

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

ASSOCIATION FOR COMMUNITY AFFILIATED
PLANS,

ET AL.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF TREASURY,

ET AL.,

Defendants.

No. 1:18-cv-02133, Hon. Richard J. Leon

**BRIEF OF AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN
LUNG ASSOCIATION, CYSTIC FIBROSIS FOUNDATION, EPILEPSY
FOUNDATION, GLOBAL HEALTHY LIVING FOUNDATION, HEMOPHILIA
FEDERATION OF AMERICA, LEUKEMIA & LYMPHOMA SOCIETY, MARCH OF
DIMES, NATIONAL COALITION FOR CANCER SURVIVORSHIP, AND NATIONAL
MULTIPLE SCLEROSIS SOCIETY AS AMICI CURIAE
SUPPORTING MOTION FOR PRELIMINARY INJUNCTION**

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Cases

Nat’l Fed. of Indep. Bus. v. Sebelius,
567 U.S. 519 (2012).....6

Statutes and Regulations

42 U.S.C. § 300gg-1(a).....12

42 U.S.C. § 300gg-6(a).....12

42 U.S.C. §§ 18022.....12

Expected Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance, 81 Fed. Reg. 75,316 (Oct. 31, 2016).....14

Proposed Rule, Short-Term, Limited-Duration Insurance, 83 Fed. Reg. 7,437 (Feb. 21, 2018).....13

Final Rule, Short-Term, Limited-Duration Insurance, 83 Fed. Reg. 38,212 (Aug. 3, 2018).....14, 15, 16, 18

Other Authorities

Ahmedin Jamal et al., *Changes in Insurance Coverage and Stage at Diagnosis Among Nonelderly Patients With Cancer After the Affordable Care Act*, 35 J. CLINICAL ONCOLOGY 3906 (2007)12

Am. Cancer Soc’y Cancer Action Network, *A National Poll: Facing Cancer in the Health Care System* (2012), https://www.fightcancer.org/sites/default/files/National%20Documents/ACS_CAN_Polling_Report_7.27.10.pdf8

American Cancer Society, *Cancer Facts and Figures 2018*, <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>6, 9, 17

Andrew P. Wilper et al., *Health Insurance And Mortality in US Adults*, 99 AM. J. PUB. HEALTH 2289 (2009)7, 8, 9

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).....8

Benjamin D. Sommers et al., *Early Changes in Health Insurance Coverage under the Trump Administration*, 378 NEW ENG. J. MED. 1061-63 (2018)12

C.E Belgley & T.L. Durgin, *The direct costs of epilepsy in the United States: A systemic review of estimates*, 56 EPILEPSIA 1376-87 (2015)10

C.J. Berg et al., *Preventability of pregnancy-related deaths: results of a state-wide review*, 8 OBSTET. GYNECOL. 1228-34 (2005)11

CDC, *Severe Maternal Morbidity*,
<https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html>11

Centers for Disease Control and Prevention, *Improving the Quality of Life for People With Arthritis*,
<https://www.cdc.gov/chronicdisease/resources/publications/aag/arthritis.htm>6

Centers for Medicare and Medicaid Services, *County by County Analysis of Current Projected Insurer Participating in Health Insurance Exchanges* (June 2017), <https://www.cms.gov/newsroom/press-releases/county-county-analysis-current-projected-insurer-participation-health-insurance-exchanges>17

Daniel M. Hartung, *Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA*, 14:4 NEUROTHERAPEUTICS 1018 (2017)10

David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741 (2009).....7

Disease Control and Prevention, *National Health Interview Survey, 2016* (June 2017)6

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 (2010)8, 9, 17

Elizabeth Ward et al., *Association of Insurance with Cancer Care Utilization and Outcomes*, 58 CANCER J. FOR CLINICIANS 9 (2018)8

Emilia J. Benjamin et al., *Heart Disease and Stroke Statistics—2018 Update*, AHA STATISTICAL UPDATE (2018),
<https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000558>.6

Fanny W.S. Ko et al., *COPD Care Programme Can Reduce Readmissions and In-Patient Bed Days*, 108:12 RESPIRATORY MED. 1771-8 (2014).....9, 10

Jay J. Shen & Elmer Washington, *Disparities in Outcomes Among Patients with Stroke Associated with Insurance Status*, 38 STROKE 1010 (2007).....9

John T. Wilkins et al., *Lifetime Risk and Years Lived Free of Total Cardiovascular Disease*, 308 J. AM. MED. ASS’N 1795 (2012).....6

