Case 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 SCHEIDMAN,

Plaintiffs - Cross-Appellants

v.

XAVIER BECERRA, Secretary, U.S. Department of 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

BRIEF OF *AMICI CURIAE* UNITED STATES OF CARE, MICHIGAN LEAGUE FOR PUBLIC POLICY, WEST VIRGINIANS FOR AFFORDABLE HEALTH CARE, CONSUMERS FOR AFFORDABLE HEALTH CARE, NEW DAY NEVADA, YOUNG INVINCIBLES, SHRIVER CENTER ON POVERTY LAW, ACADEMYHEALTH, COLORADO CONSUMER HEALTH INITIATIVE, PENNSYLVANIA HEALTH ACCESS NETWORK, COMMITTEE TO PROTECT HEALTH CARE, UTAH HEALTH POLICY PROJECT, COMMUNITY CATALYST, PROTECT OUR CARE, ACA CONSUMER ADVOCACY, AND THE NATIONAL PARTNERSHIP FOR WOMEN & FAMILIES IN SUPPORT OF THE APPELLANTS/CROSS-APPELLEES AND IN SUPPORT OF REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record for the *amici curiae* listed below certifies that the following listed persons and entities described in the fourth sentence of Local Rule 28.2.1 (in addition to those previously identified in certificates filed by the parties and other *amici*) 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. *Amici curiae* United States of Care, Michigan League for Public Policy, West Virginians for Affordable Health Care, Consumers for Affordable Health Care, New Day Nevada, Young Invincibles, Shriver Center on Poverty Law, AcademyHealth, Colorado Consumer Health Initiative, Pennsylvania Health Access Network, Committee to Protect Health Care, Utah Health Policy Project, Community Catalyst, Protect Our Care, ACA Consumer Advocacy, and The National Partnership for Women & Families have no parent corporations. No publicly-held corporation owns 10% or more the stock of any of these organizations.

B. The foregoing *amici curiae* are represented by Daniel G. Jarcho of Alston & Bird LLP.

/s/ Daniel G. Jarcho
Daniel G. Jarcho

Attorney of Record for *Amici Curiae*

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STATEMENT OF INTEREST

The *amici curiae* listed below are nonprofit organizations dedicated to assuring quality, affordable, equitable health care — including preventive care — throughout the United States. They have a significant interest in this case, because if this Court does not reverse the District Court's ruling, more than 150 million Americans will lose access to no-cost preventive care that would otherwise protect them from illness.[1]

Amicus United States of Care (USofC) is a nonpartisan nonprofit working to ensure everyone has access to quality, affordable health care regardless of health status, social need, or income. USofC drives changes at the state and federal level in partnership with everyday people, business leaders, health care innovators, fellow advocates, and policymakers. Through these partnerships, USofC advocates for new solutions to tackle health care challenges that bring peace of mind to, and a positive impact on, the lives of people of every demographic. It is through this lens, and through their advocacy on behalf of everyday people, that USofC has a deep concern for the preservation of access to preventive services without a financial barrier.

[1] No counsel for a party authored this brief in whole or in part. No party, counsel for a party, or person other than *amici curiae*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

Amicus The Michigan League for Public Policy is a nonpartisan policy institute dedicated to economic opportunity for all. The League promotes health care access, affordability, and equity to reduce health disparities and improve health outcomes.

Amicus West Virginians for Affordable Health Care is a nonpartisan organization that helps inform, educate, and help create or change health care policies for West Virginia, both on the state and federal level.

Amicus Consumers for Affordable Health Care serves as Maine's Health Insurance Consumer Assistance Program. Its Helpline advocates talk daily to Mainers about their health coverage options, including the value of coverage that provides access to preventive care.

Amicus New Day Nevada is a leading healthcare advocacy organization. Its initiatives have helped ensure all Nevadans have access to a more affordable, high-quality healthcare plan.

Amicus Young Invincibles is a nonprofit dedicated to expanding economic opportunity and affordable and accessible health care for young adults. Young Invincibles believes that recommended affordable and cost-free services should be available to young adults and that as medical data around medicines, treatments, and illnesses evolves, so should the responsibilities of medical insurance companies.

Amicus The Shriver Center on Poverty Law provides national and state leadership to promote healthcare access and coverage. The Shriver Center advances laws and policies to achieve economic, racial, and social justice for its clients. The Shriver Center represents communities that include people who need access to healthcare coverage that includes preventive services.

Amicus AcademyHealth supports health services research that improves health and health care for all by advancing research about how our health system works, how to support patients and providers in choosing the right care, and how to improve health through care delivery that includes preventive services.

Amicus The Colorado Consumer Health Initiative is a nonprofit health advocacy organization that serves Coloradans whose access to health care and financial security are compromised by structural barriers, affordability, poor benefits, or unfair business practices.

Amicus Pennsylvania Health Access Network (PHAN) assists individuals navigating high out-of-pocket costs for care and has witnessed directly the benefits of preventive care with no patient cost-sharing. PHAN is concerned that a potential return of cost-sharing would discourage people from getting care or getting medically recommended care for preventable, treatable conditions.

Amicus The Committee to Protect Health Care works to expand health care access, lower prices for patients, and protect reproductive rights. Its work includes advocating for affordable, accessible preventive care.

Amicus Utah Health Policy Project (UHPP) is a nonpartisan, nonprofit organization advancing sustainable health care solutions for underserved Utahns through better access, education, and public policy. UHPP serves individuals and families that depend on access to no-copay preventive services.

