No. 24-316

In the Supreme Court of the United States

———

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., *P*[illegible]*r*,

v.

BRAIDWOOD MANAGEMENT, INC. ET AL., *R*[illegible].

———

On Petition for a Writ of Certiorari to the United States Court of ACOLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN KIDNEY FUND, AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN OSTEOPATHIC ASSOCIATION, AMERICAN PSYCHIATRIC ASSOCIATION, AMERICAN SOCIETY OF CLINICAL ONCOLOGY, AMERICAN SOCIETY FOR GASTROINTESTINAL ENDOSCOPY, AMERICAN THORACIC SOCIETY, ARTHRITIS FOUNDATION, CANCER SUPPORT COMMUNITY, CROHN'S & COLITIS FOUNDATION, CYSTIC FIBROSIS FOUNDATION, EPILEPSY FOUNDATION, GLMA: HEALTH PROFESSIONALS ADVANCING LGBTQ+ HEALTH, HEMOPHILIA FEDERATION OF AMERICA, INFECTIOUS DISEASES SOCIETY OF AMERICA, NATIONAL HISPANIC MEDICAL ASSOCIATION, NATIONAL MEDICAL ASSOCIATION, NATIONAL MINORITY QUALITY FORUM, NATIONAL MULTIPLE SCLEROSIS SOCIETY, NATIONAL PATIENT ADVOCATE FOUNDATION, SOCIETY OF LAPAROSCOPIC AND ROBOTIC SURGEONS, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE AIDS

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20002

JOHN LONGSTRETH
BRIAN HOPKINS
K&L GATES LLP
1601 K Street, N.W.
Washington, DC 20006
(202) 778-9000
John.Longstreth@klgates.com
Brian.Hopkins@klgates.com

MARY P. ROUVELAS
[illegible]
[illegible]
AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK
655 15th Street NW
Suite 503
Washington, DC 20005
(703) 727-8500
Mary.Rouvelas@cancer.org

[illegible]

MADELINE GITOMER
SARAH GOETZ
CARRIE FLAXMAN
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, DC 20043
(202) 448-9090
mgitomer@democracyforward.org
sgoetz@democracyforward.org
cflaxman@democracyforward.org

[illegible]

October 21, 2024

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
INTEREST OF *AMICI*	1
SUMMARY OF ARGUMENT	3
ARGUMENT	4
I. PREVENTIVE CARE RECOMMENDATIONS INCREASE ACCESS TO CARE, IMPROVE TREATMENT OUTCOMES, AND SAVE LIVES	4
II. PREVENTIVE CARE RECOMMENDATIONS REDUCE COST BURDENS FOR INDIVIDUALS AND THE NATIONAL HEALTHCARE SYSTEM	12
III. THE COURT OF APPEALS DECISION COULD HINDER PATIENT ACCESS TO CRITICAL PREVENTIVE CARE SERVICES THAT REFLECT CURRENT SCIENCE	20
CONCLUSION	28

TABLE OF AUTHORITIES—Continued

Page(s)

Colorectal Cancer Facts & Figures 2023-2025, AM. CANCER SOC'Y (2023), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2023.pdf 7

Consequences of Obesity, CTRS. FOR DISEASE CONTROL AND PREVENTION (2022), https://www.cdc.gov/obesity/basics/consequences.html 12

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 23

David J. Thurman, et al., *Health-care access among adults with epilepsy: The U.S. National Health Interview Survey, 2010 and 2013*

TABLE OF AUTHORITIES—Continued

Page(s)

Final Recommendation Statement: Cervical Cancer: Screening, U.S. PREVENTIVE SERVS. TASK FORCE (Aug. 21, 2018), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening 24

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 22

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.. 25

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.................... 25

Final Recommendation Statement: Lung Cancer: Screening, U.S. PREVENTIVE SERVS. TASK FORCE (Mar. 9, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening.... 22

TABLE OF AUTHORITIES—Continued

Page(s)

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 25

G. Solanki, et al., *The direct and indirect effects of cost-sharing on the use of preventive services,* HEALTH SERVS. RSCH., 2000 Feb.;34(6):1331-50, https://pubmed.ncbi.nlm.nih.gov/10654834 16

High Cholesterol Facts, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 15, 2023), https://www.cdc.gov/cholesterol/facts.htm........ 11

