No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT, INCORPORATED; JOHN SCOTT KELLEY; KELLEY ORTHODONTICS; ASHLEY MAXWELL; ZACH MAXWELL; JOEL STARNES,

Plaintiffs - Appellees/Cross-Appellants,

JOEL MILLER; GREGORY SCHEIDEMAN,

Plaintiffs - Cross-Appellants,

v.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, IN HIS OFFICIAL CAPACITY AS SECRETARY OF HEALTH AND HUMAN SERVICES; UNITED STATES OF AMERICA; JANET YELLEN, SECRETARY, U.S. DEPARTMENT OF TREASURY, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE TREASURY; JULIE A. SU, ACTING SECRETARY, U.S. DEPARTMENT OF LABOR, IN HER OFFICIAL CAPACITY AS SECRETARY OF LABOR,

Defendants - Appellants/Cross-Appellees

On Appeal from the United States District Court for the
Northern District of Texas, Fort Worth Division

AMICI CURIAE BRIEF OF THE AMERICAN CANCER SOCIETY, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN KIDNEY FUND, ARTHRITIS FOUNDATION, CANCER*CARE*, CANCER SUPPORT COMMUNITY, CROHN'S & COLITIS FOUNDATION, CYSTIC FIBROSIS FOUNDATION, EPILEPSY FOUNDATION, HEMOPHILIA FEDERATION OF AMERICA, LEUKEMIA AND LYMPHOMA SOCIETY, NATIONAL MINORITY QUALITY FORUM, NATIONAL MULTIPLE SCLEROSIS SOCIETY, NATIONAL PATIENT ADVOCATE FOUNDATION, THE AIDS INSTITUTE, AND WOMENHEART SUPPORTING DEFENDANTS-APPELLANTS'/CROSS-APPELLEES' OPENING BRIEF

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June 27, 2023

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CERTIFICATE OF INTERESTED PERSONS

Pursuant to Fifth Circuit Rule 29.2 and Federal Rule of Appellate Procedure 26.1, *amici curiae* American Cancer Society, American Cancer Society Cancer Action Network, American Kidney Fund, Arthritis Foundation, Cancer*Care*, Cancer Support Community, Crohn's & Colitis Foundation, Cystic Fibrosis Foundation, Epilepsy Foundation, Hemophilia Federation of America, Leukemia and Lymphoma Society, National Minority Quality Forum, National Multiple Sclerosis Society, National Patient Advocate Foundation, The AIDS Institute, and WomenHeart submit this certificate of interested persons to fully disclose all those with an interest in this brief and provide the required information as to their corporate status and affiliations.

The undersigned counsel of record certifies that, in addition to the parties to this case, the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this Court may evaluate possible disqualification or recusal.

a. Amicus Curiae **American Cancer Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

b. Amicus Curiae **American Cancer Society Cancer Action Network** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

c. Amicus Curiae **American Kidney Fund** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

d. Amicus Curiae **Arthritis Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

e. Amicus Curiae **Cancer*Care*** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

f. Amicus Curiae **Cancer Support Community** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

g. Amicus Curiae **Crohn's & Colitis Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

h. Amicus Curiae **Cystic Fibrosis Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

i. Amicus Curiae **Epilepsy Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

j. Amicus Curiae **Hemophilia Federation of America** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

k. Amicus Curiae **Leukemia and Lymphoma Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

l. Amicus Curiae **National Minority Quality Forum** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

m. Amicus Curiae **National Multiple Sclerosis Society** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

n. Amicus Curiae **National Patient Advocate Foundation** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

o. Amicus Curiae **The AIDS Institute** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

p. Amicus Curiae **WomenHeart** is a non-profit entity with no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

q. The above-listed *amici* curiae are represented by Beth Petronio, John Longstreth, Adam Cooper, Gretchen Mahoney, and Brian Hopkins of K&L Gates LLP and by Mary Rouvelas of American Cancer Society Cancer Action Network, Inc.

/s/ Beth Petronio
BETH PETRONIO

Counsel for *Amici Curiae*

INTEREST OF *AMICI*[1]

The American Cancer Society, American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund, Arthritis Foundation, Cancer*Care*, Cancer Support Community, Crohn's & Colitis Foundation, Cystic Fibrosis Foundation, Epilepsy Foundation, Hemophilia Federation of America, Leukemia and Lymphoma Society, National Minority Quality Forum, National Multiple Sclerosis Society, National Patient Advocate Foundation, The AIDS Institute, and WomenHeart, (collectively, "*amici*") are among the largest, most prominent organizations representing the interests of patients, survivors, and families affected by these chronic conditions. These conditions are frequently prevented and detected in early stages by preventive services, including those recommended by the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices (ACIP), and the Health Resources and Services Administration (HRSA) pursuant to the preventive care mandate of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 300gg-13.

Amici are dedicated to supporting patients and their families across the United States. Collectively, *amici* represent millions of individuals who suffer from the

[1] Counsel for each of the parties have consented to the filing of this brief. *Amici* certify that this brief was authored in whole by counsel for *amici* and no part of the brief was authored by any attorney for a party. No party, or any other person or entity, made any monetary contribution to the preparation or submission of this brief.

respective diseases and conditions to which *amici* dedicate their efforts. *Amici*'s activities range from medical research to patient support and other services in support of curing, lessening the burden of, or otherwise minimizing the effects of the various illnesses discussed herein. Collectively, *amici* bring decades of experience to fighting these illnesses and advocating on behalf of patients.