Amicus Community Catalyst is a nonprofit health policy organization focused on supporting race equity, health justice, and a society where health is a right for all. A critical part of Community Catalyst's mission is ensuring equitable access to affordable health care for all people, regardless of income, race, gender identity, or other factors.

Amicus Protect Our Care is dedicated to making high-quality, affordable and equitable health care a right, and not a privilege, for everyone in America. Protect Our Care educates the public, influences policy, supports health care champions and holds politicians accountable.

Amicus ACA Consumer Advocacy is a health care advocacy group with the purpose of educating, motivating, and mobilizing healthcare consumers to actively participate in the process of improving our national healthcare system.

Amicus The National Partnership for Women & Families is a nonprofit, nonpartisan organization that works to make life better for women and families by fighting for issues that include health and economic justice, reproductive rights, and women's equality. The organization takes a strong interest in protecting access to free preventive care that women and families need to lead healthy lives and thrive in communities across the country.

ARGUMENT

The District Court's ruling would eliminate Americans' statutory right to cost-free preventive health care that has kept them healthy for more than a decade. Since 2010, the Affordable Care Act (ACA) has required health insurers and group health plans to cover preventive health care services fully, at no additional cost to consumers. Congress wisely decided that the best-available science would dictate the specific preventive services subject to this no-cost coverage requirement (and that the specific services covered would change as the science evolved over time). Congress determined that health care experts at the U.S. Preventive Services Task Force (USPSTF) would identify the vast majority of preventive services covered by the no-cost requirement. Specifically, most health coverage has been required to cover, with no cost-sharing, evidenced-based items or services that have a rating of "A" or "B" in the current USPSTF recommendations with respect to the individual involved. The District Court entered an injunction that would nullify the no-cost

coverage requirement as to evidence-based preventive services recommended by the USPSTF since the ACA's passage, thereby gutting Congress's pro-active plan to stave off illness before it has a chance to take root. *Amici* describe below the significance of the preventive services identified by the USPSTF, documenting how the District Court's ruling, if allowed to stand, would devastate affordable access to preventive services for, and the health of, more than 150 million people across the country.

I. THE DISTRICT COURT'S RULING WOULD DEVASTATE PREVENTIVE CARE THAT PROTECTS MILLIONS OF AMERICANS FROM SERIOUS DISEASES

The ACA mandated that insurers and group health plans must "provide coverage for and shall not impose any cost sharing requirements for" services currently subject to certain recommendations of the USPSTF. 42 U.S.C. § 300gg–13(a)(1). These USPSTF recommendations establish most of the preventive services for which the ACA requires coverage with no consumer cost-sharing.[2] The District Court's ruling would limit the requirement to USPTSF recommendations that existed at the time of the ACA's enactment in 2010. USPSTF has since updated many of these recommendations, leading to significant uncertainty among

[2] The remaining requirements unrelated to USPSTF concerned some services for women, certain immunizations, and certain requirements concerning infants, children, and adolescents. 42 U.S.C. § 300gg–13(a)(2) – (a)(4).

consumers and other stakeholders as to which version of pre-2010 recommendations would stand. The District Court's ruling would explicitly eliminate the no-cost coverage requirement for all preventive services that USPTSF has recommended with an "A" or "B" rating since 2010 (and will recommend in the future), thereby decimating affordable access to evidence-based services that protect the health of millions of Americans.

A. Eliminating Mandatory No-Cost Coverage Would Dramatically Reduce Consumer Use of Preventive Services

1. Consumers' Utilization of Preventive Services Substantially Decreases When They Must Pay Out-of-Pocket Costs

Consumers' utilization of preventive services substantially decreases when they must pay out-of-pocket costs. Americans consume health care based on their doctors' recommendations and the parameters of their health coverage. When patients face out-of-pocket costs, their use of health care services, even for urgent health issues, is sharply reduced. Mitchell Wong et al., *Effects of Cost Sharing on Care Seeking and Health Status: Results from the Medical Outcomes Study*, 91 AM. J. PUB. HEALTH 1889, 1889 (2001) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1446896/pdf/0911889.pdf.

By definition, preventive health care is typically non-urgent, so individuals are even more likely to delay or forgo such care if the cost is too high. Patient cost-sharing obligations reduce uptake of both low- and high-value care, including

preventive care. Rajender Agarwal et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 HEALTH AFFAIRS 1762 (2017), https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2017.0610. When a doctor suggests a preventive health care screening, whether a patient actually receives the recommended service depends in large part on whether it is covered by the patient's health plan and whether the patient will have out-of-pocket costs.

Even modest out-of-pocket costs reduce utilization of health care services. For instance, higher levels of cost-sharing negatively affect prescription drug adherence. Nicole Fusco et al., *Cost-Sharing and Adherence, Clinical Outcomes, Health Care Utilization, and Costs: A Systematic Literature Review*, 29 J. OF MANAGED CARE & SPECIALTY PHARM. (Jan. 2023), at 5, https://www.jmcp.org/doi/epdf/10.18553/jmcp.2022.21270?role=tab. Poor medication adherence in turn causes higher rates of mortality, hospitalization, and complications, all of which increase costs for consumers as well as other payers in the healthcare ecosystem. *Id.* Similarly, when cancer is diagnosed earlier rather than later, outcomes improve and costs are lower. Zura Kakushadze et al., *Estimating Cost Savings from Early Cancer Diagnosis*, SSRN, Data 2(30):2-16 (2017), https://papers.ssrn.com/sol3/papers.cfm?_abstract_id=2975597. Still, before the ACA was enacted, approximately one-third of low-income Americans postponed

seeking preventive care due to cost. Kaiser Fam. Found., *Preventive Services Covered by Private Health Plans under the Affordable Care Act* (May 15, 2023), https://www.kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/.

