No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT INCORPORATED, *et al.*,
Plaintiffs-Appellees,

v.

XAVIER BECERRA, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas, No. 4:20-cv-00283
Hon. Reed O'Connor, United States District Judge

BRIEF OF AMICI CURIAE AMERICAN LUNG ASSOCIATION, ADULT VACCINE ACCESS COALITION, AMERICAN HEART ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, GO2 FOR LUNG CANCER, LUNGEVITY FOUNDATION, PUBLIC CITIZEN, AND TRUTH INITIATIVE FOUNDATION d/b/a TRUTH INITIATIVE IN SUPPORT OF DEFENDANTS-APPELLANTS' MOTION FOR A STAY OF THE DISTRICT COURT'S JUDGMENT

Nicolas A. Sansone
Allison M. Zieve
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Attorneys for Amici Curiae American Lung Association, et al.

April 27, 2023

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS

No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT INCORPORATED, *et al.*,
Plaintiffs-Appellees,

v.

XAVIER BECERRA, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the Northern District of Texas, No. 4:20-cv-00283
Hon. Reed O'Connor, United States District Judge

Pursuant to this Court's Rule 29.2 and Federal Rule of Appellate Procedure 26.1, amici curiae American Lung Association, Adult Vaccine Access Coalition, American Heart Association, Campaign for Tobacco-Free Kids, GO2 for Lung Cancer, LUNGevity Foundation, Public Citizen, and Truth Initiative Foundation d/b/a Truth Initiative submit this supplemental certificate of interested persons to fully disclose all those with an interest in this brief and provide the required information as to their corporate status and affiliations.

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

A. Amicus curiae **American Lung Association** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

B. Amicus curiae **Adult Vaccine Access Coalition** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

C. Amicus curiae **American Heart Association** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

D. Amicus curiae **Campaign for Tobacco-Free Kids** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

E. Amicus curiae **GO2 for Lung Cancer** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

F. Amicus curiae **LUNGevity Foundation** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

G. Amicus curiae **Public Citizen** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

H. Amicus curiae **Truth Initiative Foundation d/b/a Truth Initiative** is a non-profit, non-stock corporation. It has no parent corporation, and no publicly traded corporation has an ownership interest in it of any kind.

I. The above-listed amici curiae are represented by **Nicolas A. Sansone** and **Allison M. Zieve** of **Public Citizen Litigation Group**.

/s/ Nicolas A. Sansone
Nicolas A. Sansone

Attorney for Amici Curiae American Lung Association, et al.

April 27, 2023

TABLE OF CONTENTS

SUPPLEMENTAL CERTIFICATE OF INTERESTED PERSONS i

TABLE OF AUTHORITIES v

INTEREST OF AMICI CURIAE 1

SUMMARY OF ARGUMENT 4

ARGUMENT 5

I. Millions of Americans rely on the ACA's guarantee of cost-free access to preventive services that have proven to be effective in protecting against life-threatening conditions. 5

II. Absent a stay, lost access to cost-free preventive services could cause countless Americans to forgo necessary care, causing irreparable harm on a nationwide scale. 11

III. No countervailing harms to plaintiffs or to the public interest counsel against a stay. 25

CONCLUSION 27

CERTIFICATE OF COMPLIANCE 28

CERTIFICATE OF SERVICE 29

TABLE OF AUTHORITIES

Statutes **Page(s)**

29 U.S.C. § 1144 19

42 U.S.C. § 300gg-13 8

Other Authorities

American Lung Association, *Lung Cancer Key Findings* (Nov. 17, 2022) 12

Centers for Disease Control & Prevention, *The Scoop on Statins: What Do You Need to Know?* (Sept. 27, 2021) 15

Centers for Medicare & Medicaid Services, *Background: The Affordable Care Act's New Rules on Preventive Care* (July 14, 2010) 5, 7

Elizabeth Guo, et al., *Eliminating Coverage Discrimination Through the Essential Health Benefit's Anti-Discrimination Provisions*, 107 Am. J. Pub. Health 253 (2017) 19

Hope C. Norris, et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, Med. Care Res. & Rev. (2021) 24

Letter from James A. Klein, President, American Benefits Council, et al., to Rep. Ron Wyden, Chairman, Senate Finance Committee, et al. (Apr. 19, 2023) 20

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) 23

Krutika Amin, et al., *Preventive Services Use Among People with Private Insurance Coverage*, Peterson-KFF Health System Tracker (Mar. 20, 2023) 8

Michael Bretthauer, et al., *Effect of Colonoscopy Screening on Risks of Colorectal Cancer and Related Death*, N. Engl. J. Med. (Oct. 27, 2022) 16

Michael V. Maciosek, et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, Health Affs. (Sept. 2010) 6