The fight against all of these diseases requires access to affordable, quality health care and health insurance that includes preventive care. *Amici* desire to assist the Court in understanding (1) why preventive care recommended by USPSTF, ACIP, and HRSA is crucial for patients battling a wide range of diseases, and (2) the immediate and devastating impact of impeding patients' access to preventive care.

SUMMARY OF ARGUMENT

All Americans use or will use health care services, and the lifetime risk that an individual American will contract one of the diseases or conditions towards which *amici* direct their efforts is high. Preventive services can aid in prevention, early detection and treatment of many diseases, which increases patients' chances of survival and extends life expectancies. Preventive care also helps control patients' costs of treating these diseases and conditions.

The ACA preventive services provision requiring private insurers cover USPSTF-, ACIP-, and HRSA- recommended services without cost sharing increases patients' ability to receive care that can prevent disease outright, identify illnesses

early, and reduce the physical and financial burdens of treating severe illnesses. Detecting severe diseases early allows for less invasive, more effective, and lower-cost treatment options, and substantially improves patient outcomes. Reducing insurance coverage for preventive services will lead to the opposite result—worsening patient outcomes, leading to preventable deaths, and creating higher long-term medical costs.

The District Court's March 30 decision threatens to drastically reduce insurance coverage of USPSTF-recommended services, deter utilization of those services, worsen patient outcomes, and potentially increase costs. If affirmed, the District Court's decision will substantially harm the patients that *amici* serve and support. Likewise, if this Court decides to invalidate ACIP- and HRSA-recommended services, patients will face even greater medical and financial hardship.

ARGUMENT

I. USPSTF, ACIP, AND HRSA PREVENTIVE CARE RECOMMENDATIONS INCREASE ACCESS TO CARE, IMPROVE TREATMENT OUTCOMES, AND SAVE LIVES.

The need for health care is difficult to predict, but is practically inevitable at some point in life.[2] The ACA recognizes that for the vast majority of Americans,

[2] *See Nat. Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2610 (2012) (Ginsburg, J., concurring) ("Virtually every person residing in the United States, sooner or later, will visit a doctor or other health-care professional."); *see also id*. at 2585 (Roberts, C.J.) ("Everyone will eventually need health care at a time and to an extent they cannot predict.").

accessing such necessary care requires health insurance coverage. Thus, the ACA provides a framework for coverage that has survived three major legal challenges at the United States Supreme Court. This framework includes insurance coverage for preventive services without cost sharing so that Americans will have greater access to such services, thereby preventing illnesses or catching them early to more successfully treat them.

Studies relevant to the diseases that are the focus of *amici*'s efforts show that preventive services improve health outcomes and save lives. The following studies, summarized by disease, illustrate the positive impact of preventive services and what could be lost if patients lose cost-free access to them.

Cancer-Related Studies:

- The five-year survival rate when lung cancer cases are diagnosed at an early stage is 61%. Unfortunately, 44% of cases are not caught until a late stage when the survival rate is only 7%.[3]
- Colorectal cancer (CRC) screening can prevent the disease through the detection and removal of precancerous growths and detect cancer at an early stage, when treatment is usually more successful. As a result, screening reduces CRC mortality both by decreasing incidence and increasing survival.

[3] *Lung Cancer Key Findings*, AM. LUNG ASS'N (2022), https://www.lung.org/research/state-of-lung-cancer/key-findings.

There are several USPSTF-recommended CRC screening methods, all of which have a comparable ability to improve life expectancy when performed at the appropriate time intervals and with the recommended follow-up.[4]

- Screenings for CRC increased from 57.3% to 61.2% between 2008 and 2013, especially among low-income, lower-educated, and Medicare-insured patients. These results are likely associated with the ACA provisions removing cost-sharing for these screenings.[5]
- The USPSTF updated its colorectal cancer screening guidelines to lower the starting age for screening to 45 in 2021. The USPSTF developed its new recommendation based on new analyses that reflect recent population trends of elevated risk for CRC incidence in younger people. These new analyses were not included in the previous recommendation and provided evidence on lives saved from lowering the CRC screening age to 45.[6]
- Improvement in screening rates for CRC in early Medicaid expansion states translated to an additional 236,573 low-income adults receiving screenings in 2016 and, if the same absolute increases were experienced in non-expansion

[4] *Colorectal Cancer Facts & Figures 2020-2022*, ATLANTA: AM. CANCER SOC'Y (2020), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf.
[5] Stacey A. Fedewa et al., *Elimination of cost-sharing and receipt of screening for colorectal and breast cancer*, 121 CANCER 3272 (2015), https://acsjournals.onlinelibrary.wiley.com/doi/10.1002/cncr.29494.
[6] Andrew Wolf et al., *Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society*, 68:4 CA: A CANCER JOURNAL FOR CLINICIANS 250 (July/Aug. 2018), https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21457.

states, 355,184 more low-income adults would have had CRC screening as of 2019. Colon cancer screenings in accordance with USPSTF recommendations have reduced the incidence of colon cancer.[7]

- Cervical cancer incidence and mortality rates have decreased by more than 50% over the past three decades and the decrease can be attributed to screening, which can detect both cervical cancer at an early stage and precancerous lesions.[8]
- The risk of breast cancer death has been shown to be reduced due to early detection of breast cancer by mammography, which increases treatment options.[9]
- Compared with non-Medicaid expansion states, states that implemented expansion saw greater improvement in breast cancer screening rates among lower-income women.[10]

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[7] Jeff Legasse, *First states to expand Medicaid saw larger screening rate increases*, HEALTHCARE FIN. (May 24, 2019), https://www.healthcarefinancenews.com/news/first-states-expand-medicaid-saw-larger-screening-rate-increases (citing Stacey A. Fedewa et al., *Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act*, 57 AM. J. PREVENTIVE MED. 3 (July 2019), https://www.sciencedirect.com/science/article/abs/pii/S0749379719301163).