In enacting the ACA, Congress recognized this problem and sought to improve Americans' access to, and uptake of, preventive health services. The preventive services coverage requirement that the District Court decision would curtail comes from the very first section of the bill. Affordable Care Act, PUB. L. No. 111–148, § 1001, 124 STAT. 119, 141 (2010).

The ACA preventive services coverage requirements have worked. In the years following the ACA, more Americans received blood pressure, cholesterol, and colon cancer screenings compared to before the ACA, and more adults and children received recommended vaccinations, such as the flu and HPV vaccines. Laura Skopec & Jessica Banthin, *Free Preventive Services Improve Access to Care*, URBAN INSTITUTE (July 2022), at 2, https://www.urban.org/sites/default/files/2022-07/Free%20Preventive%20Services%20Improve%20Access%20to%20Care.pdf. These screenings save lives and save money. Increasing current screening rates could save thousands of additional lives each year. Zhen-Qiang Ma & Lisa C. Richardson, *Cancer Screening Prevalence and Associated Factors Among US*

Adults, 19 PREVENTING CHRONIC DISEASE (Apr. 2022), at 2, https://www.cdc.gov/pcd/issues/2022/pdf/22_0063.pdf.

Improved access to mammography demonstrates the powerful impact of no-cost access to preventive care. In 2018, more than 60 percent of women eligible for no cost-sharing mammography services due to ACA requirements reported having had a mammogram within the previous two years. Claire O'Brien & Jessica Banthin, *22.2 Million Women Ages 50 to 64 May Lose Access to Free Mammogram Screening*, URBAN INSTITUTE (Apr. 2023) at 1, https://www.rwjf.org/en/insights/our-research/2023/05/22-2-million-women-ages-50-to-64-may-lose-access-to-free-mammogram-screening.html. By comparison, lung cancer screening rates are very low, despite dire outcomes associated with late stage disease. Recent USPSTF recommendations expanding eligibility for lung cancer screening may improve uptake of this care if cost-sharing is eliminated as a barrier. Rose McNulty, Estimated Lung Cancer Screening Rates "Extremely Low" Across Insurance Type, AJMC (Apr. 14, 2023), https://www.ajmc.com/view/estimated-lung-cancer-screening-rates-extremely-low-across-insurance-types.

While access to screening services without cost-sharing has reduced barriers to care and improved equity, cost remains a barrier to care more broadly, and millions of patients report having delayed or avoided medical care due to costs. *See*

Claire O'Brien, URBAN INSTITUTE, *supra*. If patients face costs for preventive care, progress made since the ACA will be reversed.

2. Polling Following the District Court's Decision Indicates That Eliminating No-Cost Coverage Would Substantially Deter Consumers From Seeking Preventive Care

Polling conducted since the District Court's decision indicates consumers will be unwilling to pay for preventive services if they are no longer covered at no cost, suggesting utilization will drop. In a survey, 60% of people said they would not pay for smoking cessation or screenings for unhealthy drug use, 58% said they would be unwilling to pay for weight loss measures to address health risks tied to obesity, 53% said they would not pay for depression screenings, and 52% said they would not pay for HIV screenings. Page Minemyer, *Patients Are Likely to Avoid Preventive Care Should Aca Coverage Ruling Stand, Survey Finds*, FIERCE HEALTHCARE (Mar. 8, 2023), https://www.fiercehealthcare.com/payers/patients-are-likely-avoid-preventive-care-should-aca-coverage-ruling-stand-survey-finds.

3. There Is No Guarantee That Insurers or Employers Would Voluntarily Provide No-Cost Coverage

There also is no guarantee that health insurers or employers would voluntarily provide no-cost coverage.

Reviewing coverage offered prior to the ACA demonstrates the potential consequences for consumers. As of 2003, half of adults aged 18–64 lacked immunization coverage (including 29 million adults considered to be at high risk),

let alone having access to this preventive care without cost-sharing. Inst. of Med. (US) Comm. on the Evaluation of Vaccine Purchase Financing in the U.S, *Financing Vaccines in the 21st Century: Assuring Access and Availability* at 89 (National Academies Press (US) 2003), https://www.ncbi.nlm.nih.gov/books/NBK221813/pdf/Bookshelf_NBK221813.pdf . At the same time, having health coverage was demonstrated to make high-risk adults twice as likely to receive flu vaccines, and access to free flu shots was extremely influential to improving vaccination rates. *Id.* at 75.

In 2011, the Institute of Medicine analyzed pre-ACA preventive services coverage for people with employer-based insurance and found that 56 percent of people had coverage for adult immunizations, 80 percent were in plans that had coverage for adult physical exams, 77 percent were in plans that covered well-baby care, and 60 percent had coverage for gynecological examinations and services, with limitations and copayments commonly required. Nat'l Acads. of Scis., Eng'g & Med., Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* (National Academies Press 2011), https://doi.org/10.17226/13181.

Prior insurer and employer practices demonstrate the consequences for consumers if preventive services coverage requirements are rolled back. If the District Court ruling is upheld, preventive care benefits consumers have come to rely

on could once again become unavailable or subject to copayments or other out-of-pocket costs that reduce access.

