 2006–2009 and January—	

<i>March 2010</i> , 59 Morbidity & Mortality Wkly. Rep. 1448 (2010)	24
Jay J. Shen & Elmer Washington, Disparities in Outcomes Among Patients with Stroke Associated with Insurance Status, 38 STROKE 1010 (2007)	26
Joanne Volk, Affordable Care Act's Ban on Lifetime Limits Has Ended Martin Addie's Coverage Circus, Georgetown Univ. Health Pol'y Inst. (Nov. 14, 2012) https://ccf.georgetown.edu/2012/11/14/affo rdable-care-acts-ban-on-lifetime-limits- has-ended-martin-addies-coverage-circus/	18
Jonaki Bose et al., Key Substance Use & Mental Health Indicators in the United States: Results from the 2017 Nat'l Survey on Drug Use & Health, DEP'T OF HEALTH & HUMAN SERVS. (Sept. 2018), https://www.samhsa.gov/data/sites/defaul t/files/cbhsq-reports/NSDUHFFR2017/NSDUHFFR2017.pdf.	13
Jusung Lee, The Impact of Medicaid Expansion on Diabetes Management, 43 DIABETES CARE 1094 (2020)	31
K. Robin Yabroff et al., Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors, 34 J. CLIN. ONCOL. 259 (2016), https://ascopubs.org/doi/pdfdirect/10.1200/ JCO.2015.62.0468	22

28	K. Robin Yabroff et al., Health Insurance Coverage Disruptions and Cancer Care and Outcomes: Systematic Review of Published Research, JNCI: J. OF THE NAT'L CANCER INST (Apr. 27, 2020), https://doi.org/10.1093/jnci/djaa048
28	Kevin Griffith et al., The Affordable Care Act Reduced Socioeconomic Disparities in Health Care Access, 36 HEALTH AFF. 1503, 1507–08 (2017), https://www.healthaffairs.org/doi/abs/10.1 377/hlthaff.2017.0083?journalCode=hltha ff
23	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 (2010)
33	L. Chen, R.G. Frank, H.A. Huskamp, Technical Memo on Coverage Expansion and Low-Income, Reproductive-Age Women, HARVARD UNIV. (Apr. 14, 2020), https://hcp.hms.harvard.edu/technical- memo-coverage-expansion-and-low- income-reproductive-age-women
23	L.I. Ionezzi et al., Working-Age Persons With Multiple Sclerosis and Access to Disease-Modifying Medications, 13 MULTIPLE SCLEROSIS J. 534 (2008), https://journals.sagepub.com/doi/abs/10.11 77/1352458507080466

Linda J. Blumberg et al., State-by-State Estimates of Coverage and Funding Consequences of Full Repeal of the ACA, URBAN INST.: HEALTH POL'Y CTR., 2 (Mar. 2019), https://www.urban.org/sites/default/files/p ublication/100000/repeal_of_the_aca_by_s tate.pdf (reflecting data collected in 2019)34
Matthew M. Zack & Rosemarie Kobau, National and State Estimates of the Numbers of Adults and Children with Active Epilepsy — United States, 2015, 66 MORBIDITY & MORTALITY WKLY. REP., CTRS. FOR DISEASE CONTROL & PREVENTION 821 (Aug. 2017), https://www.cdc.gov/mmwr/volumes/66/wr
/mm6631a1.htm12
Michael Tarantino et al., The Impact of the Economic Downturn and Health Care Reform on Treatment Decisions for Haemophilia A: Patient, Caregiver, and Health Care Provider Perspectives, 19 HAEMOPHILIA 51 (2013)
Mitchell T. Wallin et al., The Prevalence of MS in the United States: A Population- Based Estimate Using Health Claims Data, 92 Neurology 1029 (Feb. 2019), https://n.neurology.org/content/neurology/ 92/10/e1029.full.pdf
Nat'l Diabetes Statistics Report, 2020: Estimates of Diabetes & Its Burden in the United States, CTRS. FOR DISEASE CONTROL

& PREVENTION, 2 (2020), https://www.cdc.gov/diabetes/pdfs/data/st atistics/national-diabetes-statistics-report.pdf	10
Nat'l Health Interview Survey, 2018 Data Release, CTRS. FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/nchs/ nhis/nhis_2018_data_release.htm (last visited Jan. 19, 2020)	11
Nina E. Flavin et al., Health Insurance and the Development of Diabetic Complications, 102 S. MED. J. 805 (2009)	24
O. Kenrik Duru at al., Health Insurance Status and Hypertension Monitoring and Control in the United States, 20 Am. J. HYPERTENSION 348 (2007)	26
Olga Khavjou et al., Projections of Cardiovascular Disease & Costs: 2015-2035, Am. HEART ASS'N, 20 (Nov. 2016), https://healthmetrics.heart.org/wp-content/uploads/2017/10/Projections-of-Cardiovascular-Disease.pdf	11
People Who Are at Higher Risk for Severe Illness, CENTERS FOR DISEASE CONTROL AND PREVENTION (Apr. 15, 2020), https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-athigher-risk.html	8
Petition for a Writ of Certiorari, No. 19-840, App. 8a	7