Hope C. Norris, et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 MED. CARE. RSCH. & REV. 175 (2022), https://www.deepdyve.com/lp/sage/utilization-impact-of-cost-sharingelimination-for-preventive-care-bpUvb2r4Lr?key=sage....... 13-14

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 14

TABLE OF AUTHORITIES—Continued

Page(s)

James F. Wharam, *Two-year trends in colorectal cancer screening after switch to a high-deductible health plan,* MED CARE, 2011 Sept.;49(9):865-71, https://pubmed.ncbi.nlm.nih.gov/21577162 16

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 19

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 8

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 6

Krutika Amin, et al., *Preventive Services Use Among People with Private Insurance Coverage*, KAISER FAM.

TABLE OF AUTHORITIES—Continued

Page(s)

KW Davidson, et al., *Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement*, JAMA. 2021; 325(19):1965-1977, https://jamanetwork.com/journals/jama/fullarticle/2779985 8

Laura Skopec & Jessical Banthin, *Free Preventive Services Improve Access to Care*, URBAN INST., (July 2022), https://www.urban.org/sites/default/files/2022-07/Free%20Preventive%20Services%20Improve%20Access%20to%20Care.pdf...... 6, 17

N

Page(s)

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 22

NSCH Data Brief: Mental and Behavioral Health 2018-2019, HEALTH RES. & SERVS. ADMIN. (Oct. 2020), https://mchb.hrsa.gov/sites/default/files/mchb/data-research/nsch-data-brief-2019-mental-bh.pdf 23

Opinion 8.11, Health Promotion & Preventive Care, AMA Code Med. Ethics, https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/8.11.pdf.......... 2

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.......... 9

Patrick S. Sullivan, et al., *Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US 2012-2021*, Conference on Retroviruses and Opportunistic Infections, Denver, Colorado (March 2024), https://www.croiconference.org/abstract/association-of-state-level-prep-coverage-and-state-level-hiv-diagnoses-us-2012-2021/.......... 26

Page(s)

Post Braidwood Comparison of USPSTF Recommendations, AM. CANCER

Page(s)

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/ 21

Rosita van den Puttelaar, et al., *Implications of the Initial Braidwood v. Becerra Ruling for Colorectal Cancer Outcomes: A Modeling Study,* J. NAT'L CANCER INST. (Oct, 3 2024), https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djae244/7808996 .... 5, 6

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/... 21

Smoking Cessation: A Report of the Surgeon General, U.S. DEP'T HEALTH AND HUM. SERVS. (2020), https://www.ncbi.nlm.nih.gov/books/NBK555590/.......... 10, 18

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. (July 2019), https://www.sciencedirect.com/science/article/abs/pii/S0749379719301163) 8, 9

Page(s)

Stacey A. Fedewa, et al., *Elimination of*

TABLE OF AUTHORITIES—Continued

Page(s)

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/ 10

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 18

Xuesong Han, et al., *Has recommended preventive service use increased after*

INTEREST OF *AMICI* [1]

The American Cancer Society, American Cancer Society Cancer Action Network (ACS CAN), American Kidney Fund, Arthritis Foundation, Cancer Support Community, Crohn's & Colitis Foundation, Cystic Fibrosis Foundation, Epilepsy Foundation, Hemophilia Federation of America, National Minority Quality Forum, National Multiple Sclerosis Society, National Patient Advocate Foundation, The AIDS Institute, and The Leukemia and Lymphoma Society (collectively, "patient groups *amici*") are among the largest, most prominent organizations representing the interests of patients, survivors, and families affected by chronic conditions. These conditions are frequently prevented or detected in early stages by preventive services, including those recommended by the U.S. Preventive Services Task Force (USPSTF) pursuant to the preventive care mandate of the Patient Protection

Occupational and Environmental Medicine, American College of Physicians, American Medical Women's Association, American Osteopathic Association, American Psychiatric Association, American Society of Clinical

early detection of certain conditions, and improving survival rates. Impeding patients' access to preventive care would have an immediate and devastating impact.