Joyce A. Martin et al., *Births: Final Data for 2016*, NATIONAL VITAL STATISTICS REPORTS (Jan. 2018), https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf.....7

Kaiser Family Foundation et al., *National Survey of Household Affect by Cancer* (November 2006), <https://www.kff.org/health-costs/poll-finding/usa-todaykaiser-family-foundationharvard-school-of-public-2>12

Karen Pollitz et al., *Understanding Short-Term Limited-Duration Health Insurance* (Apr. 23, 2018), <https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance>14, 15

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)9

Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374:9 NEW ENG. J. MED. 843-52 (2016)16

Linda J. Blumberg et al., *Updated: The Potential Impact of Short-Term Limited-Duration Policies on Insurance Coverage, Premiums, and Federal Spending*, URBAN INSTITUTE (March 2018), https://www.urban.org/sites/default/files/publication/96781/2001727_updated_finalized.pdf14, 17

M. M. Doty et al., *Failure to Protect: Why the Individual Insurance Market is not a Viable Option for Most US Families*, THE COMMONWEALTH FUND (July 2009), http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2009/Jul/Failure%20to%20Protect/1300_Doty_failure_to_protect_individual_ins_market_ib_v2.pdf11, 12

March of Dimes, *Affordable Care is Essential to Moms and Babies* (2017), <https://www.marchofdimes.org/advocacy/affordable-care-is-essential-to-moms-and-babies.aspx>.....12

March of Dimes, *Maternal Mortality and Severe Maternal Morbidity* (June 2018), <https://www.marchofdimes.org/materials/March-of-Dimes-Maternal-Mortality-and-SMM-Position-Statement-FINAL-June-2018.pdf>11

March of Dimes, *Peristats*, <https://www.marchofdimes.org/Peristats/ViewSubtopic.aspx?reg=99&top=3&stop=64&lev=1&slev=1&obj=18>11

MMRIA, *Report From Nine Maternal Mortality Review Committees* (Feb. 2018)10, 11

Multiple Sclerosis Coalition, *The Use of Disease Modifying Therapies in MS: Principles and Current Evidence* (2014),
https://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color10

National Institute of Environmental Health Sciences, *Autoimmune Diseases*,
<https://www.niehs.nih.gov/health/topics/conditions/autoimmune/index.cfm>.....7

National Multiple Sclerosis Society, *MS Prevalence*,
<https://www.nationalmssociety.org/About-the-Society/MS-Prevalence>7

P.G. Szilagyi et al, *Improved Asthma Care After Enrollment in the State Children’s Health Insurance Program in New York*, 117:2 PEDIATRICS 486-96 (2006).....9

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)13

Scott Ramsey et al., *Washington State Cancer Patients Found to be at Greater Risk for Bankruptcy than People Without a Cancer Diagnosis*, 32:6 HEALTH AFF. 1143 (June 2013)7

Stacy A. Fedewa et al., *Association of Insurance Status and Age with Cervical Cancer Stage at Diagnosis: National Cancer Database, 2000-2007*, 102 AM. J. PUB. HEALTH 1782 (2012).....8

Tefera Gezmu et al., *Disparities in Acute Stroke Severity, Outcomes, and Care Relative to Health Insurance Status*, 23 J. STROKE & CEREBROVASCULAR DISEASE 93 (2014)9

Zheng-Yi Zhou et al., *Burden of Illness: Direct and Indirect Costs Among Persons with Hemophilia A in the United States*, 18 J. MED. ECON. 1 (2015) 7

INTEREST OF AMICI CURIAE¹

The American Cancer Society (ACS), American Cancer Society Cancer Action Network (ACS CAN), American Heart Association (AHA), American Lung Association (ALA), Cystic Fibrosis Foundation (CFF), Epilepsy Foundation, Global Healthy Living Foundation (GHLF), Hemophilia Federation of America (HFA), Leukemia & Lymphoma Society (LLS), March of Dimes, National Coalition for Cancer Survivorship (NCCS), and National Multiple Sclerosis Society (NMMS) (collectively, “Amici”) represent millions of patients and consumers across the country facing serious, acute, and chronic health conditions. Many of Amici participated in the underlying rulemaking proceeding. Amici have a unique perspective on what individuals and families need to prevent disease, manage health, and cure illness—and a deep understanding of the harm that will result if the short-term, limited-duration insurance rule is allowed to take effect.

ACS is a 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 lack of adequate insurance coverage is a major impediment to advancing the fight against cancer. Along with its nonpartisan advocacy affiliate ACS CAN, which has over a million patient and survivor advocates nationwide, ACS seeks to secure affordable, adequate, and accessible health insurance for all Americans.