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 & MENTAL HEALTH
SERVS. RES. 924 (2018),
https://doi.org/10.1007/s10488-018-0875-9
Dalad Canta Carian V.D. 0 Chief Mad 0
Rahul Gupta, Senior V.P. & Chief Med. &
Health Officer, March of Dimes,
Examining Threats to Workers With
Preexisting Conditions, Testimony Before
the H. Educ. & Labor Comm. (Feb. 6,
2019),
https://edlabor.house.gov/imo/media/doc/T
estimony_Gupta020619.pdf 12, 33
Ramin Mojtabai, Insurance Loss in the Era of
the Affordable Care Act, 57 MED. CARE 567
(2019), https://journals.lww.com/lww-
medicalcare/Citation/2019/08000/Insuran
ce_Loss_in_the_Era_of_the_Affordable_C
are.1.aspx
are.r.aspx
Rebecca L. Siegel et al., Cancer Statistics,
2020, Am. CANCER SOC'Y (2020),
https://acsjournals.online
library.wiley.com/doi/epdf/10.3322/caac.21
59010
Recommendations of Congressman Patrick J.
Kennedy to the President's Commission on
Combatting Drug Addiction and the
Opioid Crisis, The Kennedy Forum (Oct.
2017)

https://www.thekennedyforum.org/app/up loads/2017/10/PJK-recommendations-to- Opioid-Commission.pdf	32
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)	31
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), http://www.commonwealthfund.org/~/med ia/files/publications/fund- report/2013/apr/1681_collins_insuring_fut ure_biennial_survey_2012_final.pdf	23
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-	0.5
pricing-n815141	

Stacey A. Fedewa et al., Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act, 57 Am. J. Preventative Med. 1 (May 22, 2019)	31
Tefera Gezmu et al., Disparities in Acute Stroke Severity, Outcomes, and Care Relative to Health Insurance Status, 23 J. STROKE & CEREBROVASCULAR DISEASE 93 (2014)	26
Vikas Mehta et al., Case Fatality Rate of Cancer Patients with COVID-19 in a New York Hospital System, CANCER DISCOVERY (May 1, 2020), https://cancerdiscovery.aacrjournals.org/c ontent/early/2020/04/29/2159-8290.CD-20- 0516	8
Wenya Yang, Economic Costs of Diabetes in the U.S. in 2017, 41 DIABETES CARE 917 (2018)	17
William T. Cefalu et al., Insulin Access and Affordability Working Group: Conclusions and Recommendations, 41 DIABETES CARE 1299 (2018), https://care.diabetesjournals.org/content/diacare/41/6/1299.full.pdf	17, 25
Xuanping Zhang et al., The Missed Patient with Diabetes: How Access to Health Care Affects the Detection of Diabetes, 31 DIABETES CARE 1748 (2008)	25

xvi	
Xuesong Han & Ahmedin Jemal, <i>The Affordable Care Act and Cancer Care for Young Adults</i> , 20 J. CANCER 194 (2017), https://www.ncbi.nlm.nih.gov/pubmed/285 37966	30
Xuesong Han et al., Changes in Noninsurance and Care Unaffordability Among Cancer Survivors Following the Affordable Care Act, 112 J. NAT'L CANCER INST. 1 (2020), https://doi.org/10.1093/jnci/djz218	30, 31
Xuesong Han et al., Comparison of Insurance Status and Diagnosis Stage Among Patients with Newly Diagnosed Cancer Before vs After Implementation of the Patient Protection and Affordable Care Act, JAMA Oncol. 1713 (2018), https://jamanetwork.com/journals/jamaon cology/articlepdf/2697226/jamaoncology_h an_2018_oi_180065.pdf	30
Xuesong Han et al., Insurance Status and Cancer Stage at Diagnosis Prior to the Affordable Care Act in the United States, 43 J. OF REGISTRY MGMT. 143 (2016), http://www.ncra-usa.org/Portals/68/PDFs/JRM_Fall2016_V43.3.pdf?ver=2017-07-27-152307-267	21
Rules	
S. Ct. Rule 37.2(a)	1
S Ct Rulo 37 6	1

STATEMENT OF INTEREST¹

The American Cancer Society, the American Cancer Society Cancer Action Network, the American Diabetes Association. the American Association, and its division, the American Stroke Association, the American Lung Association, the Crohn's & Colitis Foundation, the Cystic Fibrosis Foundation, the Epilepsy Foundation, Hemophilia Federation of America, the Leukemia & Lymphoma Society, March of Dimes, the Muscular Dystrophy Association, the National Alliance on Mental Illness, the National Coalition for Cancer Survivorship, National Hemophilia Foundation, the National Multiple Sclerosis Society, the National Organization for Rare Disorders, the National Patient Advocate Foundation, and the Kennedy Forum (collectively, "Amici") represent millions of patients and consumers across the country facing serious, acute, and chronic diseases and 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 Patient Protection and Affordable Care Act ("ACA" or the "Act") were invalidated in whole or in part particularly because many of the individuals *Amici*

¹ In accordance with S. Ct. Rule 37.2(a), *Amici* received consent to file this brief from counsel for each of the parties. Per S. Ct. Rule 37.6, *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.

represent have preexisting conditions and depend directly on the protections provided by the ACA.

