No. 24-316

IN THE

Supreme Court of the United States

ROBERT F. KENNEDY, JR., SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.,

Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC. ET AL.,

Respondents.

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

AMICI CURIAE BRIEF OF PATIENT AND PHYSICIAN PROFESSIONAL ORGANIZATIONS IN SUPPORT OF PETITIONERS

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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, Epilepsy Foundation of America, Hemophilia Federation of America, National Minority Quality Health Forum, National Multiple Sclerosis Society, National Patient Advocate Foundation, LUNGevity Foundation, and The Leukemia and Lymphoma Society (collectively, "patient organizations *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 ("Task Force") pursuant to the preventive care mandate of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 300gg-13. Patient organizations *amici* are dedicated to supporting patients and their families across the United States and collectively represent millions of individuals who suffer from the various conditions to which *amici* dedicate their efforts.

The American Medical Association, American Academy of Family Physicians, American Academy of Ophthalmology, American Academy of Pediatrics, American College of Chest Physicians, American College of Obstetricians and Gynecologists, American College of Osteopathic Internists, American College of Occupational and Environmental Medicine, American College of

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[1] *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. *See* Supreme Court Rule 37.6.

Physicians, American Medical Women's Association, American Osteopathic Association, American Psychiatric Association, American Society of Clinical Oncology, American Society For Gastrointestinal Endoscopy, American Thoracic Society, GLMA: Health Professional Advancing LGBTQ+ Equality, Infections Diseases Society of America, National Hispanic Medical Association, and Texas Medical Association (collectively, "medical professional organizations *amici*") are medical professional associations representing hundreds of thousands of practicing clinicians providing vital preventive healthcare services to millions of patients. These *amici* have a vital interest in the health of their patients and an ethical obligation to ensure that their patients, and the public as a whole, receive medically indicated preventive services.[2]

Both *amici* groups provide medical research, patient support, and other services related to curing, lessening the burden of, or otherwise minimizing the effects of various conditions. *Amici* bring decades of experience to fighting these conditions and advocating on behalf of patients.

Amici believe that the ACA's provisions regarding preventive care recommended by the Task Force are crucial for maintaining strong public health, preventing the development of a wide range of conditions, promoting early detection of certain conditions, and improving survival rates. Impeding patients' access to

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[2] "While a physician's role tends to focus on diagnosing and treating illness once it occurs, physicians also have a professional commitment to prevent disease and promote health and well-being for their patients and the community." 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 (last accessed Feb. 22, 2025).

preventive care would have an immediate and devastating impact on health outcomes.

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.[3] 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 Task Force is "a group composed of nationally recognized non-Federal experts in prevention and evidence-based medicine."[4] "Task Force members' considerations of proposed recommendations must be guided by the members' expert and impartial judgment."[5] The ACA preventive services provision requiring private insurers cover Task Force-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

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[3] *See* HHS Br. at 4, 8 (cleaned up) ("Preventive health services include screenings and medications to avoid serious health conditions. Such services can help people avoid acute illness, identify and treat chronic conditions, prevent cancer or lead to earlier detection, and improve health. . . . Since 2010, millions of Americans have received coverage for such preventive services without cost sharing.")

[4] *See* HHS Br. at 4.

[5] *Id.* at 32.

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 enabled millions of Americans to obtain preventive care and improved utilization of these vital services nationwide for more than ten years. 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 Task Force-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 difficult to predict, but is practically inevitable at some point in life.[6] The ACA recognizes that, for the vast majority of Americans, accessing necessary care requires health insurance coverage. The ACA's framework for coverage has

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

survived three prior challenges in this Court.[7] 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 treat chronic conditions, prevent cancer or lead to earlier detection, and improve health."[8] "When provided 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."[9] As detailed below, studies relevant to many of the conditions that are the focus of *amici's* efforts and treatment show that preventive services currently recommended by the Task Force improve health outcomes and save lives.

With respect to preventive services generally, analysis by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimates 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

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[7] *Id.*; *King v. Burwell*, 141 S. Ct. 2104 (2015); *California v. Texas*, 135 S. Ct. 248 (2021).