B. The Services That Consumers Would Forgo Prevent Serious Diseases

By nullifying the no-cost incentive for consumers to seek preventive services, the District Court's ruling would substantially harm the public health by impeding the prevention of serious diseases. For example, the HIV-prevention medication Pre-Exposure Prophylaxis (PrEP), which USPSTF recommended beginning in 2019, has been shown to reduce the risk of getting HIV by 99%. Under the District Court's decision, PrEP used as recommended would no longer be required to be covered with no cost-sharing. No comparable drug exists for patients at high risk for HIV, leaving this population at risk for increased HIV transmission if plans drop coverage as would be allowed by the District Court's decision. *See* David Paltiel et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of Braidwood Management v. Becerra*, OPEN FORUM INFECTIOUS DISEASES, Vol. 10, Issue 3 (Mar. 2023), ofad139, https://doi.org/10.1093—/ofid/ofad139.

The adverse effects of the District Court's ruling do not stop there. The ruling would eliminate, in whole or in part, no-cost coverage for the following critical preventive care:

Anxiety screenings	Skin cancer prevention counseling
Application of fluoride varnish to primary teeth	Statin prescriptions to prevent cardiovascular disease
Aspirin use to prevent Preeclampsia	Tobacco prevention interventions
Behavioral counseling interventions of health weight gain	Hepatitis C screenings
Drug abuse screenings	Alcohol abuse screening & behavioral counseling interventions
Falls prevention interventions	Prediabetes & type 2 diabetes screenings
Lung cancer screenings	Colorectal cancer screenings
Medication to reduce risk of breast cancer	Hepatitis B screenings
Perinatal depression preventive interventions	HIV screenings
Pre-exposure Prophylaxis (PrEP) access	Osteoporosis screenings
Screening for gestational diabetes	Cervical cancer screenings
Screenings for intimate partner violence & elder abuse[3]	

[3] United States of Care, *2023 USPSTF Recommendations Impacted by Braidwood Decision* (2023), https://unitedstatesofcare.org/wp-content/uploads/2023/04/2023-USPSTF-Recommendations-Impacted-by-Braidwood-Decision-.pdf.

C. Limiting No-Cost Preventive Services to Those Recommended in 2010 Would Deprive Consumers of the Benefits of Current and Future Medical Advancements

Limiting no-cost preventive services to those recommended in 2010 also would deprive consumers of the benefits of current and future medical advancements. Clinical knowledge about disease prevention continues to improve. That is why USPSTF revisits its recommendations regularly in order to consider and incorporate new information. The "extent of new evidence" is a driving factor in how USPSTF prioritizes topics for review. Michael J. Barry et al., *Putting Evidence Into Practice: An Update on the US Preventive Services Task Force Methods for Developing Recommendations for Preventive Services*, 21 ANNALS OF FAM. MED. 165, 165 (2023), https://www.annfammed.org/content/annalsfm/21/2/165.full.pdf.

The harmful effects of taking away coverage requirements and cost-sharing prohibitions for services recommended after 2010 would compound over time, as the recommendations in place at that time become more and more out of date. As new preventive services and drugs are introduced and adopted, even those recommended by the USPSTF's medical experts would be covered only at the discretion of insurers and employers. The services to which the ACA requirements apply would not reflect current evidence and best practices, affecting patient care and safety.

USPSTF makes available the types of services that are currently under review and consideration for potential updating to its recommendations, giving consumers and insurers a glimpse into potential changes that are grounded in medical evidence that soon could become available without cost-sharing. Topics currently under review for potential future recommendations include chronic kidney disease and screening and weight loss to prevent obesity-related morbidity and mortality in adults. U.S. Preventive Servs. Task Force, "Recommendations in Progress", https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/recommendations-in-progress (last visited June 23, 2023). If the District Court's ruling stands, cost-free access will be eroded not only for currently recommended services, but also for any services USPSTF recommends with an "A" or "B" rating in the future.

D. The District Court's Ruling Would Reverse Progress In Reducing Barriers to Care and Inequities in the Health System

The District Court's ruling also would reverse progress in reducing barriers to care and inequities in the health system. As of 2022, more than 150 million Americans with private health coverage are eligible to receive preventive services without cost-sharing under the ACA. U.S. Dep't of Health & Hum. Servs., Office of the Assistant Secretary for Planning and Evaluation (ASPE), *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act* (Jan. 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d

70dd2/preventive-services-ib-2022.pdf. The reach of the ACA preventive services requirement has led to significant strides in reducing barriers to care, especially among underserved and underrepresented communities. If the District Court's ruling stands, it would reverse that progress.

Allowing cost-sharing for preventive services could have profound implications for communities that have historically faced limited access to essential preventive services. Steven Teutsch et. al., *Health Equity in Preventive Services: The Role of Primary Care*, 102 AM. FAM. PHYSICIAN 264, 264 (2020), https://www.aafp.org/content/dam/brand/aafp/pubs/afp/issues/2020/0901/p264.pdf. For example, following the ACA, colonoscopy screenings increased at a higher rate among Hispanic and Black adults compared with white adults. Kenneth E. Thorpe, *Racial Trends in Clinical Preventive Services Use, Chronic Disease Prevalence, and Lack of Insurance Before and After the Affordable Care Act*, 28 AM. J. MANAGED CARE 126 (2022), https://cdn.sanity.io/files/0vv8moc6/ajmc/0df02b9aa79fa4e7fa4f350bdf5053ae6411b0f0.pdf/AJMC_04_2022_Thorpe_final.pdf. But re-introducing cost-sharing as a barrier to preventive services is likely to reverse progress made in reducing disparities in screening rates. *Id.*