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, is critical in addressing and defeating the diseases that *Amici*'s constituents fight every day. Striking down the ACA, as the district court did in full and which the Fifth Circuit's decision leaves as a possibility, would disrupt the status quo placed and preserved by Congress, and substantially harm individuals who live with chronic illnesses and conditions.

The American Cancer Society's mission is to save lives and lead the fight for a world without cancer.

The American Cancer Society Cancer Action Network ("ACS CAN"), the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society,

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).

supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy changes as well as legislative and regulatory solutions that will reduce the cancer burden.

The American Diabetes Association is a nationwide, nonprofit, voluntary health organization with a mission to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

The American Heart Association is a voluntary health organization devoted to saving people from heart disease and stroke—the first and fifth leading causes of death in the United States.

The American Lung Association is the nation's oldest voluntary health organization, representing the more than 36 million Americans with lung disease.

The Crohn's & Colitis Foundation is the leading non-profit organization dedicated to finding the cures for Crohn's disease and ulcerative colitis and to improving the quality of life for individuals affected by these diseases.

The Cystic Fibrosis Foundation's mission is to cure cystic fibrosis and to provide all people with cystic fibrosis ("CF") the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

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.

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

The Leukemia & Lymphoma Society 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 can access the care they need.

March of Dimes is a nonprofit organization that leads the fight for the health of all mothers and babies by educating medical professionals and the public about best practices, lifesaving research, and by advocating for mothers and babies.

The Muscular Dystrophy Association has been committed to transforming the lives of people affected by muscular dystrophy, amyotrophic lateral sclerosis (ALS), and related neuromuscular diseases for 70 years through innovations in science and innovations in care.

The National Alliance on Mental Illness is the nation's largest grassroots organization dedicated to building better lives for the millions of Americans affected by mental illness through advocacy, support, and awareness.

The National Coalition for Cancer Survivorship is a national organization that advocates for access to quality care for survivors of all forms of cancer. The National Hemophilia Foundation is the nation's leading advocacy organization working to ensure that individuals affected by hemophilia and related inheritable bleeding disorders have timely access to high quality medical care and services, regardless of financial circumstances or place of residence.

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

The National Organization for Rare Disorders is a patient advocacy organization dedicated to individuals with rare diseases and the organizations that serve them.

The National Patient Advocate Foundation is the advocacy affiliate of the Patient Advocate Foundation, a national organization that provides direct assistance and support service for families confronting complex, chronic and serious diseases to help reduce distressing financial and other burdens they experience.

The Kennedy Forum is a non-profit organization focused on promoting mental health coverage and educating consumers, providers, and regulators on the implementation of efficient practice models for integrated service, coverage, and communication.

As organizations that fight to prevent, treat, and cure some of the most serious, debilitating and deadly diseases and conditions, *Amici* and the millions

of Americans they represent would be among those hit hardest if the ACA were invalidated. *Amici* are uniquely able to assist the Court in understanding why the Act is crucial to millions of patients, survivors, and their families. This Court should confirm that the ACA, which Congress left in place as amended in 2017 without a penalty for the individual mandate, is constitutional and that the Act should not be rewritten or overturned by the courts.

SUMMARY OF ARGUMENT

All Americans use or will use health care services, and the lifetime risk that individual Americans will be born with or acquire one of the diseases or conditions that *Amici* represent is high. Moreover, the costs of treating such serious conditions are often staggering and beyond the financial means of most individuals and families. The central question is not whether individual Americans will incur health care expenses but how those expenses will be financed, and the extent to which patients will forgo treatment if they cannot afford it. Without the health insurance facilitated by the ACA, access to vital health care services and the quality of health outcomes diminishes, making it more difficult to manage the myriad chronic diseases and conditions that Amici help Americans fight and treat every day. 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 life-saving and life-sustaining treatment.

Not only are the financial burdens of medical care staggering to uninsured Americans, but

uninsured status comes with a tragic consequence: many individuals are forced to delay or forgo screening and treatment rather than taking on the financial burden of paying out-of-pocket. Without early detection, serious diseases and conditions 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 access to care provided by the Act and data that showed the connection between lack of affordable health insurance and more costly treatment and often less successful outcomes, Congress chose not to repeal the ACA despite lengthy consideration and debate on numerous proposed measures to do so.³ Congress also expressly chose to preserve the remainder of the ACA even as it eliminated the penalty for noncompliance with the individual mandate.