¹ All parties have consented to the filing of this amicus curiae brief. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of the brief. No person other than amici curiae or their counsel made a monetary contribution to the preparation or submission of this brief.

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 has worked to represent the needs and interests of heart disease and stroke patients and advocated making health care more affordable.

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 CFF's 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 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 access to

quality, affordable, physician-directed care and effective coverage for epilepsy medications critically vital for people living with epilepsy.

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.

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.

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.

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 NMSS mobilizes people and resources so that everyone affected by multiple sclerosis (MS) can live their best lives, while also seeking to 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. The NMSS works to ensure that all people with MS have access to affordable high quality health care.

Amici are all deeply concerned about the effect the short-term, limited-duration insurance rule will have on the individuals and families they represent. As a direct result of the rule, many individuals will find themselves unable to access the medical care they need. Amici submit this brief to assist the court in understanding the nature and extent of this harm.

INTRODUCTION

Short-term, limited-duration insurance plans are intended to address temporary gaps in coverage between other, more comprehensive plans. Given their stop-gap nature, these plans are not required to adhere to important standards set forth in the Patient Protection and Affordable Care Act (ACA). These critical standards include requirements to cover certain essential health benefits without lifetime or annual limits and prohibitions on discrimination against people with pre-existing conditions.

In the challenged rule, the Departments of Treasury, Labor, and Health and Human Services (collectively, “the Departments”) have authorized a vast increase in the use of such plans. The rule allows short-term, limited-duration plans to be sold for a term of up to a year, to be renewed for up to 36 months, and to be purchased *seriatim* indefinitely. It thus effectively authorizes these plans to serve as complete replacements for the generally accessible and comprehensive plans sold in ACA-created markets.

By permitting insurers to evade the ACA’s protections, the rule has two predictable effects—each of which the Departments openly acknowledge. First, many individuals who purchase short-term plans will find themselves enrolled in policies that fail to provide coverage for necessary medical services. Second, many others who do not (or cannot) purchase such plans will suffer downstream effects when healthier individuals leave the ACA-compliant individual insurance markets to opt for short-term plans. These effects include higher premiums and, in some circumstances, an inability to access coverage at all.

Amici agree with plaintiffs that they are likely to succeed in showing that the challenged rule is both inconsistent with the text and purpose of the ACA and is arbitrary and capricious. *See* Motion for Preliminary Injunction at 12-32. In this brief, however, Amici highlight the harms that are all but certain to follow if the rule is allowed to stand. *See id.* at 32-39 (irreparable harm), 39-41 (balancing of the equities). As detailed below, the availability of affordable, accessible, and adequate health insurance is critical to health outcomes. The challenged rule, however, ensures that a greater number of individuals will purchase plans that deny coverage for, and thereby deny access to, critical treatments if and when they are needed, and that individuals with existing health conditions will incur greater expense in accessing the

treatment they need. In so doing, the rule poses a very real threat to the health of many millions of Americans.

ARGUMENT

I. Adequate Insurance Is Critical To Health Outcomes

Nearly everyone will require health care at some point in their lives. *See Nat'l Fed. of Indep. Bus. v. Sebelius*, 567 U.S. 519, 547 (2012). That much is apparent even from looking at just a subset of the diseases on which Amici focus. An estimated 1.7 million Americans will be diagnosed with cancer in 2018, while more than 15.5 million Americans have a history of cancer. American Cancer Society, *Cancer Facts and Figures 2018*, at 1.² Roughly four out of ten Americans will develop cancer in their lifetimes. *Id.* at 2. An additional 92.1 million American adults are living with cardiovascular diseases, while 131.9 million Americans are projected to have cardiovascular disease by 2035. Emilia J. Benjamin et al., *Heart Disease and Stroke Statistics—2018 Update*, AHA STATISTICAL UPDATE (2018).³ The lifetime risk for developing cardiovascular disease of those free of known disease at age 45 is almost two in three for men and greater than one in two for women. John T. Wilkins et al., *Lifetime Risk and Years Lived Free of Total Cardiovascular Disease*, 308 J. AM. MED. ASS'N 1795, 1798 (2012). Another 54 million Americans have arthritis, 33.6 million have some form of chronic lung disease, and 23.5 million suffer from autoimmune diseases, including nearly one million with multiple sclerosis (MS). Centers for Disease Control and Prevention, *Improving the Quality of Life for People With Arthritis*⁴, Centers for Disease Control and Prevention, *National Health Interview Survey, 2016* (June 2017) (analysis by ALA Epidemiology and Statistics Unit using SPSS Software);

² <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>.