SUMMARY OF ARGUMENT

As organizations representing the interests of patients, survivors, families, and their clinicians across the country, *amici* know that preventive care without cost sharing improves health outcomes and enables healthier lifestyles. All Americans use or will use health care services, and the lifetime risk that an individual American will contract a serious or chronic disease or condition is high. Preventive services aid in prevention, early detection and treatment of many conditions, increasing patients' chances of recovery and extending life expectancies. Preventive care also helps control costs of treating these conditions.

The ACA preventive services provision requiring private insurers cover USPSTF-recommended services without cost sharing increases patients' ability to receive care that can prevent disease outright, identify conditions 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. The ACA's preventive-care requirements have functioned for more than ten years, enabling millions of Americans to obtain preventive care and improving utilization of these vital services nationwide. Reducing insurance coverage for preventive services will lead to worsening patient outcomes, resulting in preventable deaths, and creating higher long-term medical costs.

The court of appeals decision threatens to drastically reduce insurance coverage for USPSTF-recommended services, deter utilization of those services, worsen patient outcomes, and potentially increase costs. If fully implemented, it will substantially harm the patients that *amici* treat, serve, and support.

ARGUMENT

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

The need for health care is dif cult to predict, but is practically inevitable at some point in life.[3] The ACA recognizes that, for the vast majority of Americans, accessing necessary care requires health insurance coverage. The ACA's framework for coverage has survived three prior challenges in this Court. This framework includes insurance coverage for preventive services without cost sharing so that Americans will have greater access to preventive services. Preventive care can "help people avoid acute illness, identify and

appropriately, these services can identify diseases at earlier stages when they are more treatable or may reduce a person's risk for developing a disease."[5] Studies relevant to many of the conditions that are the focus of *amici's* efforts and treatment show that preventive services currently recommended by USPSTF improve health outcomes and save lives.

A recent study assessed the effects of the district court decision in this case on colorectal cancer (CRC) incidence, mortality, and costs of care. The study examined the impact of reintroducing cost-sharing regarding USPSTF recommendations for CRC screening among adults aged 45-49 years and for polyp removal during (diagnostic) colonoscopy across all ages.[6] CRC screening decreases due to cost-sharing would result in additional CRC diagnoses of 7 individuals and deaths of 4 individuals per 100,000 annually by 2055. The increase in, and later stage of, diagnoses would also substantially increase treatment costs. Eliminating USPSTF recommendations for this screening would be especially harmful because early-onset CRC incidence

---

[5] *11th Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services*, U.S. PREVENTIVE SERVS. TASK FORCE 5 (2021), https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inlinefiles/2021-uspstf-annual-report-to-congress.pdf.

[6] Rosita van den Puttelaar, et al., *Implications of the Initial Braidwood v. Becerra Ruling for Colorectal Cancer Outcomes: A Modeling Study,* J. NAT'L CANCER INST. (Oct, 3 2024), https://academic.oup.com/jnci/advance-article/doi/10.1093/jnci/djae244/7808996.

on Prevention Priorities estimated that "[i]ncreasing the use of just 5 preventive services," including several USPSTF-recommended services, "would save more than 100,000 lives each year in the United States."[10] These ndings are similar for other conditions.

Cancers:

> CRC screening can prevent CRC through early detection and removal of precancerous growths, when treatment is usually more successful. As a result, screening reduces CRC mortality by both decreasing incidence and increasing survival. USPSTF recommends several CRC screening methods, all of which can improve life expectancy when performed at the appropriate time intervals and with the recommended follow-up.[11]
>
> Screenings for CRC increased from 57.3% to 61.2% between 2008 and 2013, especially among individuals with low income, lower education attainment, and Medicare insurance. These results are likely associated with the ACA provisions removing cost-sharing for these screenings.[12]
>
> Improvement in screening rates for CRC in early Medicaid expansion states translated to an additional 236,573 low-income adults receiving

---

[10] *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*, P'SHIP FOR PREVENTION 6 (2007).

[11] *Colorectal Cancer Facts & Figures 2023-2025*, AM. CANCER SOC'Y (2023), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2023.pdf.

[12] 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.

screenings in 2016 and, if the same increases were experienced in non-expansion states, 355,184 more low-income adults would have had CRC screening as of 2019.[13] CRC screenings in accordance with USPSTF recommendations have reduced the incidence of CRC and have led to earlier stage diagnosis and better survival

> The risk of breast cancer death is reduced due to early detection by mammography, which increases effective treatment options.[16]
>
> Compared with non-Medicaid expansion states, states that implemented Medicaid expansion under the ACA saw greater improvement in breast cancer screening rates among lower-income women.[17]

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.[18]

---

[16] *Breast Cancer Facts & Figures 2023-2024*, AM. CANCER SOC'Y (2023), 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.