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 and serious conditions: repeal of the ACA would have resulted in 17 million Americans losing their insurance in 2018,

³ For example, the Better Care Reconciliation Act, H.R. 1628, 115th Cong. (2017), which would have repealed ACA mandates and cost sharing subsidies and allowed providers to sell non-compliant plans outside marketplaces, failed 43-57 in the Senate. The Fifth Circuit chose to reference a closer vote on a different measure. *See* Petition for a Writ of Certiorari, No. 19-840, App. 8a n.6. Congress has rejected all repeal efforts to date and none has advanced in the current Congress.

with that total reaching 27 million by 2020. Estimate of H.R.1628 Obamacare RepealReconciliation Act of 2017, CONG. BUDGET OFF. (July 19, 2017), https://www.cbo.gov/system/files?file= 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. S4227–96 (daily ed. July 26, 2017). With good reason—as the data illustrates, the ACA has resulted in greatly improved access to affordable medical care for Americans dealing with serious illnesses.

The need is more critical now than ever. The COVID-19 pandemic is putting unprecedented pressure on our nation's health care system and the people who rely on that system for life-saving care. Preliminary data from the Centers for Disease Control and Prevention indicates that persons with underlying health conditions such as diabetes, chronic lung disease or cardiovascular disease appear at higher risk for severe COVID-19 associated disease. People Who Are at Higher Risk for Severe Illness, Centers for DISEASE CONTROL AND PREVENTION (Apr. 15, 2020), https://www.cdc.gov/coronavirus/2019-ncov/needextra-precautions/people-at-higher-risk.html. Similarly, a recent study suggests that cancer patients are more susceptible to the virus, and that the course of the infection and outcomes are worse. Vikas Mehta et al., Case Fatality Rate of Cancer Patients with COVID-19 in a New York Hospital System, CANCER

(May

https://cancerdiscovery.aacrjournals.org/content/early

1.

2020).

DISCOVERY

/2020/04/29/2159-8290.CD-20-0516. The pandemic has also resulted in record unemployment, meaning many individuals are losing employer-sponsored health insurance. Particularly in this environment, patients with pre-existing conditions must have comprehensive health insurance such as that provided through the ACA in order to access medical services that are truly a matter of life and death.

Accepting Respondents' position would require the Court to do precisely what Congress chose not to Congress expressly rejected a "repeal-withoutreplace" 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). Invalidating the ACA over Congress's clear intent to the contrary—as the district court did and as the court of appeals' ruling leaves open—has life-altering implications for patients—particularly those with serious illnesses. Cancer Facts and Figures 2020, AM. CANCER Soc'y 1. 9 (2020),https://www.cancer.org/content/dam/cancerorg/research/cancer-facts-and-statistics/annualcancer-facts-and-figures/2020/cancer-facts-andfigures-2020.pdf.

The Fifth Circuit's decision to remand the severability determination should be reversed and the Act left intact. Leaving the Act in place—as Congress intended—will improve the health of patients, survivors, and their families across this country.

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, 547 (2012). There is also a pervasive need for health care in connection with the serious diseases that are the focus of *Amici*'s efforts:

- An estimated 1.8 million Americans will be diagnosed with cancer in 2020, and more than 16.9 million Americans with a history of cancer were alive on January 1, 2019. Rebecca L. Siegel et al., Cancer Statistics, 2020, Am. CANCER SOC'Y (2020), https://acsjournals.online library.wiley.com/doi/epdf/10.3322/caac. 21590.
- An estimated 34.2 million Americans have diabetes and 88 million American adults (about one third) have prediabetes. Nat'l Diabetes Statistics Report, 2020: Estimates of Diabetes & Its Burden in the United States, CTRS. FOR DISEASE CONTROL & PREVENTION, 2, 8 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf.
- In 2019, a projected 108.8 million Americans had cardiovascular disease

("CVD"). Olga Khavjou et al., Projections of Cardiovascular Disease & Costs: 2015-2035, AM. HEART ASS'N 20 (Nov. 2016), https://healthmetrics.heart .org/wp-content/uploads/2017/10/ Projections-of-Cardiovascular-Disease.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. (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 2018, it was estimated that 16.4 million adults had chronic obstructive pulmonary disease ("COPD") and 24.8 million Americans currently had asthma, including 5.5 million children. equates to 36.6 million Americans with chronic lung disease. Nat'l Health Interview Survey, 2018 Data Release, CTRS. FOR DISEASE CONTROL PREVENTION https://www.cdc.gov/nchs/ nhis/nhis 2018 data release.htm visited Jan. 19, 2020) (data analysis by Epidemiology ALA's and Statistics department).