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

[9] *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.

number of people enrolled in private healthcare coverage subject to Task Force recommendations.[10]

A majority of recent studies have shown increases in use when there is no cost-sharing, and these findings suggest that individuals of low-socioeconomic-status and those who experience the greatest financial barriers to care appear to benefit the most from cost-sharing elimination.[11] Similarly, a 2007 study by the National Commission on Prevention Priorities estimated that "[i]ncreasing the use of just 5 preventive services," including several Task Force-recommended services, "would save more than 100,000 lives each year in the United States."[12] These findings are similar for other conditions.

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.

Braidwood **Litigation-Specific Studies**

Amici are aware of, and present in this brief, a number of trustworthy and peer-reviewed studies on

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

[11] 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; Laura Skopec and 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.

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

the positive effects on medical outcomes of the preventive services currently recommended by the Task Force. Considerable research has already been undertaken on the potential impact of the district court's opinion in this case, including the following two notable studies related to cancer.

A study published in the fall of 2024 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 the Task Force's recommendations for CRC screening among adults aged 45-49 years and for polyp removal during (diagnostic) colonoscopy across all ages.[13] Decreased CRC screening due to reintroduction of cost-sharing would result in additional CRC diagnoses of 7 individuals and deaths of 4 individuals per 100,000 annually by 2055. Treatment costs for CRC would also substantially increase due to an increase in diagnoses overall, as well as an increase in later-stage diagnoses. Eliminating the Task Force's recommendations for CRC screening would be especially harmful because early-onset CRC incidence in adults younger than 50 years is increasing in the United States.[14]

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[13] 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.

[14] *Id.; see also* Andrew Wolf et al., *Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society*, 68:4 CA: A CANCER J. FOR CLINICIANS 250 (July/Aug. 2018), https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21457.

Another study published in January 2025 found that if the ACA's requirement that plans cover Task Force-recommended services without cost-sharing was overturned, it would result in millions of commercially-insured individuals losing access to no-cost cancer screenings. According to this research, individuals at risk of losing no-cost coverage include 9 million individuals who are currently getting screened for breast cancer and 5 million more that are eligible for breast cancer screening; 3 million individuals who are currently getting screening for CRC and 11 million more that are eligible; and 500,000 individuals currently getting screening for lung cancer and 2.5 million more individuals that are eligible for such screenings. It is also important to note that of those who are current in their CRC screenings, 500,000 used new screening strategies that were not covered under the Task Force's recommendations in place at the time the ACA was enacted. Similarly, 1 million individuals currently being screened for cervical cancer are using new screening strategies. If no-cost coverage for these Task Force-recommended preventive screenings is lost, the negative impact on health outcomes is undeniable.

The same can be said of numerous other Task Force preventative care recommendations.

Additional Cancer Screening Studies:

- CRC screening can prevent CRC through removal of precancerous growths and can also detect CRC early, when treatment is usually more successful. As a result, regular screening reduces CRC mortality by both decreasing incidence and increasing survival rates. The Task Force recommends several CRC screening methods, all of which can improve survival and reduce mortality when performed at the

appropriate time intervals and with the recommended follow-up.[15]

- 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.[16]
- The ACA provision at issue also requires preventive services without cost-sharing for the Medicaid expansion population. 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 increases were experienced in non-expansion states, 355,184 more low-income adults would have had CRC screening as of 2019.[17] CRC screenings in accordance with Task Force recommendations have reduced the incidence of CRC and have led

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[15] *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.

[16] 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.

[17] 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).

to earlier stage diagnosis and better survival rates among those diagnosed.[18]

- Cervical cancer incidence and mortality rates have decreased by more than 50% over the past three decades and the decrease can be attributed to regular screenings, which can detect both precancerous lesions and cervical cancer at an early stage.[19]
- The risk of breast cancer death is reduced due to early detection by regular mammography, which increases effective treatment options.[20]
- 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.[21]

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[18] 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.

[19] *Cancer Prevention & Early Detection Facts & Figures 2023-2024*, AM. CANCER SOC'Y (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.

[20] *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.

[21] 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.

Smoking Cessation:

- Smoking cessation reduces the risks of twelve different cancers and can help improve health outcomes after a cancer diagnosis.[22] Smoking cessation also reduces risk and improves health outcomes after a diagnosis of cardiovascular diseases, strokes, aneurisms, respiratory diseases, asthma, pregnancy, and reproductive health.[23]
- Smoking cessation results in a decrease in smoking and reduces the risk of developing all cancers caused by smoking.[24]

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

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[22] *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/.