[8] *Cancer Prevention & Early Detection Facts & Figures*, ATLANTA: AM. CANCER SOC'Y, at 33 (2022), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/2021-cancer-prevention-and-early-detection.pdf.

[9] *Breast Cancer Facts & Figures 2022-2024*, ATLANTA: AM. CANCER SOC'Y (2022), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2022-2024-breast-cancer-fact-figures-acs.pdf.

[10] Stacey A. Fedewa et al., *Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act*, 57 AM. J. PREVENTIVE MED. 3 (July 2019), https://www.sciencedirect.com/science/article/abs/pii/S0749379719301163.

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

- Use of blood pressure checks, cholesterol checks, and flu vaccinations increased significantly in the years after the ACA's passage.[11]
- Childhood vaccines in accordance with expert recommendations had saved 732,000 lives as of 2014.[12]
- Children on immunosuppressive therapy for cancer or organ transplantation are highly predisposed to infection from all types of pathogens while they are immunosuppressed, and therefore at increased risk for complications due to vaccine-preventable diseases.[13] For example, two thirds of children receiving cancer therapy who contract influenza are hospitalized for respiratory complications. Such infections can delay cancer treatments for several weeks, impacting long-term prognoses.[14] These children oftentimes cannot receive vaccinations while immunosuppressed, so they rely on the vaccination of others for safety. Thus, wide-ranging access to ACIP-recommended vaccines

[11] Xuesong Han et al., *Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States?*, 78 PREVENTIVE MED. 85 (Jul. 23, 2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589867/.
[12] Cynthia G. Whitney et al., *Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013*, 63 MORBIDITY AND MORTALITY WKLY. REP. 352 (Apr. 25, 2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4584777/.
[13] Russell W. Steele, *Managing Infection in Cancer Patients and Other Immunocompromised Children*, 12 OCHSNER J. 202 (Fall 2012) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3448241/pdf/i1524-5012-12-3-202.pdf.
[14] Elizabeth M. Ward et al., *The importance of immunization in cancer prevention, treatment, and survivorship*, 67 CA: CANCER J. FOR CLINICIANS 398 (Jul. 28, 2017), https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21407.

for illnesses like influenza, measles, and mumps is essential for protecting these vulnerable children.

- Preventive services without cost sharing, in part, led to 854,000 young women completing the Human Papillomavirus (HPV) vaccine series from 2010-2012.[15] High-risk types of HPV cause the majority of throat, cervical, vaginal, vulvar, anal, and penile cancers, and *amici* strongly support coverage of the HPV vaccine without cost sharing.[16] Coverage without cost-sharing was associated with a 4.3% increase in HPV vaccine completion for females aged 9-26 who were privately insured, and a 5.7% increase for Medicaid enrollees in three states.[17] High-risk types of HPV cause the majority of throat, cervical, vaginal, vulvar, anal, and penile cancers.[18] Since HPV vaccination was first recommended in 2006, infections with HPV types that cause most HPV

[15] Office of Health Policy: Assistant Secretary for Planning and Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, U.S. DEP'T HEALTH AND HUM. SERVS., at 8 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.

[16] *See The Need for Increased HPV Vaccination*, AM. CANCER SOC'Y (2022), https://www.cancer.org/health-care-professionals/hpv-vaccination-information-for-health-professionals/the-need-for-increasing-hpv-vaccination.html. In the first 10 years after the vaccine was recommended in the U.S., quadrivalent type HPV infections decreased by 86% in female teens 14 to 19 years old, and by 71% in women in their early 20s. *HPV Vaccine Safety and Effectiveness*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2022), https://www.cdc.gov/vaccines/vpd/hpv/hcp/safety-effectiveness.html#:~:text=The%20HPV%20vaccine%20works%20extremely,women%20in%20their%20early%2020s.

[17] *See id*. at 8, 10.

[18] *See The Need for Increased HPV Vaccination*, AM. CANCER SOC'Y (2022), https://www.cancer.org/health-care-professionals/hpv-vaccination-information-for-health-professionals/the-need-for-increasing-hpv-vaccination.html.

cancers and genital warts have dropped 88% among teen girls and 81% among young adult women.[19]

- Hormone therapy is critical to many who live with life-threatening bleeding disorders and coverage of it is required under HRSA guidelines.[20] Contraception methods (hormonal therapies such as the pill, ring, and hormonal IUD) in particular are important to people with bleeding disorders who menstruate.[21] Hormonal therapies offer a cost-effective, first-line therapeutic option to mitigate heavy menstrual bleeding, which can lead to iron deficiency anemia and poor quality of life.

Studies Related to Diabetes:

- Type 1 diabetes (T1D) is an autoimmune disease that has distinct metabolic stages. Screening can identify people at risk of developing T1D before they become symptomatic, reducing their risk of developing diabetic ketoacidosis, which can be fatal. Screening in pediatric populations also showed lower average blood glucose levels and shorter hospital stays at diagnosis.[22]

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[19] *Human Papillomavirus (HPV) Vaccination: What Everyone Should Know*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 16, 2021), https://www.cdc.gov/vaccines/vpd/hpv/public/.