³ <https://www.ahajournals.org/doi/pdf/10.1161/CIR.0000000000000558>.

⁴ <https://www.cdc.gov/chronicdisease/resources/publications/aag/arthritis.htm>

National Multiple Sclerosis Society, *MS Prevalence*⁵; National Institute of Environmental Health Sciences, *Autoimmune Diseases*.⁶ And approximately four million babies are born in the U.S. every year. Joyce A. Martin et al., *Births: Final Data for 2016*, NATIONAL VITAL STATISTICS REPORTS (Jan. 2018).⁷

Absent insurance, the cost of treatment for these conditions is beyond the reach of all but the wealthiest individuals. For example, treatment for an individual with severe hemophilia A (but no complications), averages over \$300,000 per year, and must continue for the individual's lifetime. Zheng-Yi Zhou et al., *Burden of Illness: Direct and Indirect Costs Among Persons with Hemophilia A in the United States*, 18 J. MED. ECON. 1, 6 (2015).⁸ One 2013 study found that cancer patients were more than two and a half times as likely to file for bankruptcy as people without cancer. Scott Ramsey et al., *Washington State Cancer Patients Found to be at Greater Risk for Bankruptcy than People Without a Cancer Diagnosis*, 32:6 HEALTH AFF. 1143, 1147-48 (June 2013).⁹ Cardiovascular disease is also 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).

As one might expect, health outcomes improve when individuals have access to insurance adequate to cover the treatment they need. One 2009 Harvard Medical School study found that approximately 45,000 deaths annually could be attributed to the lack of health insurance among working-age Americans. Andrew P. Wilper et al., *Health Insurance And*

⁵ <https://www.nationalmssociety.org/About-the-Society/MS-Prevalence>

⁶ <https://www.niehs.nih.gov/health/topics/conditions/autoimmune/index.cfm>

⁷ https://www.cdc.gov/nchs/data/nvsr/nvsr67/nvsr67_01.pdf.

⁸ <https://scholarship.org/uc/item/5d79b9fc>.

⁹ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.1263>

Mortality in US Adults, 99 AM. J. PUB. HEALTH 2289, 2292 (2009). These uninsured individuals had a 40 percent higher risk of death than their privately insured counterparts. *Id.*

The increased risks associated with inadequate health insurance stem from a variety of factors. For cancer patients, early detection and treatment is key. But an ACS CAN poll conducted before passage of the ACA found that 34 percent of individuals under the age of 65 with cancer or a history of cancer had delayed care because of cost in the preceding twelve months. Am. Cancer Soc’y Cancer Action Network, *A National Poll: Facing Cancer in the Health Care System* (2012), at 17.¹⁰ And at all levels of education, individuals with health insurance are nearly twice as likely to have access to critical cancer early-detection procedures, such as mammography or colorectal screenings. Elizabeth Ward et al., *Association of Insurance with Cancer Care Utilization and Outcomes*, 58 CANCER J. FOR CLINICIANS 9, 21 (2018).

Insured patients’ access to preventive care has a notable impact. One study found that of those between the ages of 15 to 39, uninsured females are nearly twice as likely, and uninsured males are nearly 1.5 times as likely, to be diagnosed with cancer that has already metastasized. 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, 1214 (2014). Other studies demonstrate that uninsured patients are 1.4 times more likely to be diagnosed with advanced-stage cervical cancer, two times more likely to be diagnosed with advanced-stage breast cancer, and 1.3 times more likely to be diagnosed with colorectal cancer. Stacy A. Fedewa et al., *Association of Insurance Status and Age with Cervical Cancer Stage at Diagnosis: National Cancer Database, 2000-2007*, 102 AM. J. PUB. HEALTH 1782, 1784-85 (2012); Elizabeth M. Ward et al., *The*

¹⁰ https://www.fightcancer.org/sites/default/files/National%20Documents/ACS_CAN_Pollin_g_Report_7.27.10.pdf.