[23] *Id.*

[24] *Cancer Prevention & Early Detection Facts & Figures 2023-2024*, at 13 (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/).

blood pressure, cholesterol, Type 2 diabetes (T2D), obesity, and various other diseases.[25]

- Use of blood pressure and cholesterol checks increased significantly in the years after the ACA's passage and implementation of the provision eliminating cost-sharing for preventative services.[26]
- Blood pressure screenings are important because uncontrolled blood pressure is strongly linked to 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]

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[25] *Preventive Services Covered by Private Health Plans under the Affordable Care Act,* KFF (2024), https://www.kff.org/womens-health-policy/fact-sheet/preventive-services-covered-by-private-health-plans.

[26] 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.

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

- 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 go undetected.

These studies confirm 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 illustrates 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

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

the ACA was improving access to health care by making coverage more affordable.[30] Congress required coverage of preventive services recommended by the Task Force 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 more likely, improving patient outcomes. Identifying serious illnesses in early stages narrows the scope and invasiveness of successful treatments, 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 eventual outcome if the court of appeals' decision stands—would cause patients to choose between treating current conditions or trying to prevent new ones. Prior to the enactment of the ACA, many Americans either lacked health insurance or were enrolled in insurance plans that did not cover preventive care without cost-sharing[31]—creating a substantial barrier to widespread use of preventive care. A 2022 review of 35 separate studies conducted by the University of Michigan Center for Value-Based Insurance Design determined that "[t]he majority of findings in our literature conclude that cost-sharing

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[30] *Nat. Fed'n of Indep. Bus.*, 132 S. Ct. at 2580.

[31] *Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States?*, *supra* note 26.

elimination led to increases in utilization for select preventive services."[32]

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.[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]

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

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[32] Hope C. Norris, et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 MED. CARE. RSCH. & REV. 175, 192 (2022), https://www.deepdyve.com/lp/sage/utilization-impact-of-cost-sharingelimination-for-preventive-care-bpUvb2r4Lr?key=sage.

[33] *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] *Id*.

[35] *Id*.

disease-modifying therapy (DMT) due to cost, including skipping or delaying 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. These challenges can cause delays in starting a medication or changing medications when a treatment is no longer working. 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. Similarly, 21% of adults with epilepsy reported not being able to afford prescription medications within the last year.[38]

Studies show preventive services recommended by the Task Force also reduce costs for individuals and the U.S. health system. Preventive services facilitate early detection of conditions, leading to treatment of those conditions at less severe stages, which reduces individual and collective healthcare costs. Reduced healthcare costs for individuals not only has immediate positive health outcomes resulting from treatment but can also mitigate chronic stress arising from financial barriers to care. Chronic stress can increase an individual's risk of anxiety, depression, digestive

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[36] *Make MS Medications Accessible*, NAT'L MULTIPLE SCLEROSIS SOC'Y (2022), https://www.nationalmssociety.org/Treating-MS/Medications/Make-MS-Medications-Accessible.

[37] *Id*.

[38] 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/.

issues, headaches, heart disease, heart attack, high blood pressure, stroke, and immunosuppression.[39]

Examining 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.[40] Removing cost-sharing for preventive services has been proven to increase the use of those services.[41] Cost-sharing reduces the use of both low- and high-value care, including preventive care. Because preventive care services do not address acute health

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[39] *How stress affects your health*, AM. PSYCHOLOGICAL ASSOC. (2013), https://www.apa.org/topics/stress/health.

[40] G. Solanki et al., *The direct and indirect effects of cost-sharing on the use of preventive services,* HEALTH SERVS. RESEARCH, 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.

[41] *Has recommended preventive service use increased after elimination of cost-sharing as part of the Affordable Care Act in the United States?*, *supra* note 26; *see also* Michael Fiore, et al., *A Clinical Practice Guideline for Treating Tobacco Use and Dependence 2008 Update*, AM. J. PREV. MED. 2008 Aug; 35(2):158-76, https://pubmed.ncbi.nlm.nih.gov/18617085.

problems, some people may skip such care if cost-sharing is required.[42]

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-sharing on all medications recommended by the Task Force, employer spending would fall by 0.3 percent."[43]

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 fluoride treatments.[44] 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.[45] Approximately 67.7 million adult women with private insurance can receive a

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[42] 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.

[43] *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.

[44] Laura Skopec & Jessica 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.