Young adults, who are disproportionately non-white compared to the general population, have historically experienced the lowest levels of health care utilization

of all age groups. Josephine S. Lau, et al, Young Adults' Health Care Utilization and Expenditures Prior to the Affordable Care Act, NAT'L LIBRARY OF MED. 2014), (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4142567/#:~:text=Young%20adults%20had%20the%20lowest,%25%2C%20p%3C0.001). Since the passage of the ACA, young adults' use of preventive services, such as cholesterol checks and flu shorts, increased significantly. Sally H. Adams et al., Young Adult Preventive Healthcare: Changes in Receipt of Care Pre- to Post-Affordable Care Act, J. OF ADOLESCENT HEALTH, Vol. 64, Issue 6 (June 2019), https://nahic.ucsf.edu/resource_center/ya-preventive-healthcare-aca/; https://jamanetwork.com/journals/jamapediatrics/fullarticle/1913624/). While the health care utilization rates of young adults still lag those of their older or younger counterparts, gains made among young adults stand to be reversed should the District Court's ruling stand.

The District Court's ruling would be particularly damaging in reversing gains made in reducing HIV prevalence, especially among underserved and underrepresented communities. High costs led to underutilization of pre-exposure prophylaxis (PrEP), particularly among Black and Hispanic adults. Karishma Srikanth et. al., *Associated Costs Are a Barrier to HIV Preexposure Prophylaxis Access in the United States*, 112 AM. J. PUB. HEALTH 834 (2022), https://ajph.aphapublications.org/doi/epdf/10.2105/AJPH.2022.306793. Cost-

sharing for PrEP has been eliminated for people at "high risk of HIV acquisition" due to the USPSTF's 2019 recommendations, but could return if the District Court's decision is upheld. U.S. Preventive Servs. Task Force, *Recommendation Statement: Preexposure Prophylaxis for the Prevention of HIV Infection*, 321 J. AM. MED. ASS'N 2203, 2203 (2019), https://jamanetwork.com/journals/jama/fullarticle/2735509.

Other relatively new USPSTF recommendations support access to important mental health care for at risk populations. In February 2019, USPSTF recommended that "clinicians provide or refer pregnant and postpartum persons who are at increased risk of perinatal depression to counseling interventions." U.S. Preventive Servs. Task Force, *Recommendation Statement: Interventions to Prevent Perinatal Depression*, 321 J. AM. MED. ASS'N 580, 581 (2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/perinatal-depression-preventive-interventions. In October 2022, USPSTF recommended "screening for anxiety in children and adolescents aged 8 to 18 years." U.S. Preventive Servs. Task Force, *Recommendation Statement: Screening for Anxiety in Children and Adolescents*, 328 J. AM. MED. ASS'N 1438, 1438 (2022), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-anxiety-children-adolescents. To roll back access to these screenings – and

particularly to do so just as the clinical evidence supporting their use has been recognized – would negatively impact vulnerable women and children.

The ACA expanded access to preventive services and reduced health coverage disparities across racial groups. ASPE, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, *supra* at 7. To avoid reversing progress toward equitable access to preventive health care, including for underserved and underrepresented populations, we urge this Court to reverse the decision of the District Court.

II. DISTRICT COURT'S RULING WOULD INCREASE COSTS THROUGHOUT THE HEALTH CARE SYSTEM

Access to cost-free preventive services helps lower health care costs not only for the individual patient, but also for the overall health care system.

A. Preventive Services Save Costs

Preventing the occurrence, risk, and development of chronic conditions can decrease costs in the long-run and reduce the use of health care resources. Chronic illnesses are the leading drivers of health care costs in the U.S. and can significantly affect people's quality of life and ability to work. Nearly 60 percent of adults have at least one chronic condition, and 40 percent have two or more. Nat'l Ctr. for Chronic Disease Prevention & Health Promotion (NCCDPHP), *Chronic Diseases in America*, *Centers for Disease Control and Prevention*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 13, 2022),

https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm. Approximately 90 percent of the nation's $4.1 trillion in annual health care expenditures is spent on people with chronic and mental health conditions. Nat'l Ctr. for Chronic Disease Prevention & Health Promotion (NCCDPHP), *Health and Economic Costs of Chronic Diseases*, CTRS. FOR DISEASE CONTROL & PREVENTION (Mar. 23, 2023), https://www.cdc.gov/chronicdisease/about/costs/index.htm. The financial and economic burden chronic illnesses can have on individuals and on the overall health care system can be avoided through robust preventive care.

B. USPSTF's Recommendations Address Some Of the Costliest Preventable Diseases

As demonstrated below, USPSTF's recommendations address some of the costliest preventable diseases.

1. Diabetes

Consider *diabetes*. More than 37 million Americans have diabetes, and another 96 million adults in the United States have a condition called prediabetes, which puts them at risk for type 2 diabetes. Diabetes can cause serious complications, including heart disease, kidney failure, and blindness. In 2017 alone, the total estimated cost of diagnosed diabetes was $327 billion in medical costs and lost productivity. Am. Diabetes Ass'n, *Economic Costs of Diabetes in the U.S. in 2017*, 41 DIABETES CARE 917-928 (May 2018), https://diabetesjournals.org/care/article/41/5/917/36518/Economic-Costs-of-

Diabetes-in-the-U-S-in-2017. In 2022, the Centers for Disease Control and Prevention (CDC) estimated that $1 out of every $4 in U.S. health care costs is spent on caring for people with diabetes, resulting in a total of nearly $237 billion annual spending on direct medical costs and another $90 billion on reduced productivity. Nat'l Ctr. for Chronic Disease Prevention & Health Promotion (NCCDPHP), *Health and Economic Benefits of Diabetes Interventions*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 21, 2022), https://www.cdc.gov/chronicdisease/programs-impact/pop/diabetes.htm#:~:text=%24237%20billion%E2%80%A1(a)%20is,(a)%20on%20reduced%20productivity.&text=61%25%20of%20diabetes%20costs%20are,is%20mainly%20paid%20by%20Medicare. Further, research shows that the average medical cost for a patient with either type 1 or type 2 diabetes is more than two times higher than for a patient without diabetes. Ctrs. for Disease Control & Prevention, *Diabetes Report Card 2021* (Nov. 14, 2022), https://www.cdc.gov/diabetes/library/reports/reportcard.html.