Mitchell D. Wong, et al., *Effects of Cost Sharing on Care Seeking and Health Status: Results from the Medical Outcomes Study*, Am. J. Pub. Health (2001) 23

National Bureau of Economic Research, *Lessons for Health Care from Behavioral Economics*, Bull. on Aging & Health (2008) 24

Patrick M. Catalano, et al., *Obesity and Pregnancy: Mechanisms of Short Term and Long Term Adverse Consequences for Mother and Child*, Brit. Med. J. (Feb. 8, 2017) 14

Paul Fronstin, Employee Benefit Research Institute, *Trends in Self-Insured Health Plans Since the ACA* (Sept. 30, 2021) 21

Rajender Agarwal, et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 Health Affs. 1762 (2017) 23

Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care If ACA Coverage Falls Through*, Morning Consult (Mar. 8, 2023) 23

Robert Pear, *Economy Led to Cuts in Use of Health Care*, N.Y. Times (Aug. 16, 2010) 7

Sabrina Corlette, *A World Without the ACA's Preventive Services Protections: The Impact of the* Braidwood *Decision*, Health Affs. (Apr. 11, 2023) 19

Sebastian Schneeweiss, et al., *Adherence to Statin Therapy Under Drug Cost Sharing in Patients with and Without Acute Myocardial Infarction*, 115 Circulation 2128 (2007) 22

Small Business & Entrepreneurship Council, *Facts & Data on Small Business and Entrepreneurship* 21

Steven H. Woolf, *The Price Paid for Not Preventing Diseases*, *in* Institute of Medicine of the National Academies, *The Healthcare Imperative: Lowering Costs and Improving Outcomes* (2010) 6

Teresa B. Gibson, et al., *The Effects of Prescription Drug Copayments on Statin Adherence*, Am. J. of Managed Care (Sept. 1, 2006) 22

U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning & Evaluation, *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act* (Jan. 11, 2022) 11, 25

U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning & Evaluation, *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act* (June 27, 2014) 8

U.S. Preventive Services Task Force, *A & B Recommendations* (2023) 10

U.S. Preventive Services Task Force, *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* (Oct. 26, 2015)..... 17

U.S. Preventive Services Task Force, *Colorectal Cancer: Screening* (May 18, 2021) 16

U.S. Preventive Services Task Force, *Colorectal Cancer: Screening* (Oct. 15, 2008)..... 15

U.S. Preventive Services Task Force, *Diabetes Mellitus (Type 2) in Adults: Screening* (June 15, 2008) 16

U.S. Preventive Services Task Force, *Falls Prevention in Community-Dwelling Older Adults: Interventions* (Apr. 17, 2018) 13

U.S. Preventive Services Task Force, *Falls Prevention in Older Adults: Counseling and Preventive Medication* (May 15, 2012) 13

U.S. Preventive Services Task Force, *Grade Definitions* (June 2018) 9

U.S. Preventive Services Task Force, *Healthy Weight and Weight Gain in Pregnancy: Behavioral Counseling Interventions* (May 25, 2021) 13, 14

U.S. Preventive Services Task Force, *Hepatitis B Virus Infection: Screening, 2014* (June 18, 2014) 12

U.S. Preventive Services Task Force, *Hepatitis C: Screening* (June 15, 2013) 12

U.S. Preventive Services Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening* (Apr. 15, 2013), ... 17, 18

U.S. Preventive Services Task Force, *Human Immunodeficiency Virus (HIV) Infection: Screening, 2005* (July 5, 2005) 17

U.S. Preventive Services Task Force, *Lipid Disorders in Adults (Cholesterol, Dyslipidemia): Screening* (Dec. 30, 2013) 15

U.S. Preventive Services Task Force, *Lung Cancer: Screening* (Dec. 31, 2013) 12

U.S. Preventive Services Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication* (Nov. 13, 2016) 15

U.S. Preventive Services Task Force, *USPSTF: Who We Are & How We Work* (2022) 8, 9, 10

UnitedHealth Group, *UnitedHealthcare: Health Care Coverage and Benefits* 20

World Health Organization, *Guidelines on Hepatitis B and C Testing* (Feb. 16, 2017) 13

INTEREST OF AMICI CURIAE[1]

Amici curiae are eight organizations with strong interests in ensuring that Americans retain cost-free access to the preventive care—including lung cancer screening, medications that reduce the risk of heart attack and stroke, and behavioral counseling to improve lung and heart health—threatened by the district court's judgment in this case.

The American Lung Association is a non-profit organization that has worked for more than 115 years to improve lung health and prevent life-threatening lung disease. One of the organization's central missions is to reduce the incidence of lung cancer by encouraging prevention and effective treatment.

The Adult Vaccine Access Coalition was formed to advocate for federal policies that improve access to and increase utilization of vaccines among adults. It advocates for policies, including the elimination of cost-sharing, that reduce the barriers that discourage patients from utilizing effective forms of preventive care.