- 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 & MORTALITY WKLY. REP. 821, 823 (Aug. 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a1.htm.
- Estimates indicate approximately 1 million individuals in the U.S. have 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 (Feb. 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. Rahul Gupta, Senior V.P. & Chief Med. & Health Officer, March of Dimes, Examining Threats to Workers With Preexisting Conditions, Testimony Before the H. Educ. & Labor Comm. (Feb. 6, 2019), https://edlabor.house.gov/ imo/media/doc/Testimony_Gupta020619. pdf (citing Chronic Diseases in America, FOR DISEASE CONTROL PREVENTION: NAT'L CTR. FOR CHRONIC **PREVENTION** & DISEASE HEALTH PROMOTION, https://www.cdc.gov/chronic

disease/pdf/infographics/chronic-disease-H.pdf (Mar. 18, 2019)).

- Each year in the US, over 3 million women deliver about 4 million babies. Gupta, Examining Threats to Workers, supra, at 3 (citing Birth Data, CTRS, FOR DISEASE CONTROL & PREVENTION: NAT'L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, https://www.cdc.gov/nchs/nvss/births.ht m (last viewed Feb. 21, 2019)). Adequate health insurance allows pregnant women to receive essential prenatal care, which results in healthier pregnancies. healthier babies, and lower costs overall.
- In 2017, there were an estimated 46.6 million adults aged 18 or older in the United States with mental illness, representing 18.9% of all adults. Jonaki Bose et al., Key Substance Use & Mental Health Indicators in the United States: Results from the 2017 Nat'l Survey on Drug Use & Health, DEP'T OF HEALTH & HUMAN SERVS. 2 (Sept. 2018), https://www.samhsa.gov/data/sites/defau lt/files/cbhsq-reports/NSDUHFFR2017/ NSDUHFFR2017.pdf.

These statistics confirm the virtual certainty that all Americans will need health care at some point in their lives to prevent or combat serious chronic diseases or a myriad of other health conditions. Without affordable, accessible health insurance, patients, survivors, 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.

In passing the ACA, Congress recognized what *Amici* have long advocated, that good health and the chance for positive outcomes when dealing with illness should not depend upon a person's ability to afford care. 156 Cong. Rec. E618-04 (daily ed. Apr. 22, 2010) (speech of Hon. John McNerney). Patients with earlystage cancer should not forgo potentially life-saving chemotherapy treatments because of cost. Patients with diabetes should not ration their life-saving insulin and risk amputation or death because of cost. Americans experiencing heart attack symptoms should not hesitate to call 9-1-1 and lose the benefit of immediate medical attention because of cost. Parents should not be forced to rush a child to the emergency room for a severe asthma attack that could have been prevented for the price of an inhaler. Patients with MS should not be forced to stop treatment that decreases the frequency and severity of relapses and disability and increases years of survival, because of cost. People living with CF should not forgo critical therapies or skip appointments with their care team, which can increase risk of hospitalizations and fatal lung infections, because of cost. Yet Americans without access to affordable health care routinely find themselves in these and a myriad of other impossible positions that ask (or, more often, force) patients, survivors, and their families to put finances before health and well-being.

Congress passed the ACA to improve Americans' access to health care. As nonpartisan

organizations dedicated to studying and preventing the devastating impact of 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 successfully reduced: (i) the financial burden of necessary medical expenses: (ii) the uninsured rates among adults many whose pre-existing conditions prevented them from obtaining coverage; and (iii) the demonstrable gap between household income and insurance coverage. Due to the harmful effect on both the nation's economic well-being and the health and wellness of individual Americans, the failures of our health care system and the high cost of health insurance spurred Congress's enactment of the ACA. 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 enactment of the ACA, the mere prospect of the exorbitant cost of treating chronic disease and serious conditions frequently caused uninsured Americans to delay or forgo necessary screening and treatment at the expense of their health. Additionally, insurance providers could turn conditions awav individuals with pre-existing altogether, regardless of willingness or ability to pay. Enactment of the ACA reflected a national legislative effort to remedy these systemic failures.

Improving access to health care by making coverage more affordable was a primary purpose of 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 burden 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 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.

For example, the high cost of treating cardiovascular disease 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 suffering from the disease lacked insurance, and nearly one of four cardiovascular disease patients and one of three stroke patients went without coverage at some point following their diagnosis—more than half cited cost as the reason they lacked coverage. See Breaking Down the Barriers: The Uninsured With Heart Disease & Stroke, Am. HEART ASS'N 1 (2013), http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_304486.pdf (citing Geo. Wash. Univ. Ctr. for Health Pol'y Research, Analysis of 2006-10 NHIS Data, Am. HEART ASS'N (Aug. 2011) (on file with the American Heart Association)); Affordable Access to Health Care: Top Priorities of Heart Disease & Stroke Patients: Results from an Am. Heart Ass'n Patient Survey, Am. HEART ASS'N 2 (2010), https://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_432322.pdf.