[17] 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.

[18] 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.

Smoking Cessation:

> Smoking cessation reduces the risks of 12 different cancers and can help improve health outcomes after a cancer diagnosis.[19] Smoking cessation also reduces risk and improves health outcomes after a diagnosis of cardiovascular diseases, strokes, aneurisms, respiratory diseases, asthma, pregnancy and reproductive health.[20]
>
> Smoking cessation results in a decrease in smoking and reduces the risk of developing all cancers caused by smoking.[21]

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. Under current law, preventive care and screening without cost sharing are provided for blood pressure,

---

[19] *Smoking Cessation: A Report of the Surgeon General, Ch. 4: The Health Benefits of Smoking Cessation*, U.S. DEP'T HEALTH AND HUM. SERVS. (2020), https://www.ncbi.nlm.nih.gov/books/NBK555590/.

[20] *Id.*

[21] *Cancer Prevention & Early Detection Facts & Figures 2023-2024*, AM. CANCER SOC'Y at 13 (2024), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-prevention-and-early-detection-facts-and-figures/2024-cped-files/cped-2024-cff.pdf (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/).

cholesterol, Type 2 diabetes, obesity, and various other diseases.[22]

Use of blood pressure and cholesterol checks increased signi cantly in the years after the ACA's passage and implementation of the provision eliminating cost sharing for preventative services.[23]

Blood pressure screenings are important because uncontrolled blood pressure is strongly linked to ischemic heart and peripheral vascular disease,

> Obesity increases the risk for high blood pressure and high cholesterol which are risk factors for heart disease.[26]
>
> 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 go undetected.

These studies con rm that access to preventive services, facilitated by insurance coverage, increases the likelihood that healthcare providers will diagnose conditions earlier than they otherwise could and that diseases can be prevented before they develop. The data also illustrate that when providers diagnose conditions early, the likelihood of successfully treating patients and extending their lives increases. As organizations dedicated to preventing, treating, and addressing the devastating impact of these conditions, *amici* know that access to affordable preventive health care is fundamental to successful health outcomes.

II. 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

---

[26] *Consequences of Obesity*, CTRS. FOR DISEASE CONTROL AND PREVENTION (2022), https://www.cdc.gov/obesity/basics/consequences.html.

was improving access to health care by making coverage more affordable.[27] Congress required coverage of preventive services recommended by the USPSTF so that patients could obtain those services without cost-sharing.

Affordable coverage increases patients' access to screenings and preventive treatments, which makes prevention and early diagnosis of serious illnesses

For example, while most 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.[30]

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).[31] 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.[32]

Individuals with multiple sclerosis (MS) also 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, includ-

---

79 MED. CARE. RSCH. & REV. 175, 192 (2022), https://www.deepdyve.com/lp/sage/utilization-impact-of-cost-sharingeliminat ion-for-preventive-care-bpUvb2r4Lr?key=sage.

[30] *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.

[31] *Id.*

[32] *Id.*

ing skipping or delaying treatment.[33] Forty percent also said they experience stress or other emotional impact due to high out-of-pocket costs and are making lifestyle sacri ces to be

patients on a xed income, for whom these payments can represent a significant percentage of their income.[36] Removing cost-sharing for preventive services has been proven to increase the use of those services.[37] 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.[38]

Removal of coverage for preventive care would have minimal impact on employers' cost of providing health care coverage and overall employer health care spending. "If employers imposed 20 percent cost

---

[36] G. Solanki et al., *The direct and indirect effects of cost-sharing on the use of preventive services,* HEALTH SERVS. RSCH, 2000 Feb.;34(6):1331-50, https://pubmed.ncbi.nlm.nih.gov/10654834; James F. Wharam, *Two-year trends in colorectal cancer screening after switch to a high-deductible health plan,* MED CARE, 2011 Sept.;49(9):865-71, https://pubmed.ncbi.nlm.nih.gov/21577162; Amal N. Trivedi, et al., *Effect of cost sharing on screening mammography in Medicare health plans,* N. ENG. J. MED., 2008 Jan.;358(4):375-83, https://pubmed.ncbi.nlm.nih.gov/18216358.