Of the 37 million Americans who have diabetes, over 35 million of them have type 2, which is preventable and can be delayed from progressing to worse stages. Ctrs. for Disease Control & Prevention, *Type 2 Diabetes* (Apr. 18, 2023), https://www.cdc.gov/diabetes/basics/type2.html. If the District Court decision is upheld, policy related to screenings for Type 2 diabetes would revert to June 2008 USPSTF recommendations that would mean prediabetes screenings and

interventions would not be uniformly covered without cost-sharing. U.S. Preventive Servs., *Prediabetes and Type 2 Diabetes: Screening* (Aug. 24, 2021), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes; U.S. Preventive Servs., *Diabetes Mellitus (Type 2) in Adults: Screening* (June 15, 2008), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/diabetes-mellitus-type-2-in-adults-screening-2008. Losing access to this coverage would make the nation's fight against diabetes harder.

2. Cancer

Consider *cancer*. CDC reports that in 2020, over 1.6 million people were diagnosed with cancer and over 600,000 died from cancer, making it the second leading cause of death in America. Ctrs. for Disease Control & Prevention, *Cancer Data & Statistics* (June 8, 2023), https://www.cdc.gov/cancer/dcpc/data/index.htm#:~:text=In%20the%20United%20States%20in,which%20incidence%20data%20are%20available. The cost of cancer care is significant across the board. Studies estimate that overall national costs are projected to increase 34 percent to $246 billion by 2030. Angela B. Mariotto et al., *Medical Care Costs Associated with Cancer Survivorship in the United States*. 29 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1304–1312 (2020), https://doi.org/10.1158/1055-9965.EPI-19-1534.

For individual patients, the National Cancer Institute (NCI) estimates that the average annual costs between 2007-2013 in 2020 U.S. dollars for cancer care was over $43,500 for initial care, over $5,500 for continuing care, and nearly $110,000 in the last year of life. National Cancer Institute, *Cancer Trends Progress Report*, FINANCIAL BURDEN OF CANCER CARE (Apr. 2022), https://progressreport.cancer.gov/after/economic_burden.

According to the World Health Organization (WHO), 30 to 50 percent of all cancer cases are preventable, and prevention offers the most cost-effective long-term strategy for the control of cancer. World Health Org., *Preventing Cancer* (Feb. 2, 2022), https://www.who.int/activities/preventing-cancer#:~:text=Between%2030%E2%80%9350%25%20of%20all,for%20the%20control%20of%20cancer. Prevention is particularly cost-effective because its effects extend to an entire population regardless of socio-economic and other risk factors, as well as empower future generations by promoting healthy behaviors, increasing screening programs, implementing public health regulations (e.g., smoking regulations), and advancing other preventive services. Ivana Valle et al., *Cancer Prevention: State of the Art & Future Prospects*, 56 J. OF PREVENTIVE MED. & HYGIENE, E21–E27 (2015). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4718348/pdf/2421-4248-56-E21.pdf. Reverting to the USPSTF recommendations in place when the ACA was

enacted would limit access to: lung cancer screenings for asymptomatic persons; medication to reduce risk of breast cancer; skin cancer prevention counseling; and colorectal cancer and cervical cancer screenings for certain populations. This is the opposite of progress towards preventing cancer.

3. Heart Disease

Consider *heart disease*. Over 877,500 Americans die from heart disease or stroke each year, which is one-third of all deaths each year. *Health & Economic Costs of Chronic Diseases*, *supra*. Heart disease and stroke cost the U.S. health care system nearly $216 billion per year and result in nearly $147 billion in lost productivity. *Id.*

But 90 percent of heart disease is preventable. Cleveland Clinic, *90 Percent of Heart Disease is Preventable through Healthier Diet, Regular Exercise, and Not Smoking* (Sept. 29, 2021), https://newsroom.clevelandclinic.org/2021/09/29/90-percent-of-heart-disease-is-preventable-through-healthier-diet-regular-exercise-and-not-smoking/. By offering preventive services and screening to promote cardiovascular health, the U.S. can improve the health and wellbeing of the 121.5 million American adults with cardiovascular disease (or nearly 50 percent of all adults) and save costs to the overall health care system. Am. Heart Ass'n, *Cardiovascular Diseases Affect Nearly Half of American Adults, Statistics Show*, (Jan. 31, 2019), https://www.heart.org/en/news/2019/01/31/cardiovascular-

diseases-affect-nearly-half-of-american-adults-statistics-show. In light of these statistics, reverting to narrower 2008 USPSTF recommendations related to screening for lipid disorders in adults, rather than current, 2022 USPSTF recommendation for prescriptions to prevent cardiovascular disease, would be a travesty. U.S. Preventive Servs. Task Force, *Lipid Disorders in Adults (Cholesterol, Dyslipidemia); Screening* (Dec. 30, 2013), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lipid-disorders-in-adults-cholesterol-dyslipidemia-screening-2008; U.S. Preventive Servs. Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication* (Aug. 23, 2022), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication. Yet that would appear to be the effect of the District Court's decision.