MS patients also suffer substantial financial burdens. The cost of disease-modifying treatment is extremely high, averaging \$81,731 per 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 34 million people who live with the disease. People diagnosed with diabetes incur medical expenditures averaging \$16,750 per year. Wenya Yang, Economic Costs of Diabetes in the U.S. in 2017, 41 DIABETES CARE 917 (2018). 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 1 Working Group: Conclusions Recommendations, 41 Diabetes Care 1299, 1301 https://care.diabetesjournals.org/content/ diacare/41/6/1299.full.pdf.

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.13 084. 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 of 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 UNIV. HEALTH POLY INST. (Nov. 14, 2012) https://ccf.georgetown.edu/2012/11/14/affordable-careacts-ban-on-lifetime-limits-has-ended-martin-addiescoverage-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 REP. 2 (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 Americans seeking treatment for chronic conditions often face. Potentially more worrisome is the fact that without insurance, many patients are unable to incur these costs, putting their well-being—and often, their lives—at risk.

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

Prior to the ACA taking effect, 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, 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.").

Before the ACA, 34 percent of individuals under the age of 65 who had 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 17 (2010), https://www.acscan.org/sites/default/files/National%2 0Documents/ACS_CAN_Polling_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 patients at every step of cancer care: patients delay preventative screenings due to cost; the cancer is not discovered until it has developed to an advanced stage as a result; individuals who receive later 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 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 a 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 J. 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. In another study of over 1.2 million newly diagnosed cancer patients aged 18-64 years, researchers found uninsured or Medicaid patients had a higher risk of being diagnosed with advanced stage cancer than privately insured patients. Xuesong Han et al., Insurance Status and Cancer Stage at Diagnosis Prior to the Affordable Care Act in the United States, 43 J. OF REGISTRY MGMT. 143, 146 (2016), http://www.ncra-usa.org/Portals/68/PDFs/ JRM_Fall2016_V43.3.pdf?ver=2017-07-27-152307-267.

Inability to get screenings and treatment results in more deaths. Strikingly, the five-year lung cancer survival rate is only 6 percent for those diagnosed at a late stage after the tumor spreads, but increases to 57 percent for those diagnosed at an early stage before the tumor has spread. See SEER Cancer Statistics Review 1975–2017, NAT'L CANCER INST. SURVEILLANCE, EPIDEMIOLOGY, & END RESULTS PROGRAM, https://seer.cancer.gov/csr/1975_2017/

browse_csr.php?sectionSEL=15&pageSEL=sect_15_t able.12.

Similarly, a 2009 Harvard Medical School study found approximately 45,000 deaths annually could be attributed to lack of health insurance among workingage Americans: those uninsured 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.

For cancer survivors, lack of insurance is associated with financial hardship. Data showed that among 18-64 year-old cancer survivors, uninsured survivors reported higher levels of material financial hardship and psychological financial compared to those who were privately insured. K. Robin Yabroff et al., Financial Hardship Associated with Cancer in the United States: Findings from a Population-Based Sample of Adult Cancer Survivors, CLIN. ONCOL. 259, 261-64(2016),https://ascopubs.org/doi/pdfdirect/10.1200/JCO.2015.6 2.0468 (2011 data).

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. *Affordable Access to Health Care*, Am. HEART ASS'N, *supra*. Consequently, 46 percent of chronically ill patients said they delayed getting needed medical care, 28 percent who took regular medication had not filled a prescription, and nearly 30 percent 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 Health Insurance Survey, 2012, The 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 because of the financial implications. 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).

MS patients are no different. A 2007 survey concluded that 27.4 percent postponed seeking needed health care because of the expense and 22.3 percent delayed filling prescriptions, skipped doses medications, or split pills because of cost. L.I. Ionezzi Health, Disability and Life Insurance Experiences of Working-Age Persons with Multiple Sclerosis, 13 Multiple Sclerosis J. 534, 538 (2008), https://www.ncbi.nlm.nih.gov/pubmed/17463076. 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 negatively impact MS patients, increasing the frequency and severity of relapses or worsening symptoms. Bruce Cohen et al., MS Therapy Adherence & Relapse Risk, 80 NEUROLOGY (7 Supplement) (2013), http://n.neurology.org/content/80/7_Supplement/P01. 193. Without health insurance to defray the cost of MS treatment, most patients living with the disease are unable to access their prescribed medications, 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 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. *Economic Costs* of Diabetes in U.S. in 2012, Am. Diabetes Ass'n, 36 DIABETES CARE 1033, 7–9 tbls. 9, 10 (Supp. 2013), http://care.diabetesjournals.org/content/suppl/2013/03 /05/dc12-2625.DC1/DC122625Supplementary Data.pdf. Those without insurance are more than 30 percent more likely to visit emergency departments than those with private insurance. Id.patients without 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).

Similarly, the cost of insulin has caused patients with diabetes to ration insulin or skip doses simply because they 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 well 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 carerelated financial worry prior to 2014 and 25.4 percent of patients reported delaying medical care citing cost concerns 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 Disease 224 (2017), https://www.ncbi.nlm.nih.gov/pubmed/27997434.