[20] *Women's Preventive Services Guidelines: Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being*, HEALTH RES. & SERVS. ADMIN. (Dec. 2022), https://www.hrsa.gov/womens-guidelines.

[21] *Hormonal Therapies*, HEMOPHILIA FED'N OF AM. (2023), https://www.hemophiliafed.org/resource/hormonal-therapies/.

[22] Anne Peters, *Screening for Autoantibodies in Type 1 Diabetes: A Call to Action*, 70 J. FAM. PRAC. (SUPPLEMENT) S47 (July/Aug. 2021), https://cdn.mdedge.com/files/s3fs-public/jfp_hot_topics2021_0722_v3.pdf; Parth Narendran, *Screening for type 1 diabetes: are we nearly there yet?*, 62 DIABETOLOGIA 24 (Nov. 13 2018), https://link.springer.com/article/10.1007/s00125-018-4774-0.

Studies Related to Smoking Cessation:

- Smoking cessation reduces the risks of twelve different cancers and can help improve health outcomes after a cancer diagnosis. Smoking cessation also reduced risk and improved health outcomes after a diagnosis as to cardiovascular diseases, strokes, aneurisms, respiratory diseases, asthma, pregnancy and reproductive health.[23]
- Smoking cessation assistance also results in a decrease in smoking.[24]

Studies Related to Cardiovascular Diseases:

- It is widely known that many types of cardiovascular disease are preventable. It is critical that people have access to screenings so they can understand their own risk factors and make lifestyle and treatment decisions that are effective at reducing risk and preventing disease. There are several preventive care and screening benefits related to cardiovascular disease in adults that, under current law, must be covered without copay or coinsurance.[25] These include blood pressure screening, cholesterol screening, Type 2 diabetes screening,

[23] U.S. DEP'T HEALTH AND HUM. SERVS., SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL, CH. 4: THE HEALTH BENEFITS OF SMOKING CESSATION (2020), https://www.ncbi.nlm.nih.gov/books/NBK555590/.
[24] *Cancer Prevention & Early Detection Facts & Figures 2021-2022*, at 33 (citing U.S. Preventive Services Task Force et al., *Interventions for Tobacco Smoking Cessation in Adults, Including Pregnant Persons: US Preventive Services Task Force Recommendation Statement*, 325 J. Am. Med. Ass'n 265 (Jan. 19, 2021), https://pubmed.ncbi.nlm.nih.gov/33464343/).
[25] *See* U.S. Dep't Health and Hum. Servs., *Preventive care benefits for adults*, HEALTHCARE.GOV (2022), https://www.healthcare.gov/preventive-care-adults/.

obesity screening, and others.[26] These measures are important because, for example, there is a strong link between uncontrolled blood pressure and ischemic heart and peripheral vascular disease, heart failure, stroke, kidney disease, and complications of pregnancy.[27]

- While high cholesterol has no apparent symptoms, having high blood cholesterol raises the risk for heart disease.[28]
- Obesity increases the risk for high blood pressure and high cholesterol which are risk factors for heart disease.[29]

Eliminating mandatory coverage without cost sharing for the preventive blood pressure, cholesterol, diabetes, obesity, and other screenings related to cardiovascular diseases would reduce patient access, meaning risk factors for heart disease would increasingly go undetected. Such circumstances would prevent patients from managing their risk factors and reducing their risk of developing heart disease.

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[26] *Id*.
[27] *See* William J. Oetgen and Janet S. Wright, *Controlling Hypertension: Our Cardiology Practices Can Do a Better Job*, 77 J. AM. COLL. CARDIOLOGY 2973 (June 15, 2021), https://www.sciencedirect.com/science/article/pii/S0735109721047902?via%3Dihub#bib4.
[28] *See High Cholesterol Facts*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 15, 2023), https://www.cdc.gov/cholesterol/facts.htm.
[29] *See Consequences of Obesity*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2022), https://www.cdc.gov/obesity/basics/consequences.html.

Studies Related to Preventive Services Generally:

- Analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated that approximately 137 million Americans with private insurance had access to preventive services without cost sharing in 2015, which increased to 151.6 million by 2020. ASPE attributed the increase to growth in the number of people enrolled in private healthcare coverage subject to USPSTF recommendations, and a decrease in the share of such people enrolled in plans not subject to USPSTF recommendations.[30] A majority of recent studies have shown increases in use when there is no cost sharing, and the findings suggest that low-socioeconomic status groups, and those who experience the greatest financial barriers to care, appear to benefit the most from cost-sharing elimination.[31]

These studies confirm that access to preventive services, facilitated by insurance coverage, increases the likelihood that healthcare providers will diagnose diseases earlier than they could without such services. The data also illustrate that when providers can diagnose these diseases early, the likelihood of successfully treating patients and extending their lives increases. As organizations dedicated to

[30] *See* Office of Health Policy: Assistant Secretary for Planning and Evaluation, *supra* note 17, at 6.
[31] Kara Gavin, *What happens when preventive care becomes free to patients?*, UNIV. OF MICHIGAN HEALTH LAB (June 28, 2021), https://labblog.uofmhealth.org/industry-dx/what-happens-when-preventive-care-becomes-free-to-patients.

addressing the devastating impact of diseases, *amici* know that access to affordable preventive health care is fundamental to successful health outcomes.

II. USPSTF, ACIP, AND HRSA PREVENTIVE CARE RECOMMENDATIONS REDUCE COST BURDENS FOR INDIVIDUALS AND THE NATIONAL HEALTHCARE SYSTEM.