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). The five-year survival rates of those diagnosed at later stages are significantly lower than the rates for those diagnosed when their cancer is less advanced. American Cancer Society, *Cancer Facts & Figures 2018* at 21.¹¹

The story is similar for lung and heart disease. Even during a heart attack, uninsured patients are more likely to delay seeking medical care. Kim G. Smolderen et al., *Health Care Insurance, Financial Concerns in Accessing Care, and Delays to Hospital Presentation in Acute Myocardial Infarction*, 303 *J. AM. MED. ASS'N* 1392, 1395-99 (2010). Uninsured patients with cardiovascular disease experience higher mortality rates and poorer blood pressure control than their insured counterparts. 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); Andrew P. Wilper et al., *Health Insurance and Mortality in US Adults*, 99 *AM. J. PUB. HEALTH* 2289, 2292 (2009). Uninsured patients who suffer an ischemic stroke (the most common type of stroke) experience greater neurological impairments, longer hospital stays, and up to a 56 percent higher risk of death. Jay J. Shen & Elmer Washington, *Disparities in Outcomes Among Patients with Stroke Associated with Insurance Status*, 38 *STROKE* 1010, 1013 (2007). Children with asthma experience worse health outcomes when they lack access to health insurance, including increases in asthma-related attacks and hospitalizations. P.G. Szilagyi et al., *Improved Asthma Care After Enrollment in the State Children's Health Insurance Program in New York*, 117:2 *PEDIATRICS* 486-96 (2006). And the ability to access management programs for chronic obstructive pulmonary disease reduces hospital readmissions. See Fanny W.S. Ko et al.,

¹¹ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>

COPD Care Programme Can Reduce Readmissions and In-Patient Bed Days, 108:12 RESPIRATORY MEDICINE 1771-8 (2014).

Individuals with chronic diseases like MS, cystic fibrosis, and epilepsy likewise experience improved results when they have access to adequate insurance. Most people with MS are diagnosed between the ages of 20 and 50, and early treatment is critical. Comment of National Multiple Sclerosis Society, Apr. 23, 2018, at 1 [“NMSS Comment”]; Multiple Sclerosis Coalition, *The Use of Disease Modifying Therapies in MS: Principles and Current Evidence* (2014).¹² MS patients face a reduction in survival of between 8 to 12 years if they do not receive proper treatment, but few can afford the \$70,000 annual cost of such treatment without health insurance. *Id.*; see Daniel M. Hartung, *Economics and Cost-Effectiveness of Multiple Sclerosis Therapies in the USA*, 14:4 NEUROTHERAPEUTICS 1018 (2017). Similarly, individuals with cystic fibrosis risk further progression of their disease and its symptoms if cost concerns force them to take less medication or delay care. Comment of Cystic Fibrosis Foundation, April 23, 2018, at 5. And total annual healthcare costs for the 1 in 26 Americans who develop epilepsy in their lifetimes can be up to \$48,000—treatment that is critical for such individuals to reduce their risk of accident, injury, or sudden unexpected death in epilepsy (SUDEP). C.E Belgley & T.L. Durgin, *The direct costs of epilepsy in the United States: A systemic review of estimates*, 56 EPILEPSIA 1376-87 (2015).

Access to health insurance is also crucial for pregnant women and their children. Nearly 700 women in the U.S. die each year as a result of pregnancy or pregnancy-related complications, and up to 60% of these deaths are preventable. MMRIA, *Report From Nine*

¹² https://www.nationalmssociety.org/getmedia/5ca284d3-fc7c-4ba5-b005-ab537d495c3c/DMT_Consensus_MS_Coalition_color

Maternal Mortality Review Committees (Feb. 2018);¹³ C.J. Berg et al., *Preventability of pregnancy-related deaths: results of a state-wide review*, 8 OBSTET. GYNECOL. 1228-1234 (2005). Another 50,000 women annually experience severe maternal morbidity. CDC, *Severe Maternal Morbidity*.¹⁴ Access to adequate insurance is critical to reduce these preventable deaths and pregnancy-related complications. March of Dimes, *Maternal Mortality and Severe Maternal Morbidity* (June 2018).¹⁵ Similarly, insurance is essential for the pre- and post-natal care that can ensure that every child is able to reach his or her full potential. Comment of American Academy of Pediatrics et al., April 23, 2018, at 3. That is particularly true of the tens of thousands of babies born every year very preterm (less than 32 weeks), who may require weeks or months of intensive hospital care. March of Dimes, *Peristats*.¹⁶

II. The ACA Was Intended To Ensure Greater Access To Adequate Health Care

The ACA sought to guarantee Americans meaningful access to adequate health insurance and the improved outcomes such insurance entails. Two particular aspects of the ACA are important here.