Twenty-one percent of adults with epilepsy reported in 2010 and 2013 surveys 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/PMC53173

uninsured patients CVD Likewise. with experience higher mortality rates and poorer bloodpressure 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 at 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 stroke⁴ 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*

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*, AM. HEART ASS'N (2018).

Among Patients with Stroke Associated with Insurance Status, 38 Stroke 1010, 1013 (2007).

More than 50% of individuals with hemophilia and their health care providers, surveyed about the impact of the last national economic downturn, reported delaying care, skipping doses of medication, postponing surgeries, and making other suboptimal treatment modifications due to economic pressures. Michael Tarantino et al., The Impact of the Economic Downturn and Health Care Reform on Treatment Decisions for Haemophilia A: Patient, Caregiver, and Health Care Provider Perspectives, 19 HAEMOPHILIA 51, 53-54 (2013).

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' burden and allowed financial Americans who need treatment the most to receive it.

Since enactment of 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.

Losing ones' insurance coverage is associated with difficulty accessing medical providers, reduced affordability, and problems adhering medication regiments to save costs. Implementation of the ACA is associated with a lower risk of insurance loss. Ramin Mojtabai, Insurance Loss in the Era of the Affordable Care Act, 57 MED. CARE 567 (2019), https://journals.lww.com/lww-medicalcare/ Citation/2019/08000/Insurance_Loss_in_the_Era_of_t he Affordable Care. 1. aspx. Similarly, research has shown that individuals who are diagnosed with cancer and have disruptions in coverage, including gaps in coverage, are more likely to have worse survival than similar individuals with cancer, but without coverage disruptions, and is associated with less screening, later stage diagnosis, and lack of timely guidelineconsistent treatment. K. Robin Yabroff et al., Health Insurance Coverage Disruptions and Cancer Care and Outcomes: Systematic Review of Published Research, JNCI: J. OF THE NAT'L CANCER INST (Apr. 27, 2020), https://doi.org/10.1093/jnci/djaa048.

These data are 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 HEALTH AFF. 1503, 1507–08 (2017),

https://www.healthaffairs.org/doi/abs/10.1377/hlthaff. 2017.0083?journalCode=hlthaff.

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-chronicdisease-under-affordable-care-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 - 69(2015).63, https://ajph.aphapublications.org/doi/10.2105/AJPH.2 015.302925.

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 Impact of the Affordable*

Care Act: Improved Medical Care and Health among Low-Income Adults, 36 Health Aff. 1119 (2017).

Increased coverage tangibly affects health outcomes. Researchers observed a shift to early stage at diagnosis for cancer patients associated with Medicaid expansion. Xuesong Han et al., Comparison of Insurance Status and Diagnosis Stage Among Patients with Newly Diagnosed Cancer Before vs After Implementation of the Patient Protection and Affordable Care Act, 4(12) JAMA ONCOL. 1713, 1717 (2018), https://jamanetwork.com/journals/ jamaoncology/articlepdf/2697226/jamaoncology han 2018 oi 180065.pdf. Furthermore. expansion was associated with a reduction in noninsurance and care unaffordability, as well as a reduction in disparities by sociodemographic factors. Xuesong Han et al., Changes in Noninsurance and Care Unaffordability Among Cancer Following the Affordable Care Act, 112 J. NAT'L Inst CANCER 1. 3 (2020),https://doi.org/10.1093/jnci/djz218.

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 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 20 CANCER Adults. J. 194 (2017),https://www.ncbi.nlm.nih.gov/pubmed/28537966.

In addition, Medicaid expansion is associated with colorectal cancer ("CRC") screening, which improved at a faster rate in states initially expanding Medicaid to those who did not. In one study, the improvement in screening rates in very early expansion states translated to an additional 236,573 low income adults receiving recent CRC screening in 2016. If the same absolute increase was experienced in non-expansion states, 355,184 more low-income adults would have had recent CRC screening than what was observed. Stacey A. Fedewa et al., Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act, 57 Am. J. PREVENTATIVE MED. 1, 3 (May 22, 2019).

The proportion of cancer survivors reporting delayed or forgone care and inability to afford health care services also significantly decreased after the ACA passed. Ryan D. Nipp et al., Patterns in Health Care Access and Affordability among Cancer Survivors During Implementation of the Affordable Care Act, 29, JAMA ONCOLOGY (Mar. 2018). Following enactment of the ACA, the percentage of cancer patients who were uninsured or reporting care unaffordability decreased nationwide. Xuesong Han Changes inNoninsurance andUnaffordability Among Cancer Survivors Following the Affordable Care Act, J. NAT'L CANCER INST. 112 (2020), https://doi.org/10.1093/jnci/djz218.

In states that expanded Medicaid under the ACA, a surge of individuals were screened for and diagnosed with diabetes, compared with states without expansion which showed 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 treated earlier and experience better outcomes. Id. at 835; Jusung Lee, The Impact of Medicaid Expansion on Diabetes Management, 43 DIABETES CARE 1094, 1097–98 (2020).