4. Depression

Consider *depression*. In 2020, 21 million Americans had at least one major depressive episode, including 17 percent of people ages 18 to 25 years. Nat'l Inst. of Mental Health, *Transforming the understanding and treatment of mental illnesses* (Jan. 2022), https://www.nimh.nih.gov/health/statistics/major-depression. The economic costs of untreated and treating major depressive disorder (MDD) are high and increasing. For example, the economic costs to care for adults with MDD

increased by 37.9 percent between 2010 to 2018, from $236.6 billion per year to $326.2 billion per year. Of these total economic costs, workplace costs accounted for the largest proportion of the growing economic burden of MDD, resulting from lost productivity or decreased workforce capacity. Paul E. Greenberg et al., *The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)*, 39 PHARMACOECONOMICS 653, 656 (2021), https://doi.org/10.1007/s40273-021-01019-4. Depression is also a leading cause of disability.

The impacts of depression, coupled with treatment challenges, highlight the importance of investing in and promoting access to preventive care. Joanna R. Beames et al., *Prevention and Early Intervention of Depression in Young People: An Integrated Narrative Review of Affective Awareness and Ecological Momentary Assessment*, BMC PSYCHOL. 9:113 (2021). https://bmcpsychology.biomedcentral.com/counter/pdf/10.1186/s40359-021-00614-6.pdf. Studies highlight that prevention may help reduce the disease burden of depressive disorders. Pim Cuijpers et al., *Preventing Depression: A Global Priority*, 307 J. AM. MED. ASS'N 1033–34 (2012). https://doi.org/10.1001/jama.2012.271; Beames et al., *supra*. By preventing depressive disorders, the U.S. can save lives and health care costs. As discussed

above, coverage for mental health screenings for children and pregnant and postpartum women are vulnerable under the District Court's decision.

5. Tobacco Use

Consider *tobacco use*. Tobacco kills over 480,000 people each year from cigarette smoking or exposure to secondhand smoke. Approximately 28.3 million American adults smoke cigarettes and an additional 3 million high school and middle school students use tobacco in some form. Office on Smoking & Health – Nat'l Ctr. for Chronic Disease Prevention & Health Promotion, *Smoking & Tobacco Use: Data and Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 4, 2023), https://www.cdc.gov/tobacco/data_statistics/index.htm#:~:text=Tobacco%20use%20is%20the%20leading,product%2C%20including%20e%2Dcigarettes. Cigarette smoking is the leading form of preventable death in the U.S. and more than 16 million Americans have at least one disease caused by smoking. *Health and Economic Costs of Chronic Diseases*, *supra*. Further, cigarette smoking costs the health care system over $241 billion per year and nearly $365 billion in lost productivity. Tobacco Free Kids, *The Toll of Tobacco in the United States* (May 5, 2023), https://www.tobaccofreekids.org/problem/toll-us. The U.S. also spends nearly $6.5 billion per year on health care expenditures solely from second hand smoke exposure. *Id.* Health plan coverage for comprehensive, cost-free smoking cessation treatment increases use of treatment services, improves outcomes, and is

cost-effective. U.S. Dep't Health & Human Servs., *Smoking Cessation: A Report of the Surgeon General – Key Findings* (Jan. 23, 2020), https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/2020-cessation-sgr-factsheet-key-findings/index.html.

Yet the District Court's decision would seem to disregard the 2020 USPSTF recommendation for primary care clinicians to provide interventions to prevent initiation of tobacco use among school-aged children and adolescents, instead reverting to a 2003 determination citing insufficient evidence in this population. U.S. Preventive Servs. Task Force, *Tobacco Use in Children and Adolescents: Primary Care Interventions* (Apr. 28. 2020), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-and-nicotine-use-prevention-in-children-and-adolescents-primary-care-interventions; U.S. Preventive Servs., *Tobacco Use and Tobacco-Caused Disease: Counseling, 2003* (Nov. 1, 2003), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/tobacco-use-tobacco-caused-disease-counseling-2003.

III. THE RULING WOULD HARM CONSUMERS MORE BROADLY

A. The Ruling Would Increase Consumer and Clinician Confusion and Administrative Burdens by Fracturing Uniform Coverage Requirements

Consumers want care that is easy to navigate and understand, but the District Court's ruling would create a patchwork of coverage decisions by insurers and plans that will create both consumer and clinician confusion. United States of Care, *United Solutions for Care* (2022), https://unitedstatesofcare.org/wp-content/uploads/2022/05/USOC_PolicyAgenda_UnderstandableSystem_Proof_05.03.22.pdf. As a result of this confusion, consumers will need additional support to navigate care, causing an influx of inquiries to the Department of Labor, the Department of Health and Human Services, state Departments of Insurance and consumer agencies with calls and requests. Similarly, employers and other group health plan sponsors are likely to face questions from individuals about whether care they have come to count on will continue to be available.

In 2023, eight in ten adults have a favorable opinion of the ACA requirement for health plans to cover recommended preventive services without cost-sharing, indicating widespread familiarity with the availability of this coverage. *KFF Health Tracking Poll May 2023: Health Care in the 2024 Election and in the Courts*, KFF (May 26, 2023), https://www.kff.org/report-section/kff-tracking-poll-may-2023-health-care-in-the-2024-election-and-in-the-courts-prep-and-preventive-care/.