[37] *Has recommended preventive service use increased after*

sharing on all medications recommended by USPSTF, employer spending would fall by 0.3 percent."[39]

In addition, 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 uoride treatments.[40] Preventive care is also critical for 132.2 million privately-insured adults, who receive cancer screenings, preventive medications like PrEP to prevent HIV, and statins and aspirin to prevent cardiovascular disease.[41]

becomes more cost effective and even provides cost savings.[43]

One study tracked the health and cost outcomes of forty- ve-year-old Americans who received lung cancer screenings beginning at age 50 until age 90, and determined that USPSTF's screening recommendations were cost effective.[44]

With regard to CRC, "[a] modeling study indicated that screening at ages 50-64 years under commercial insurance in the United States yields substantial clinical and economic bene ts that accrue primarily at ages [less than or equal to] 65 years under Medicare."[45]

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.[46]

---

[43] Angela B. Mariotto, et al., *Medical Care Costs Associated with Cancer Survivorship in the United States,* CANCER EPIDEMIOL BIOMARKERS PREV. 2020 Jul;29(7):1304-1312, https://pubmed.ncbi.nlm.nih.gov/32522832.

[44] Steven D. Criss, et al., *Cost-Effectiveness Analysis of Lung Cancer Screening in the United States*, ANNALS I

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% ($81.8 billion) and 7.2% ($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 identi cation and treatment intervention to limit CKD progression in all populations, particularly in people with T2D and cardiovascular risk factors.[47]

PrEP Services:

> The percentage of individuals with no existing co-pay who would not ll a PrEP prescription if a co-pay were required increased as the amount of the co-pay increased, with 11.1% of patients stopping the prescription with the implementation of a co-pay of less than $10 and 42.9%

---

[47] 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.

science, so the court of appeals' decision threatens patient access to state-of-the-art preventive care.

A review of 65 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."[49] A 2023 survey revealed that three out of ten people had delayed or skipped healthcare within the last year, largely due to income constraints.[50] At least half of the respondents said they would not pay out of pocket for preventive services such as tobacco cessation or screenings for HIV, depression and unhealthy drug use if out of pocket expenditure was required. More than one-third stated that they would not even pay for cancer screenings.[51] 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 coverage, resulting in patient out-of-pocket costs, is overturned.[52]

---

[49] 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/.

[50] 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/.

[51] *Id.*

[52] *Survivor Views: Majority Less Likely to Get Recommended Screenings if Coverage is Lost*, AM. CANCER SOC'Y CANCER ACTION NETWORK (May 11, 2023), https://www.fightcancer.org/policy-resources/survivor-views-majority-less-likely-get-recommended-screenings-if-coverage-lost.

diagnosed at an early stage is 63%—a stark contrast to the 8% survival rate for late-stage diagnoses.[57]

In February 2019, USPSTF recommended counseling interventions for pregnant and post-partum individuals at increased risk of perinatal depression.[58] This care is vital, as one in seven post-partum individuals experience postpartum depression and anxiety disorders.[59]

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.[60] Over half of those children received treatment or counseling from a mental health professional.[61] In October 2022, USPSTF recommended screenings for anxiety in children and adolescents aged eight to eighteen.[62]

---

[57] *Cancer Facts and Figures 2024*, AM. CANCER SOC'Y (2024), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2024/2024-cancer-facts-and-figures-acs.pdf.

[58] *A & B Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations.

[59] Dara Lee Luca, et al., *Issue Brief: Societal Costs of utt 8.2 (tf-)] TJ -0.0001aCCsss*

In July 2019, USPSTF recommended Hepatitis B Virus (HBV) screenings for pregnant individuals at their rst prenatal visit, and HBV screening for adolescents and adults at increased risk for infection in December 2020.[63] These screenings are crucial because chronic HBV has been shown to cause liver cancer and increase risk of non-Hodgkin lymphoma.[64]

In August 2022, USPSTF recommended use of statins for adults aged 40 to 75 with one or more risk factors for cardiovascular disease.[65]

In August 2018, USPSTF recommended cervical cancer screening, at either three or ve-year intervals, for women aged 21 to 65.[66] This update to the 2003 recommendation added the option for HPV testing and information regarding speci c testing modalities and intervals.[67]

---

[63] *Id.*

[64] *Cancer Prevention & Early Detection Facts & Figures 2021-2022*, 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.