[45] *Id.*

range of specialized care without cost-sharing, including well-woman visits, prenatal screenings, birth control, and cancer screenings.[46]

Numerous disease-specific studies further support the conclusion that Task Force-recommended preventative care leads to lower healthcare costs and less burden on the healthcare industry as a whole:

Cancers:

- Annualized costs associated with cancer are lower among individuals diagnosed with earlier stage cancers. As treatment costs for advanced cancers increase, screening for early detection becomes more cost effective and can even provide cost savings.[47]
- One study tracked the health and cost outcomes of 45 year old Americans who received lung cancer screenings beginning at age 50 until age 90, and determined that the Task Force's screening recommendations were cost effective.[48]
- 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

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[46] *Id*.

[47] 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.

[48] 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.

benefits that accrue primarily at ages [less than or equal to] 65 years under Medicare."[49]

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.[50]

Kidney Disease:

- 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 identification

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[49] 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.

[50] *Smoking Cessation: A Report of the Surgeon General*, *supra* note 22, at *Ch. 5: The Benefits of Smoking Cessation on Overall Morbidity, Mortality, and Economic Costs.*

and treatment intervention to limit CKD progression in all populations, particularly in people with T2D and cardiovascular risk factors.[51]

PrEP Services:

- The percentage of individuals with no existing co-pay who would not fill 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% dropping the medication if the co-pay were more than $500.[52]

In sum, preventive care services recommended by the Task Force, provided without cost-sharing, facilitate earlier diagnosis and less invasive, more successful treatment, which reduces costs to individual patients and the U.S. health system as a whole.

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[51] 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.

[52] Lorraine T. Dean, et al. *Estimating the Impact of Out-Of-Pocket Cost Changes on Abandonment of HIV Pre-Exposure Prophylaxis,* 43 HEALTH AFFAIRS, 36-45 (2024) https://doi.org/10.1377/hlthaff.2023.00808; *see also* Rahel Dawit, et al., *Identifying HIV PrEP Attributes to Increase PrEP Use Among Different Groups of Gay, Bisexual, and Other Men Who Have Sex with Men: A Latent Class Analysis of a Discrete Choice Experiment,* AIDS BEHAV, 28(1): 125–134 (2024), https://doi.org/10.1007/s10461-023-04131-y (finding that the potential cost of PrEP mediation was a significant factor in the decision to use or not to use the medication).

III. THE COURT OF APPEALS DECISION COULD 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 conditions, diagnosing them earlier, and more successfully treating them. If insurers and employers choose to implement cost-sharing for preventive services or drop them altogether, many patients, especially low-income patients, could be forced to utilize preventive services less frequently or not at all. The recommendations at issue are supported by current science, so the court of appeals' decision threatens patient access to state-of-the-art preventive care.

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."[53] A 2023 survey revealed that three out of ten people had delayed or skipped healthcare within the last year, largely due to income constraints.[54] At least half of the respondents said they would not pay out of pocket for preventive services such as tobacco cessation or

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[53] 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/.

[54] Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through*, MORNING CONSULT (Mar. 8, 2023), https://morningconsult.com/2023/03/08/affordable-care-act-polling-data/.

screenings for HIV, depression and unhealthy drug use if out of pocket expenditure was required. More than a third stated that they would not even pay for cancer screenings.[55] Similarly, a study in 2023 found 58% of cancer patients and survivors would be less likely to maintain preventive care, including recommended cancer screenings, if the mandate for coverage is overturned and results in patient out-of-pocket costs.[56]

The ACA's framework sought to increase use of preventive care by requiring health insurers to cover Task Force-recommended services with "A" and "B" grades. Congress's goal was to allow individuals greater access to evidence-based care as science evolves.

Numerous Task Force recommendations have changed as science has evolved. For example, in 2008, the Task Force recommended CRC screenings for adults 50 and older.[57] The current CRC screening recommendation has reduced the screening age to 45 and added screening modalities not present in and/or not yet developed at the time of the original recommendation.[58]

Similarly, the Task Force first recommended lung cancer screenings in 2013 and updated its

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[55] *Id*.

[56] *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.

[57] *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.