Congress enacted the ACA, including its preventive care mandate, in response to our health care system's failures and the high costs of health insurance. Because these known failures impeded the nation's economic wellbeing, one of Congress's primary aims for the ACA was improving access to health care by making coverage more affordable.[32] Congress extended this coverage to preventive services recommended by the USPSTF, ACIP, and HRSA. Affordable coverage increases patients' access to screenings and preventive treatments, which make diagnosing serious illnesses at early stages more likely and improves patient outcomes. Identifying serious illnesses in early stages narrows the scope and invasiveness of successful treatment, reducing the costs of treating serious illnesses over patients' lifetimes. Long-term cost savings reduce the strain our healthcare system places on U.S. economic wellbeing.

Adding costs to routine preventive services—the outcome if the District Court's decision stands as to USPSTF-recommended services, or is overturned on ACIP- and HRSA-recommended services —would cause patients to choose between

[32] *See NFIB*, 132 S. Ct. at 2580.

treating a current illness or trying to prevent new ones. For example, while the vast majority of people with cystic fibrosis (CF) are insured, this insurance does not shield them from burdensome out-of-pocket costs. Even when individual co-payments or cost-sharing are relatively modest for any single drug or service, the multitude of out-of-pocket expenses incurred by people with CF can quickly add up. According to a 2020 Health Insurance study by the George Washington University, 71% of people with CF have experienced financial hardship due to medical expenses.[33] Furthermore, 45% of people with CF delayed their care in some way due to cost (including skipping medication doses, taking less medicine than prescribed, delaying the refill of a prescription, or not getting a provider-recommended treatment or test).[34] Reinstituting financial barriers to preventive services could force people with CF to forego essential care, jeopardizing their health and leading to costly hospitalizations and fatal lung infections.[35]

Similarly, individuals with multiple sclerosis (MS) struggle with the cost of care even with insurance. In one survey, 40% of respondents altered their use of a disease-modifying therapy (DMT) due to cost, including skipping or delaying

[33] *See The Importance of Cost and Affordability for People with CF*, CYSTIC FIBROSIS FOUND. (2022), https://www.cff.org/about-us/importance-cost-and-affordability-people-cf.
[34] *See id*.
[35] *See id*.

treatment.[36] Forty percent also said they experience stress or other emotional impact due to high out-of-pocket costs and are making lifestyle sacrifices to be able to pay for their DMT.[37] More than half of MS patients are concerned about being able to afford their DMT over the next few years.[38] These challenges can cause delays in starting a medication or changing medications when a treatment is no longer working.[39] Delays may result in new MS activity (risking disease progression without recovery) and cause even more stress and anxiety about the future for people already living with the complex challenges and unpredictability of MS.[40]

In addition, 21% of adults with epilepsy reported not being able to afford prescription medications within the last year.[41]

Studies relevant to the diseases that are the focus of *amici's* efforts show USPSTF-, ACIP-, and HRSA-recommended preventive services also reduce costs for individuals and the U.S. health system. The following studies, organized by disease, show that preventive services facilitate early detection of disease, leading to treatment of illnesses at less severe stages, which reduces individual and collective healthcare costs.

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[36] *See Make MS Medications Accessible*, NAT'L MULTIPLE SCLEROSIS SOC'Y (2022), https://www.nationalmssociety.org/Treating-MS/Medications/Make-MS-Medications-Accessible.
[37] *See id*.
[38] *See id*.
[39] *See id*.
[40] *See id*.
[41] David J. Thurman et al., *Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013*, 55 EPILEPSY & BEHAVIOR 184 (Feb. 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5317396/.

Cancer-Related Studies:

- A study published in the Annals of Internal Medicine sought to evaluate the cost effectiveness of lung cancer screenings as recommended by the USPSTF, the Centers for Medicare & Medicaid Services (CMS), and the National Lung Cancer Screening Trial (NLST). The study tracked the health and cost outcomes of forty-five-year-old Americans who received lung cancer screenings, and determined that USPSTF's, CMS's, and NLST's screening recommendations were cost effective.[42]
- "As the costs of treatments for advanced CRC have increased, with proportionately modest gains in survival, the cost-effectiveness of CRC screening has improved, with many strategies becoming cost-saving in the United States."[43] Further, "[a] modeling study indicated that screening at ages 50-64 years under commercial insurance in the United States yields substantial clinical and economic benefits that accrue primarily at ages [less than or equal to] 65 years under Medicare."[44]

[42] *See* Steven D. Criss et al., *Cost-Effectiveness Analysis of Lung Cancer Screening in the United States*, ANNALS INTERNAL MED. (Dec. 3, 2019), https://www.acpjournals.org/doi/10.7326/M19-0322?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
[43] Uri Ladabaum et al., *Strategies for Colorectal Cancer Screening*, 158 GASTROENTEROLOGY 418, (Jan. 2020), https://www.gastrojournal.org/article/S0016-5085(19)41185-2/fulltext#secsectitle0060.
[44] *Id.*

Studies Related to Smoking Cessation:

- Smoking cessation interventions reduce the likelihood that individuals will develop smoking-related diseases and conditions, which ultimately cuts healthcare costs on a system-wide basis.[45]

Studies Related to Kidney Disease:

- Type 2 diabetes (T2D) is the leading cause of chronic kidney disease (CKD) and end-stage kidney disease (ESKD). More than one-third of people with T2D also have CKD, and this population is associated with a ten-fold or greater increase in all-cause mortality compared with T2D alone. Furthermore, CKD progression leads to ESKD, which is irreversible and fatal in the absence of kidney replacement therapy. CKD and ESKD are associated with high economic burden, accounting for 22.3% (US$81.8 billion) and 7.2% (US$36.6 billion), respectively, of all Medicare fee-for-service spending in 2018. Medicare expenditures for people with CKD have risen at a rate higher than expenditures for the general Medicare population and have been found costlier for people with CKD and comorbid heart failure or diabetes (type 1 or 2), highlighting clear clinical and economic rationales for early identification and treatment intervention to limit CKD progression

[45] *See* SMOKING CESSATION: A REPORT OF THE SURGEON GENERAL, *supra* note 25, at CH. 5: THE BENEFITS OF SMOKING CESSATION ON OVERALL MORBIDITY, MORTALITY, AND ECONOMIC COSTS.

in all populations, particularly in people with T2D and cardiovascular risk factors.[46]

Studies Related to Preventive Services Generally:

- Research shows that required cost sharing, including co-pays, co-insurance and deductibles, can be a significant barrier for patients who need preventive services. This finding is especially true for lower-income patients and patients on a fixed income, for whom these payments can represent a significant percentage of their income. Removing cost-sharing for preventive services has been proven to increase the use of those services.[47]
- Cost sharing reduces the use of both low- and high-value care, including preventive care. Because preventive care services do not address acute health problems, some people may skip such care if cost sharing is required.[48]
- Removal of coverage for preventive care would have minimal impact on employers' cost of providing health care coverage. The costs of covering select preventive services are very low. Reintroduction of patient cost sharing

[46] *See* Janet B. McGill et al., *Making an impact on kidney disease in people with type 2 diabetes: the importance of screening for albuminuria*, 10 BMJ OPEN DIABETES RSCH. & CARE 1 (May 9 2022), https://drc.bmj.com/content/10/4/e002806.
[47] *See Strong Prevention Policies Will Reduce the Cancer Burden*, AM. CANCER SOC'Y ACTION NETWORK (Jan. 5, 2017), https://www.fightcancer.org/sites/default/files/Prevention%20Factsheet%2001-05-17.pdf.
[48] *See* Rajender Agarwal et al., *High-Deductible Health Plans Reduce Health Care Cost And Utilization, Including Use of Needed Preventive Services*, 36 HEALTH AFFS. 1762 (Oct. 2017), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.0610?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

will make little difference on overall employer health care spending. "If employers imposed 20 percent cost sharing on all medications recommended by USPSTF, employer spending would fall by 0.3 percent."[49]

- Much of the health care that 35.3 million privately-insured children receive falls under the ACA's preventive care provision, including well-child visits, immunizations, screenings, and important dental services like oral health assessments and fluoride treatments.[50] Preventive care is also critical for 132.2 million privately-insured adults, and the preventive services requirement of the ACA covers the following services for adults without cost sharing: cancer screenings, immunizations like flu vaccines and shingles vaccine, and preventive medications like PrEP to prevent HIV and statins and aspirin to prevent cardiovascular disease. Approximately 67.7 million adult women with private insurance can receive a range of specialized care without cost sharing, including well-woman visits, prenatal screenings, birth control, and cancer screenings.[51]

In sum, USPSFT-, ACIP-, and HRSA-recommended preventive care services, provided without cost sharing, facilitate earlier disease diagnosis and less invasive,

[49] *EBRI Fast Facts: The Impact of Covering Select Preventive Services on Employer Health Care Spending*, EMP. BENEFIT RSCH. INST., at 2 (Oct. 20, 2022), https://www.ebri.org/docs/default-source/fast-facts/ff-444-preventiveservices-20oct22.pdf?sfvrsn=8efb382f_2.
[50] *See* Laura Skopec & Jessica Banthin, *Free Preventive Services Improve Access to Care*, URBAN INST., at 1 (July 2022), https://www.urban.org/sites/default/files/2022-07/Free%20Preventive%20Services%20Improve%20Access%20to%20Care.pdf.
[51] *See id*. at 2.

more successful disease treatment, which reduces costs to individual patients and the U.S. health system.

III. THE DISTRICT COURT'S DECISION ON USPSTF WILL IMMINENTLY HINDER PATIENT ACCESS TO CRITICAL PREVENTIVE CARE SERVICES THAT REFLECT CURRENT SCIENCE

The ACA provides a framework for coverage for preventive services without cost sharing so that Americans will have greater access to such services, thereby preventing illnesses and diagnosing them earlier to more successfully treat them. The District Court's March 30 ruling as to USPSTF-recommended services will have the opposite effect. Whether insurers and employers choose to implement cost sharing for preventive services or drop them altogether, many patients, especially low-income patients, will be forced to utilize preventive services less frequently or not at all. A review of sixty-five papers published from 2000-2017 found that "even relatively small levels of cost sharing in the range of $1 to $5 are associated with reduced use of care, including necessary services."[52]

A survey conducted just before the District Court's decision revealed that three out of ten respondents had delayed or skipped healthcare within the last year,

[52] Samantha Argita et al., *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings*, KAISER FAM. FOUND. (June 1, 2017), https://www.kff.org/medicaid/issue-brief/the-effects-of-premiums-and-cost-sharing-on-low-income-populations-updated-review-of-research-findings/.

largely due to income constraints.[53] Two out of five respondents stated that they would not pay out-of-pocket for eleven out of twelve preventive services included in the survey.[54] This data underscores the damaging gap in patient care the District Court's decision will contribute to if permitted to take effect.