[65] *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.

[66] *Final Recommendation Statement: Cervical Cancer: Screening*, U.S. PREVENTIVE SERVS. TASK FORCE (Aug. 21, 2018), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cervical-cancer-screening.

[67] *Id.*

25

In March 2020, USPSTF updated its Hepatitis C

rates by 8%, while the bottom 10 states reduced HIV diagnosis rates by just 1.7%.[73]

Comparing the pre-ACA preventive care requirements with the post-ACA recommendations from USPSTF illustrates the improvements in preventive care services that directly result from those recommendations. Recent USPSTF recommendations include new screening modalities not previously available and new recommendations based on current scienti c 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 including screenings/testing, counseling, behavioral interventions, and preventive treatment for high-risk patients.[74]

Over 150 million individuals in the U.S. have health insurance coverage subject to the ACA's preventive services requirement and receive preventive services cost-free.[75] A recent study found that six out of eight privately insured American adults, roughly 100

---

[73] Patrick S. Sullivan, et al., *Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US 2012-2021*, Conference on Retroviruses and Opportunistic Infections, Denver, Colorado (March 2024), https://www.croiconference.org/abstract/association-of-state-level-prep-coverage-and-state-level-hiv-diagnoses-us-2012-2021/.

[74] *Post Braidwood Comparison of USPSTF Recommendations*, AM. CANCER SOC'Y CANCER ACTION NETWORK (Apr. 24, 2023), https://www.fightcancer.org/sites/default/files/post-braidwood_coverage_of_uspstf_recommendations.pdf.

[75] *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, *supra* note 4 at 8.

million people, received some form of ACA preventive healthcare in 2018.[76]

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. Seven out of ten American children received ACA preventive services in 2018.[77] Among the most utilized services were screenings for heart disease, cervical cancer, and diabetes, all of which have been the subject of USPSTF updated recommendations.[78]

USPSTF has recommended lifesaving screenings and treatments for a wide array of diseases and conditions, including those which *amici* and their members seek to treat, prevent, and eradicate. These recommendations and their implementation have reduced nancial barriers to preventive care services, increased utilization of those services, and saved and prolonged lives.

The court of appeals' decision threatens to erect formidable nancial barriers to these life-saving services and reverse over a decade's worth of progress in improving health outcom.1 ( )]TJla1.00014ou -1.le8snoTJ 50.38 Tmn 20

nancial barriers that Congress sought to remove. If this Court allows the court of appeals' decision on USPSTF to stand, millions of Americans could struggle to access current, evidence-based preventive care services.

CONCLUSION

For the foregoing reasons, *amici* respectfully request that this petition for certiorari be granted, and that the Court take the case and reverse the court of appeals' decision as to constitutionality of the provisions relating to USPSTF's recommendations. The ACA's preventive care mandate has saved lives and should continue to do so.

Respectfully submitted,

BETH PETRONIO
Counsel of Record
K&L GATES LLP
1717 Main Street, Suite 2800
Dallas, TX 75201
(214) 939-5500
Beth.Petronio@klgates.com

JOHN LONGSTRETH
BRIAN HOPKINS
K&L GATES LLP
1601 K Street, N.W.
Washington, DC 20006
(202) 778-9000
John.Longstreth@klgates.com
Brian.Hopkins@klgates.com

MARY P. ROUVELAS
Managing Counsel and
Legal Advocacy Director
AMERICAN CANCER SOCIETY
CANCER ACTION NETWORK
655 15th Street NW
Suite 503
Washington, DC 20005
(703) 727-8500
Mary.Rouvelas@cancer.org

Counsel for Patient Groups

MADELINE GITOMER
SARAH GOETZ
CARRIE FLAXMAN
DEMOCRACY FORWARD
FOUNDATION
P.O. Box 34553
Washington, DC 20043
(202) 448-9090
mgitomer@democracyforward.org
sgoetz@democracyforward.org
c axman@democracyforward.org

Counsel for Medical Professional
Organizations

October 21, 2024