Patients with mental illnesses have also greatly benefited from 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 guarter 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 (Jan. 11, 2017) https://aspe.hhs.gov/system/ files/pdf/255456/ACAOpioid.pdf. The ACA increased the rate of health insurance coverage among nonelderly adults with serious psychological distress and 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 to Health Care Access Among Individuals with Serious Psychological Distress Following the Affordable Care Act, 45 Admin. Pol'y Mental Health & MENTAL HEALTH SERVS. RES. https://doi.org/10.1007/s10488-018-0875-9.

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

Between the summer of 2013 and the winter of 2014, the uninsured rate among women 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, ASPE ISSUE BRIEF (June 14, https://aspe.hhs.gov/system/files/pdf/ 205066/ACAWomenHealthIssueBrief.pdf.

A Harvard study, funded by March of Dimes, looked at implications of overturning the ACA for low income, reproductive age women. It found that coverage, especially by Medicaid, receipt of treatment, and use of prescription drugs (in particular, psychotherapeutic agents, and hormones and hormone modifiers) would likely decrease, putting the health and wellbeing of low income, reproductive age women at further risk and increase risk for poor birth outcomes. L. Chen, R.G. Frank, H.A. Huskamp, Technical Memo on Coverage Expansion and Low-Income, Reproductive-Age Women, HARVARD UNIV. (Apr. 14, 2020),

https://hcp.hms.harvard.edu/technical-memo-coverage-expansion-and-low-income-reproductive-age-women.

The ACA also made positive changes for people with hemophilia and other bleeding disorders. As ACA implementation approached, 22% of patients and 58% of health care providers reported that the ACA's elimination of lifetime caps would allow them to initiate treatment decisions they had previously delayed. Tarantino, supra, at 55-56. Additional ACA changes—prohibiting annual limits on coverage for essential benefits, offering coverage for uninsured with pre-existing conditions. individuals expanding Medicaid eligibility—were also recognized as beneficial to people with hemophilia. Dan Dalton, Hemophilia in the Managed Care Setting, 21 Am. J. OF MANAGED CARE S123. S128 (Apr. 1. https://www.ajmc.com/journals/supplement/2015/ace0 024 mar15 hemophiliace/ace0024 mar15 hemophili a dalton?p=3.

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

III. INVALIDATION OF THE ACA WOULD IGNORE CONGRESS'S POLICY-BASED DECISION TO PRESERVE THE ACA BECAUSE IT 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 was not lost. If the ACA were eliminated entirely, the number of uninsured Americans would increase by 19.9 million (or 65 Linda J. Blumberg et al., State-by-State percent). Estimates of Coverage and Funding Consequences of Full Repeal of the ACA, URBAN INST.: HEALTH POL'Y CTR., (Mar. 2019), https://www.urban.org/sites/default/files/publication/1 00000/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).

Congress was unwilling to leave millions without coverage in a "repeal-without-replace" scenario. Congress chose to leave the rest of the Act intact even while zeroing out the individual mandate. By invalidating the ACA in its entirety, the district 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. The Fifth Circuit's decision to remand the severability analysis rather than promptly give effect to Congress's express intent continues that threat by maintaining substantial uncertainty around the law.

In enacting the ACA, Congress was aware of—and relied upon—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.").

This Court 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, 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, 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 Insuring America's Health, Principles & Recommendations, INST. OF MED.. 43 (2004).https://www.nap.edu/catalog/10874/insuringamericas-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 the legislature.

CONCLUSION

Congress, in altering only one, discrete provision of the ACA, expressly chose not to repeal the whole Act and its important provisions designed to provide access to health care. The ACA operates to help patients and survivors of chronic diseases and conditions—exactly as Congress intended—and has continued to do so even after altering the individual mandate while leaving the rest of the Act in place. For the foregoing reasons, *Amici* respectfully request the Court reverse the Fifth Circuit's ruling, and give effect to Congress's clearly expressed intent to leave the Act in place.

Respectfully submitted,

John Longstreth
Counsel of Record
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
Claire Piepenburg
K&L GATES LLP
1717 Main Street, Suite 2800
Dallas, Texas 75201
(214) 939-5500
Beth.Petronio@klgates.com
Adam.Cooper@klgates.com
Claire.Piepenburg@klgates.com

Counsel for All Amici Curiae

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

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

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

Dale G. Nissenbaum

Executive Vice President &
General Counsel
THE LEUKEMIA & LYMPHOMA
SOCIETY
3 International Drive
Rye Brook, NY 10573
(914) 821-8824
Dale.Nissenbaum@lls.org
Co-Counsel for Amici LLS

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

Eric Hilty
Chief Legal Officer
NATIONAL MULTIPLE
SCLEROSIS SOCIETY
900 S. Broadway, 2nd Floor
Denver, CO 80209
(303) 698-6100
Eric.Hilty@nmss.org
Co-Counsel for Amici
National MS Society