Similarly, a recent study found 58% of cancer patients and survivors would be less likely to maintain preventive care, including recommended cancer screenings, if the mandate for full coverage, resulting in patient out-of-pocket costs, is overturned.[55] The ACA's framework sought to increase use of preventive care by requiring health insurers to cover USPSTF-recommended services with "A" and "B" grades and ACIP- and HRSA-recommended services without cost sharing. Congress's goal was to allow individuals greater access to evidence-based care as science evolves. Numerous USPSTF recommendations have changed since the March 2010 cut-off designated by the District Court. The same is true for ACIP and HRSA recommendations. For example, before March 2010, the USPSTF recommended CRC screenings for adults 50 and older.[56] The current CRC screening recommendation has reduced the screening age to forty-five and added screening

[53] *See* Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through*, MORING CONSULT (Mar. 8, 2023), https://morningconsult.com/2023/03/08/affordable-care-act-polling-data/.
[54] *See id*.
[55] *See Survivor Views: Majority Less Likely to Get Recommended Screenings if Coverage is Lost*, AM. CANCER SOC'Y ACTION NETWORK (May 11, 2023), https://www.fightcancer.org/policy-resources/survivor-views-majority-less-likely-get-recommended-screenings-if-coverage-lost.
[56] *See Final Recommendation Statement: Colorectal Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Oct. 15, 2008), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening-2008.

modalities not present in and/or not yet developed at the time of the original recommendation.[57]

The USPSTF first recommended lung cancer screenings in 2013 and updated its recommendation in 2021.[58] The USPSTF developed its new recommendation based, in part, on data from the NLST. The NLST provided direct evidence of moderate certainty that lung cancer screening in high-risk populations was effective in reducing lung cancer deaths.[59] These screenings are essential to catching lung cancer early, when it is more treatable. The five-year survival rate when lung cancer is diagnosed at an early stage is 61%—a stark contrast to the 7% survival rate for late-stage diagnoses.[60]

Additionally, in February 2019, the USPSTF recommended counseling interventions for pregnant and post-partum individuals at increased risk of perinatal depression.[61] This care is vital, as one in seven post-partum individuals experience postpartum depression and anxiety disorders.[62]

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[57] *See Final Recommendation Statement: Colorectal Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (May 18, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening.
[58] *See Final Recommendation Statement: Lung Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Mar. 9, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening.
[59] *See* The Nat'l Lung Screening Trial Rsch. Team, *Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening*, 365 N. ENG. J. MED. 395 (Aug. 4, 2011), https://www.nejm.org/doi/full/10.1056/nejmoa1102873.
[60] *Lung Cancer Key Findings*, AM. LUNG ASS'N (2022), https://www.lung.org/research/state-of-lung-cancer/key-findings.
[61] *See A & B Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations.
[62] *See* Dara Lee Luca et al., *Issue Brief: Societal Costs of Untreated Perinatal Mood and Anxiety Disorders in the United States*, MATHMATEICA (Apr. 2019), https://www.mathematica.org/publications/societal-costs-of-untreated-perinatal-mood-and-anxiety-disorders-in-the-united-states.

In 2019, over eight million American children aged three to seventeen had a current, diagnosed mental or behavioral health condition, the most common of which were anxiety and depression.[63] In that year, over half of those children received treatment or counseling from a mental health professional.[64] In October 2022, the USPSTF recommended screenings for anxiety in children and adolescents aged eight to eighteen.[65]

Further, in July 2019, the USPSTF recommended Hepatitis B Virus (HBV) screenings for pregnant individuals at their first prenatal visit, and HBV screening for adolescents and adults at increased risk for infection in December 2020.[66] These screenings are crucial because chronic HBV has been shown to cause liver cancer and increase risk of non-Hodgkin lymphoma.[67]

There are additional examples of the USPSTF updating recommendations made prior to March 23, 2010. Notably, in August 2022, the USPSTF recommended use of statins for adults aged forty to seventy-five with one or more risk factors for cardiovascular disease.[68] In August 2018, the USPSTF recommended cervical

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[63] *See NSCH Data Brief: Mental and Behavioral Health*, HEALTH RES. & SERVS. ADMIN (Oct. 2020), https://mchb.hrsa.gov/sites/default/files/mchb/data-research/nsch-data-brief-2019-mental-bh.pdf.
[64] *See id*.
[65] *See A & B Recommendations*, *supra* note 63.
[66] *See id.*
[67] *See Cancer Prevention & Early Detection Facts & Figures*, ATLANTA: AM. CANCER SOC'Y (2022), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/2021-cancer-prevention-and-early-detection.pdf.
[68] *See Statin Use for the Primary Prevention of Cardiovascular Disease in Adults*, U.S. PREVENTIVE SERVS. TASK FORCE (Aug. 23, 2022), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication.

cancer screening, at either three or five-year intervals, for women aged twenty-one to sixty-five.[69] This update to the 2003 recommendation added the option for HPV testing and information regarding specific testing modalities and intervals.[70]

In March 2020, the USPSTF updated its Hepatitis C Virus screening recommendation.[71] The new version "incorporates new evidence" and "expands the ages for screening to all adults from 18-79 years."[72] In June 2019, the USPSTF added HIV screening and treatment recommendations, leading to an extension of mandatory screening coverage to adolescents and adults aged fifteen to sixty-five, adolescents and adults at increased risk of infection, and pregnant individuals.[73] It simultaneously extended PrEP coverage to individuals at high risk of HIV acquisition.[74] These recommendations are especially important because many people experience no symptoms of HIV infection, meaning the only way to identify an infection and prevent the spread of HIV is to test/screen.[75]