[58] *Id.*

recommendation in 2021.[59] The Task Force developed its new recommendation based, in part, on data from the National Lung Cancer Screening Trial (NLST). NLST provided direct evidence of moderate certainty that lung cancer screening in high-risk populations was effective in reducing lung cancer deaths.[60] 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 64%—a stark contrast to the 9% survival rate for late-stage diagnoses.[61]

In February 2019, the Task Force recommended counseling interventions for pregnant and post-partum individuals at increased risk of perinatal depression.[62] This care is vital, as one in seven post-

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

[60] 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.

[61] *Cancer Facts and Figures 2025*, AM. CANCER SOC'Y (2025), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2025/2025-cancer-facts-and-figures-acs.pdf.

[62] *A & B Recommendations*, U.S. PREVENTIVE SERVS. TASK FORCE https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations (last accessed Feb. 22, 2025).

partum individuals experience postpartum depression and anxiety disorders.[63]

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.[64] Over half of those children received treatment or counseling from a mental health professional.[65] In October 2022, the Task Force recommended screenings for anxiety in children and adolescents aged eight to eighteen.[66]

In July 2019, the Task Force 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.[67] These screenings are crucial because chronic HBV has been shown to cause liver cancer and increase risk of non-Hodgkin lymphoma.[68]

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[63] Dara Lee Luca, et al., *Issue Brief: Societal Costs of Untreated Perinatal Mood and Anxiety Disorders in the United States*, MATHMATECA (Apr. 2019), https://www.mathematica.org/publications/societal-costs-of-untreated-perinatal-mood-and-anxiety-disorders-in-the-united-states.

[64] *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.

[65] *Id*.

[66] *A & B Recommendations*, *supra* note 62.

[67] *Id.*

[68] *Cancer Prevention & Early Detection Facts & Figures 2023-2024, supra* note 19.

In August 2022, the Task Force recommended use of statins for adults aged 40 to 75 with one or more risk factors for cardiovascular disease.[69]

In August 2018, the Task Force recommended cervical cancer screening, at either three or five-year intervals, for women aged 21 to 65.[70] This update to the 2003 recommendation added the option for HPV testing and information regarding specific testing modalities and intervals.[71]

In March 2020, the Task Force updated its Hepatitis C Virus screening recommendation.[72] The new version "incorporates new evidence" and "expands the ages for screening to all adults from 18-79 years."[73]

In June 2019, the Task Force added HIV screening and treatment recommendations, leading to an extension of mandatory screening coverage to adolescents and adults aged 15-65, adolescents and adults at increased

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[69] *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.

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

[71] *Id*.

[72] *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.

[73] *Id.*

risk of infection, and pregnant individuals.[74] It simultaneously extended its PrEP recommendation to individuals at high risk of HIV acquisition.[75] 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.[76] Between 2012 and 2021, states with the highest PrEP coverage rates had significantly greater decreases in HIV diagnosis, with the top ten states reducing HIV diagnosis rates by 8%, while the bottom ten states reduced HIV diagnosis rates by just 1.7%.[77]

Comparing the pre-ACA preventive care requirements with the post-ACA recommendations from the Task Force illustrates the improvements in preventive care services that directly result from those recommendations. Recent Task Force recommendations

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[74] *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.

[75] *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.

[76] *About HIV*, CTRS. FOR DISEASE CONTROL AND PREVENTION (June 30, 2022), https://www.cdc.gov/hiv/basics/whatishiv.html.

[77] 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/.

include new screening modalities not previously available 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 including screenings/testing, counseling, behavioral interventions, and preventive treatment for high-risk patients.[78]

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.[79] 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.[80]

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.[81] Among the most utilized services were screenings for heart disease, cervical cancer, and

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

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

[80] 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/.

[81] *Id.*

diabetes, all of which have been the subject of the Task Force's updated recommendations.[82]

The Task Force 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 financial barriers to preventive care services, increased utilization of those services, and saved and prolonged lives.

The court of appeals' 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. *Amici* know from experience that patients will be less likely to obtain these services that will save lives if the preventive care mandate is stricken. Ultimately, *amici* will see many of their patients and the individuals they serve turn down medically indicated services because of the very financial barriers that Congress sought to remove. If this Court allows the court of appeals' decision on the Task Force to stand, millions of Americans could struggle to access current, evidence-based preventive care services.

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[82] *Id.*

CONCLUSION

For the foregoing reasons, *amici* respectfully request that this Court reverse the court of appeals' decision as to constitutionality of the provisions relating to the Task Force's recommendations. The ACA's preventive care mandate has saved lives and should continue to do so.

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