---

[1] This brief was not authored in whole or part by counsel for a party, and no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of the brief. Counsel for all parties have consented to its filing.

The American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke, and it represents more than 40 million volunteers and supporters. The patients it represents benefit directly from the Affordable Care Act's preventive services provisions, without which millions of patients would no longer have the same access to life-saving, evidence-based healthcare that supports long-term cardiovascular health.

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from using tobacco products, help smokers quit, educate the public about the dangers of smoking and tobacco use, and protect everyone from secondhand smoke.

GO2 for Lung Cancer, founded by patients and survivors of lung cancer, is dedicated to increasing survival for those at risk of, diagnosed with, and living with lung cancer, and it provides one-on-one assistance, supportive connections, treatment information, and help finding care close to home. The organization offers information about the latest

research and special initiatives that increase survivorship, and it works to improve health policies and public awareness.

LUNGevity Foundation is the largest national non-profit organization that funds research, provides education and support, and builds communities for the 600,000 Americans living with lung cancer. LUNGevity strongly supports provisions in the Affordable Care Act that allow for no-cost coverage of life-saving services such as lung cancer screening.

Public Citizen is a non-profit consumer advocacy organization with members in all fifty states. Among other things, Public Citizen works to advance healthcare access and to ensure strong protections for public health.

Truth Initiative Foundation d/b/a Truth Initiative, created out of a 1998 master settlement agreement between forty-six states and the tobacco industry, seeks to create a world where young people reject tobacco and nicotine in all its forms and where anybody can quit using tobacco or nicotine. Truth Initiative has a strong interest in ensuring that individuals retain access to the cost-free tobacco-cessation programs guaranteed by the Affordable Care Act.

SUMMARY OF ARGUMENT

The provisions of the Affordable Care Act (ACA) that require insurers to provide coverage for certain preventive services without cost to patients reflect Congress's recognition that barrier-free access to preventive care is critical for safeguarding Americans' health. The district court's judgment upends Congress's careful policy choices and creates the risk that insurers will reinstate cost-sharing for vital preventive services or even exclude them from coverage entirely. To avoid the hazardous consequences the district court's judgment could hold for public health, this Court should stay the judgment pending appeal.

As the government explains in its brief, there is a substantial likelihood that this Court will ultimately vacate the district court's judgment. In the meantime, that judgment threatens millions of Americans' cost-free access to a wide range of medical services that have proven to be effective in preventing serious health conditions and reducing mortality. These services range from cancer screenings to neonatal care to life-saving medications that dramatically reduce the risk of stroke, heart attacks, and Human Immunodeficiency Virus (HIV). A robust body of research has shown that even modest cost barriers can

meaningfully reduce uptake of preventive services, especially for patients in socioeconomically vulnerable populations. The risk that insurers will follow the financial incentives created by the district court's judgment and reinstitute the cost-sharing or coverage gaps that the ACA sought to prevent could compromise the health and even the lives of countless Americans, causing irreparable harm. As against this risk, plaintiffs and the public at large will experience no harm at all if this Court grants a stay. The equities thus overwhelmingly favor staying the district court's judgment to ensure stability and continuity in Americans' healthcare while this Court considers the merits of the government's appeal.

ARGUMENT

I. Millions of Americans rely on the ACA's guarantee of cost-free access to preventive services that have proven to be effective in protecting against life-threatening conditions.

Even before the ACA became law on March 23, 2010, the medical community had long recognized the important role of "[h]igh-quality preventive care" in "help[ing] Americans stay healthy, avoid or delay the onset of disease, lead productive lives, and reduce costs." Ctrs. for Medicare & Medicaid Servs., *Background: The Affordable Care Act's New Rules on Preventive Care* (July 14, 2010) (CMS, *Background*),

https://tinyurl.com/yefyrsek. Reputable expert studies showed that targeted lifestyle changes and early detection could reduce the incidence of and mortality from chronic diseases like diabetes and cancer by as much as seventy percent. *See* Steven H. Woolf, *The Price Paid for Not Preventing Diseases*, *in* Inst. of Med. of the Nat'l Acads., *The Healthcare Imperative: Lowering Costs and Improving Outcomes* 220, 221 (2010), https://tinyurl.com/vb4nss25. And the National Commission on Prevention Priorities estimated that more effective provision of just five preventive measures could save 100,000 lives per year. *Id*. at 222–23. Experts explained that the economic "price paid for inadequate emphasis on prevention," meanwhile, is high, *id*. at 223, amounting to hundreds of billions of dollars annually, by some calculations. *See, e.g.*, *id*.; Michael V. Maciosek, et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, Health Affs. (Sept. 2010), https://tinyurl.com/z3a422pd (abstract) (reporting at the time of the ACA's enactment that greater use of twenty "proven clinical preventive services" could save "more than two million life-years annually," along with billions of dollars).