First, ACA-compliant plans are prohibited from engaging in various forms of discrimination that proliferated before passage of the Act. Before the statute took effect, for example, individuals with serious health conditions were often denied coverage or charged higher rates for their coverage. M. M. Doty et al., *Failure to Protect: Why the Individual Insurance Market is not a Viable Option for Most US Families*, THE COMMONWEALTH FUND

¹³ <https://www.cdcfoundation.org/building-us-capacity-review-and-prevent-maternal-deaths>

¹⁴ <https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html>

¹⁵ <https://www.marchofdimes.org/materials/March-of-Dimes-Maternal-Mortality-and-SMM-Position-Statement-FINAL-June-2018.pdf>

¹⁶ <https://www.marchofdimes.org/Peristats/ViewSubtopic.aspx?reg=99&top=3&stop=64&lev=1&slev=1&obj=18>

(July 2009).¹⁷ The ACA, however, prohibits insurers from denying coverage based on pre-existing conditions—ensuring that those most in need of care are nevertheless able to purchase insurance. 42 U.S.C. § 300gg-1(a).

Second, ACA-compliant plans must provide what are known as “essential health benefits.” *Id.* § 300gg-6(a). These “essential health benefits” encompass a number of necessary medical services, including “[p]reventive and wellness services,” “[m]aternity and newborn care,” and “[p]rescription drugs.” *Id.* § 18022(b). ACA-compliant plans are prohibited from imposing any lifetime or annual limits on coverage of “essential health benefits.” *Id.* §§ 18022(c), (d). Before the ACA, as many as one in ten cancer patients reported reaching the limit of what their insurance plans would pay for their cancer treatment, at which point they were effectively uninsured for their illness. Kaiser Family Foundation et al., *National Survey of Household Affect by Cancer* (November 2006).¹⁸ Similarly, only 13% of health plans in the individual market covered maternity care. March of Dimes, *Affordable Care is Essential to Moms and Babies* (2017).¹⁹

With these and other measures making insurance more accessible, uninsured rates have dropped significantly. Benjamin D. Sommers et al., *Early Changes in Health Insurance Coverage under the Trump Administration*, 378 *NEW ENG. J. MED.* 1061-63 (2018). This increase in coverage has already had a positive effect on health outcomes. One study found a small but statistically significant shift toward early-stage diagnosis for colorectal cancer, lung cancer, female breast cancer, pancreatic cancer, and melanoma. Ahmedi Jemal et al., *Changes*

¹⁷ http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2009/Jul/Failure%20to%20Protect/1300_Doty_failure_to_protect_individual_ins_market_ib_v2.pdf.

¹⁸ <https://www.kff.org/health-costs/poll-finding/usa-todaykaiser-family-foundationharvard-school-of-public-2>

¹⁹ <https://www.marchofdimes.org/advocacy/affordable-care-is-essential-to-moms-and-babies.aspx>

in Insurance Coverage and Stage at Diagnosis Among Nonelderly Patients With Cancer After the Affordable Care Act, 35 J. CLINICAL ONCOLOGY 3906 (2017). Another demonstrated the ACA's positive effect on the initiation and completion of the human papillomavirus (HPV) vaccination, early diagnosis and receipt of fertility-sparing treatments for cervical cancer, and increased early-stage diagnoses for other forms of cancer among adults aged 19 to 25. Xuesong Han & Ahmedin Jemal, *the Affordable Care Act and Cancer Care for Young Adults*, 20:3 J. CANCER 194 (2017). Overall, the proportion of cancer survivors reporting delayed or foregone care significantly decreased between 2010 and 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).

III. The Challenged Rule Will Allow Short-Term, Limited-Duration Plans To Proliferate

The challenged rule will upend this progress toward greater coverage and better health outcomes. It does so by permitting insurers to evade the ACA's requirements through the sale of short-term, limited-duration plans.

As the name suggests, short-term, limited-duration insurance is intended to be *temporary*: it is a "type of health insurance coverage that was designed to fill temporary gaps in coverage that may occur when an individual is transitioning from one plan or coverage to another plan or coverage." Proposed Rule, Short-Term, Limited-Duration Insurance, 83 Fed. Reg. 7,437, 7,443 (Feb. 21, 2018). Such temporary plans are exempt from many of the ACA's requirements, including the requirement to provide coverage for "essential health benefits" without annual or lifetime limits, and the prohibitions against discrimination based on pre-existing conditions. Thus, such plans do not cover many routine medical services, impose limits on the total amount of services they will cover, and exclude many consumers (*i.e.*, those with preexisting conditions)

entirely. *See* Karen Pollitz et al., *Understanding Short-Term Limited-Duration Health Insurance* (Apr. 23, 2018).²⁰ For these reasons, premiums for such plans tend to be lower. To ensure that these short-term plans remain temporary, and do not supplant ACA-compliant policies, the Departments previously had issued a rule limiting their term to three months and allowing them to be extended only a total of 12 months. *Expected Benefits; Lifetime and Annual Limits; and Short-Term, Limited-Duration Insurance*, 81 Fed. Reg. 75,316 (Oct. 31, 2016).