Contrast this with the state of play in 2001, when only around half of large employers and 17 percent of small employers required that their plans cover clinical preventive services. Nat'l Acads. of Scis., Eng'g & Med., Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* (National Academies Press 2011), https://nap.nationalacademies.org/read/13181/chapter/1. In 2009, the National Business Group on Health "compiled a purchaser's guide that recommends 46 clinical preventive services that should be included in employer health benefit plans", stepping in to try to inform consumers in need of certainty. *Id.* While the ACA created the consumer confidence necessary to support utilization of recommended preventive health care, the District Court's ruling will erode the certainty Congress sought to build up.

The District Court's decision has already created confusion. Federal agencies released guidance clarifying what they could, yet questions remain. Ctrs. for Medicare & Medicaid Servs., *FAQS About Affordable Care Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 59* (Apr. 13, 2023), https://www.cms.gov/files/document/faqs-part-59.pdf. The decision has produced uncertainty for consumers about whether they will have coverage or face cost-sharing for services that are the subject of the many significant recommendations USPSTF has made since March 23, 2010. Confusion also abounds with respect to

"pre-March 23, 2010 recommendations" about which the government anticipates providing additional guidance. *Id.* at 3.

Clinical practice must evolve with scientific advancement, and third-party clinical experts are foundational to health care operations. For example, coding updates facilitated by the American Medical Association (AMA) are relied on throughout the health care system. 45 C.F.R. § 162.1002 (adoption of codes "maintained and distributed by" the AMA as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification rules). Even as used in Medicare, the AMA's "Editorial Panel has the sole responsibility to revise, update, or modify" codes as clinical practice evolves. MEDICARE CLAIMS PROCESSING MANUAL, Ch. 23, Sec. 20.1 (rev. Oct. 6, 2022), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf. Absent updates made by the AMA, the health care coding system used for health records and billing would quickly fall behind the times.

Preventive services that would be held scientifically and clinically hostage by the ruling include screenings for cancer, diabetes, and mental health, among others.

B. The Decision Would Lead to Broader Health Insurance Market Changes that Would Harm Consumers

Changes to insurance markets and consumer behavior on the basis of the District Court's ruling would lead to broader harms if consumers or their employers

can decline coverage that they think they do not need. Variation in coverage inevitably leads to risk segmentation (through which sicker or higher-risk consumers pay more) and adverse selection (through which consumers wait until they are sick to purchase insurance or purchase coverage based on their known health status). Offered a choice between a plan that covers cancer screenings and one that does not, people who believe they are at higher risk for cancer (perhaps due to family history or known personal risk factors) will select the plan offering screenings at a higher rate. If in fact their group is higher risk, they will pay higher premiums, defeating broader efforts to reduce adverse selection and discriminatory benefit design. *See* Michael Geruso & Timothy J. Layton, *Selection in Health Insurance Markets and Its Policy Remedies*, J. OF ECON. PERSPECTIVES, 31 (4): 23-50 (2017), https://pubs.aeaweb.org/doi/pdfplus/10.1257/jep.31.4.23.

Without the requirement for nearly all health plans to provide access to preventive services, plans may see little to gain from doing so. In 2008, before the ACA was enacted, "short expected duration of insurance relationships undermine[ed] insurers' incentives to invest in preventative care and disease management" and contributed to gaps in care. Randall D. Cebul et al., *Organizational Fragmentation and Care Quality in the U.S. Healthcare System*, J. OF ECON. PERSPECTIVES, Vol. 22, No. 4 (Fall 2008), https://www.aeaweb.org/articles?id=10.1257/jep.22.4.93. Thus, it is plausible that

insurers revert back to their pre-ACA practice of not providing preventive care services given a lack of incentives to do so. By ensuring that the upfront cost is borne across all insurers and health plans, the ACA required collective action to ensure that the benefits of investing in preventive care would be felt even if individuals switch jobs or switch plans. This also ensures that even seemingly healthy individuals see value from maintaining health insurance coverage.

Furthermore, renewed variation in coverage of preventive services across health plans and across the country will exacerbate inequities. Increased cost-sharing disproportionately affects marginalized communities. Samantha Artiga et al., *The Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings*, KFF (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/. The ACA sought to ensure coverage of preventive services across markets, whether an individual was covered through employment or in the individual market. Large employers may once again outpace individual market plans in covering prevention, creating divisions between employer sponsored insurance and other forms of coverage. If employers select plans for their employees that do not cover preventive screenings, the District Court's ruling would put employers between individuals and doctors recommending care and wedge employers into selecting which preventive services to make available to their

employees, possibly with steep copayments of coinsurance. State Departments of Insurance and other regulators may step in to update coverage requirements in some areas, but state-to-state variation will exacerbate health disparities.

The ACA dramatically increased access to affordable preventive health care in America by requiring that health coverage keep pace with clinical advancements recognized by the USPSTF. Reversing course would be a tragedy.

CONCLUSION

This Court should reverse the District Court's judgment.

June 27, 2023

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5) because this brief contains 6,462 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Local Rule 32.2.

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Dated: June 27, 2023

/s/ Daniel G. Jarcho
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CERTIFICATE OF SERVICE

I hereby certify that on July 3, 2023, I electronically served the foregoing Brief on the following counsel for the parties through the Court's CM/ECF system:

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No. 23-10326 Braidwood Mgmt v. Becerra
USDC No. 4:20-CV-283

Dear Mr. Jarcho,

The following pertains to your brief electronically filed on June 27, 2023.

Caption on the brief does not agree with the caption of the case in compliance with **FED. R. APP. P.** 32(a)(2)(C). Caption must exactly match the Court's Official Caption (See Official Caption below)

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Case No. 23-10326

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