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[69] *See Final Recommendation Statement: Cervical Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Aug. 21, 2018), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening.
[70] *See id*.
[71] *See Final Recommendation Statement: Hepatitis C Virus Infection in Adolescents and Adults: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Mar. 2, 2020), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening.
[72] *Id*.
[73] *See Final Recommendation Statement: Human Immunodeficiency Virus (HIV) Infection: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening.
[74] *See Final Recommendation Statement: Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*, U.S. PREVENTIVE SERVS. TASK FORCE (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.
[75] *See About HIV*, CTRS. FOR DISEASE CONTROL AND PREVENTION (June 30, 2022), https://www.cdc.gov/hiv/basics/whatishiv.html.

Comparing the pre-ACA preventive care requirements with the post-ACA recommendations from the USPSTF, as well as those made by ACIP and HRSA, illustrates the improvements in preventive care services that directly result from those recommendations. Specifically:

- USPSTF recommendations issued after March 23, 2010 include new screening modalities not available in 2010 and new recommendations based on current scientific evidence for myriad diseases—such as cervical cancer, CRC, lung cancer, breast cancer, skin cancer, obesity, tobacco use, Hepatitis B, Hepatitis C, and alcohol use—that greatly improved access to preventive services that include screenings/testing, counseling and behavioral interventions, and preventive treatment for high-risk patients.[76]
- ACIP HPV vaccinations recommendations expanded coverage from only females to also include males.[77]
- ACIP Hepatitis B vaccinations recommendations expanded coverage from at-risk adults and children to universal vaccination at birth.[78]

[76] *See* Am. Cancer Soc'y Action Network, *Post*-Braidwood *Comparison of USPSTF Recommendations* (Apr. 24, 2023), https://www.fightcancer.org/sites/default/files/post-braidwood_coverage_of_uspstf_recommendations.pdf.
[77] *See Human Papillomavirus (HPV) ACIP Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Nov. 21, 2014), https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html.
[78] *See Hepatitis B ACIP Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 8, 2023), https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.

- HRSA breast and cervical cancer recommendations established guidelines that did not exist pre-ACA, covering breast cancer screenings for women no earlier than the age of forty and for cervical cancer beginning at age twenty-one.[79]

Over 150 million individuals in the U.S. have health insurance coverage subject to the ACA's preventive services requirement and receive preventive services recommended by the USPSTF, ACIP, and HRSA cost-free.[80] A recent study found that six out of eight privately insured American adults, roughly 100 million people, received some form of ACA preventive healthcare in 2018.[81]

Also in 2018, 61% of individuals covered by large employers, 57% of those covered by small employers, and 55% of those in the individual insurance market received ACA preventive care. Further, seven out of ten American children received ACA preventive services in 2018.[82] Among the most utilized services were screenings for heart disease, cervical cancer, and diabetes, all of which were the subject of USPSTF updated recommendations after March 23, 2010.[83]

The District Court's decision to vacate all agency actions taken to implement the USPSTF's recommendations since the enactment of the ACA, and to enjoin

[79] *See Women's Preventive Services Guidelines*, *supra* note 22.
[80] *See* Office of Health Policy: Assistant Secretary for Planning and Evaluation, *supra* note 17, at 8.
[81] *See* Krutika Amin et al., *Preventive Services Use Among People with Private Insurance Coverage*, KAISER FAM. FOUND. (Mar. 20, 2023), https://www.healthsystemtracker.org/brief/preventive-services-use-among-people-with-private-insurance-coverage/.
[82] *See id*.
[83] *See id.*; *A & B Recommendations*, *supra* note 63.

enforcement of all future recommendations, will allow some insurers to either drop preventive care coverage altogether, while others must continue to cover preventive care but may re-introduce cost sharing for preventive services.

Since March 23, 2010, the USPSTF, ACIP, and HRSA have recommended lifesaving screenings and treatments for a wide array of diseases and conditions, including those which *amici* seek to eradicate. These recommendations and their implementation have reduced financial barriers to preventive care services, increased utilization of those services, and saved and prolonged lives. The District Court's decision threatens to erect formidable financial barriers to these life-saving services and reverse over a decade's worth of progress in improving health outcomes. If this Court allows the District Court's decision on USPSTF to stand, millions of Americans, including those *amici* serve and support, will imminently struggle to access current, evidence-based preventive care services.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that this Court reverse the District Court's decision as to the USPSTF's recommendations. The ACA's preventive care mandate has saved lives and should continue to do so.

Respectfully submitted,

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CONSENT DECREE

I certify that counsel for *Amici* conferred with counsel for Defendants-Appellants/Cross-Appellees and Plaintiffs-Appellees/Cross-Appellants regarding the filing of this brief, and no party opposes the filing of this brief.

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CERTIFICATE OF COMPLIANCE

This document complies with the word limit established by Fed. R. App. P. 27(d)(2) because, excluding portions of the brief exempted by Federal Rule of Appellate Procedure 32(f) and the Rules of this Court, this document contains 2,220 words.

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CERTIFICATE OF SERVICE

I certify that a copy of this brief was served, via the Court's CM/ECF Document Filing System, on all counsel of record who have appeared in this case on June 27, 2023. I further certify that a copy of this brief was served on Christopher M. Lynch, counsel for U.S. Department of Justice, via United States mail.

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