The challenged rule now makes these “short-term” policies long-term. Under the rule, a plan with a contract term of up to 364 days—one day less than an ACA-qualified health plan—counts as “short-term.” *Final Rule, Short-Term, Limited-Duration Insurance*, 83 Fed. Reg. 38,212, 38,214-15 (Aug. 3, 2018). Such plans may also be renewed for a total of 36 months. *Id.* at 38,215. And consumers may stack one 36-month “short-term, limited-duration” contract on top of another indefinitely. *Id.* at 38,222. One study estimated that as many as 4.3 million people will enroll in these expanded, effectively indefinite, short-term plans. Linda J. Blumberg et al., *Updated: The Potential Impact of Short-Term Limited-Duration Policies on Insurance Coverage, Premiums, and Federal Spending*, URBAN INSTITUTE (March 2018).²¹

IV. The Challenged Rule Will Have Acknowledged Harmful Effects

The challenged rule will have two predictable consequences: relatively younger and healthier people will be more likely to purchase short-term, limited-duration insurance plans instead of ACA-compliant policies; and those who purchase or retain ACA-compliant policies will likely face higher premiums and diminished access. Both of these effects are acknowledged

²⁰ <https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance>

²¹ https://www.urban.org/sites/default/files/publication/96781/2001727_updated_finalized.pdf

in the final rule itself. *E.g.*, Final Rule, 83 Fed. Reg. at 38,217, 38,235. Both consequences would cause very real harm to individuals in need of medical care.

First, the rule will lead many individuals who purchase short-term plans to lack the coverage they need if and when medical care is necessary. As Amici explained in their comments on the proposed rule, many consumers may purchase these short-term plans without realizing they do not cover benefits these consumers will need, such as preventive services, maternity care, or new cancer care. *E.g.*, Comment of American Cancer Society Cancer Action Network, April 20, 2018, at 7 [“ACS CAN Comment”]. Other individuals may purchase these plans because they are unaware that their preexisting conditions will preclude them from securing the treatment they need. *E.g.*, Comment of American Cancer Society Cancer Action Network et al., April 23, 2018, at 6 [“Joint Comment”]. And still others may find themselves with unexpected medical needs that are not covered by these short-term policies—leaving them with a gap in critical coverage until the open enrollment period for ACA-compliant policies. *E.g.*, Comment of American Lung Association, April 23, 2018, at 2 [“ALA Comment”]; Karen Pollitz et al., *Understanding Short-Term Limited-Duration Health Insurance* (Apr. 23, 2018)²² (no available short-term plans cover maternity care). Such concerns are magnified because insurance brokers have in the past fraudulently misled consumers into believing that short-term plans are ACA-compliant. ACS CAN Comment at 9; Comment of Federal AIDS Policy Partnership, April 23, 2018, at 3.

The Departments themselves have recognized these likely impacts. In the final rule, the Departments expressly note that “consumers who switch to such policies from individual market plans will experience loss of third-party payments for some services and providers and

²² <https://www.kff.org/health-reform/issue-brief/understanding-short-term-limited-duration-health-insurance>

potentially an increase in out-of-pocket expenditures,” and that “consumers who purchase short-term limited-duration insurance policies and then develop chronic conditions may face financial hardship as a result.” Final Rule, 83 Fed. Reg. at 38,231. The Departments further acknowledge that “those individuals who lose coverage in these plans may not qualify for a special enrollment period in the individual market and may face a period of time in which they have no medical coverage.” *Id.*

Yet—aside from noting that notice requirements and state regulations may eliminate some consumer confusion, *e.g.*, *id.* at 38,219—the Departments provide no basis to disregard these very real harms. Instead, they rely on the repeated refrain that the rule “empowers consumers to make decisions.” *E.g.*, *id.* at 38,232. But consumers often have an insufficient understanding of the complex health insurance market and may lack sufficient information about plan limitations to make informed decisions. And even if fully informed, many individuals will fail to anticipate *unexpected* health care needs. For example, fully 45% of pregnancies in the U.S. are unplanned. *See* Lawrence B. Finer & Mia R. Zolna, *Declines in Unintended Pregnancy in the United States, 2008-2011*, 374:9 NEW ENG. J. MED. 843-52 (2016). Likewise, most cancer diagnoses are unexpected by the individual being diagnosed; and about 1.7 million people will be diagnosed with cancer in 2018. ACS CAN Comment at 1. Some individuals with short-term, limited-duration insurance will be unable to afford the care needed to respond to such a life-threatening diagnosis, and they will be forced to push off treatment for the months it may take to secure adequate coverage or will face serious financial hardship and potential bankruptcy paying for their care. ALA Comment at 2 (“disease does not pay attention to a calendar”). Delaying treatment may be all the more problematic if, because of short-term plans’ lack of coverage for preventive services, these diagnoses occur at a later stage. As explained above

(*supra* pp. 8-9), such delays can be the difference between life and death. *E.g.*, 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); American Cancer Society, *Cancer Facts & Figures 2018* at 21.²³

Second, allowing short-term plans to proliferate will undermine the stability of the markets for ACA-compliant plans, to the detriment of those who purchase them. That is because short-term, limited-duration plans will attract relatively younger and healthier individuals, leaving relatively older and sicker individuals in the risk pool for ACA-compliant plans. Joint Comment at 6. Premiums for these comprehensive, available-to-all plans will rise as a result. Indeed, one study estimated that, between the elimination of the individual mandate and the Department's expansion of short-term, limited-duration policies, premiums for consumers who remain in the ACA-compliant individual markets in those states that do not counteract the challenged rule will increase by an average of 18.3 percent. Linda J. Blumberg et al., *Updated: The Potential Impact of Short-Term Limited-Duration Policies on Insurance Coverage, Premiums, and Federal Spending*, URBAN INSTITUTE (March 2018).²⁴ Moreover, in some cases, issuers might opt to leave the market rather than insure this increasingly high-risk pool, leaving certain particularly vulnerable populations without access to coverage at all. ACS CAN Comment at 6; *see* Centers for Medicare and Medicaid Services, *County by County Analysis of Current Projected Insurer Participating in Health Insurance Exchanges* (June 2017) (many counties were already projected to have only one issuer).²⁵

²³ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>

²⁴ https://www.urban.org/sites/default/files/publication/96781/2001727_updated_finalized.pdf

²⁵ <https://www.cms.gov/newsroom/press-releases/county-county-analysis-current-projected-insurer-participation-health-insurance-exchanges>

Although the Departments attempted to minimize the extent of these impacts (*e.g.*, Final Rule, 83 Fed. Reg. at 38,236), they did not deny the rule will negatively affect individual markets. To the contrary, they expressly acknowledged the rule may lead to an “increase in premiums for individual market plans.” *Id.* at 38,233. They further admitted that “due to the potential increase in risk segmentation, in which healthier individuals choos[ing] products outside the individual market may result in an individual market risk pool with higher medical expenses, it is possible that fewer issuers may offer plans in the individual market.” *Id.*

These increases in premiums, and decreases in availability, will fall particularly hard on those with significant medical needs. Indeed, while the Departments tout that the rule “empowers consumers to make decisions,” *id.* at 38,232, individuals with chronic or other serious health conditions have no such choice. Because they need comprehensive care, and because issuers of short-term plans are empowered to discriminate against those with preexisting conditions, such individuals will remain reliant on their ability to secure ACA-compliant plans. *See, e.g.*, NMSS Comment at 2 (“The medical underwriting process that applications for [short-term, limited-duration] plans would be subject to virtually assures no application from a person with MS would be approved.”); ALA Comment at 2 (“Current lung disease patients, including kids with asthma, lung cancer survivors and patients with [chronic obstructive pulmonary disease], would be rejected for coverage by one of these plans, instead paying more for the comprehensive care they need in order to access physicians, medications, and other treatments and services to stay healthy and manage their conditions.”). Accordingly, because of the challenged rule, some of the individuals most in need of comprehensive care will find themselves unable to afford treatment. They will likely suffer substantial harm as a result. *See supra* pp. 7-13.

CONCLUSION

For the foregoing reasons, Amici respectfully submit that the court should grant plaintiffs' request for a preliminary injunction.

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APPENDIX: LIST OF AMICI CURIAE

1. American Cancer Society (ACS)
2. American Cancer Society Cancer Action Network (ACS CAN)
3. American Heart Association (AHA)
4. American Lung Association (ALA)
5. Cystic Fibrosis Foundation (CFF)
6. Epilepsy Foundation
7. Global Healthy Living Foundation (GHLF)
8. Hemophilia Federation of America (HFA)
9. Leukemia & Lymphoma Society (LLS)
10. March of Dimes
11. National Coalition for Cancer Survivorship (NCCS)
12. National Multiple Sclerosis Society (NMMS)

CERTIFICATE OF SERVICE

I hereby certify that on October 8, 2018, I filed this Motion with the United States District Court for the District of Columbia using the CM/ECF system, which will cause it to be served on all counsel of record.

Dated: October 8, 2018

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