Despite the "proven benefits" of preventive measures, "financial barriers"—including lack of coverage for people without health insurance and copayments and deductibles for people with health insurance—deterred people from seeking preventive care, such as "cancer screenings, immunizations for their children and themselves, and well-baby check-ups." CMS, *Background*. In the wake of the 2007 global financial crisis, 26.5 percent of Americans participating in a study by the National Bureau of Economic Research reported a reduction in their use of routine medical care, while 70 percent of the American Hospital Association's member hospitals reported fewer patient visits "as family budgets remain[ed] tight and patients continue[d] to delay or forgo care." Robert Pear, *Economy Led to Cuts in Use of Health Care*, N.Y. Times (Aug. 16, 2010), https://tinyurl.com/nbym72zx.

With Americans "us[ing] preventive services at about half the recommended rate," CMS, *Background*, one of the ACA's central innovations was to encourage increased utilization by requiring covered health plans and insurers to provide cost-free coverage for certain evidence-based preventive care measures. As a result of the new law, approximately 76 million Americans became eligible for expanded

coverage for preventive services. U.S. Dep't of Health & Human Servs. (HHS), Off. of the Ass't Sec'y for Planning & Eval., *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, 1 (June 27, 2014), https://tinyurl.com/zh4rdwac. Since then, vast numbers of people have relied on the ACA's guarantee of cost-free coverage for preventive services, with about 60 percent of insured Americans—roughly 100 million people—utilizing such services in 2018. Krutika Amin, et al., *Preventive Services Use Among People with Private Insurance Coverage*, Peterson-KFF Health System Tracker (Mar. 20, 2023) (Amin, *Preventive Services*), https://tinyurl.com/5n8ctmts.

Among the preventive measures included under the ACA's cost-free coverage requirement are "evidence-based items or services" that have received an "A" or "B" rating from the U.S. Preventive Services Task Force (USPSTF). 42 U.S.C. § 300gg-13(a)(1). The USPSTF is composed of sixteen volunteer experts who specialize in preventive medicine and primary care and who make "evidence-based recommendations about preventive services such as screenings, behavioral counseling, and preventive medications." USPSTF, *USPSTF: Who We Are & How We Work*, 1 (2022) (USPSTF, *Who We Are*), https://tinyurl.com/22e9ewek.

These recommendations "cover more than 80 preventive service topics for people across the lifespan—from vision screening in young children, to heart disease prevention in adults, to colorectal cancer screening in older adults." *Id.* When a recommended service receives an "A" grade, the USPSTF has "high certainty that the net benefit" of the service "is substantial," and when a recommended service receives a "B" grade, the USPSTF has "high certainty that the net benefit is moderate or … moderate certainty that the net benefit is moderate to substantial." USPSTF, *Grade Definitions* (June 2018), https://tinyurl.com/3mcx9hsu.

The USPSTF follows a "scientifically rigorous" four-step process in creating its recommendations. USPSTF, *Who We Are* at 2–3. First, the USPSTF selects a preventive-care topic to prioritize based on, among other things, "the topic's importance for public health" and "the potential impact of [a] recommendation." *Id.* at 3. Second, the USPSTF partners with "an academic or research organization with expertise in conducting systematic evidence reviews" to draft a research plan on the topic, which it finalizes after a four-week public comment period. *Id.* Third, the partner organization's researchers "gather, review, and analyze evidence on the topic from high-quality studies published in peer-reviewed

scientific journals," after which USPSTF members assess the findings of the evidence review, create a draft recommendation, and open the draft to public comment. *Id.* Last, the USPSTF finalizes the recommendation based on the evidence reviews and public comments and assigns the recommendation a letter grade. *Id.* Although an "A" or "B" grade triggers the ACA's mandatory-coverage requirement, coverage considerations do not influence the USPSTF's grading, which is based entirely on a preventive service's demonstrated efficacy. *Id.* at 6.

More than fifty types of preventive services currently have an "A" or "B" grade from the USPSTF. *See* USPSTF, *A & B Recommendations* (2023), https://tinyurl.com/382atn5d. These services include nutritional supplements to support healthy pregnancies, behavioral counseling interventions to reduce the risk of cardiovascular disease, topical medications to reduce the risk of blindness in newborns, tobacco cessation treatment, prophylactic treatments to reduce the risk of HIV transmission, and screenings that can lead to the early detection and treatment of life-threatening conditions like cancer, HIV, hypertension, and diabetes. *Id.* Prior to the district court's judgment, approximately 151.6 million Americans enjoyed cost-free access to these services

through their private insurance, and tens of millions more had similar access through Medicaid and Medicare. *See* HHS, Off. of the Ass't Sec'y for Planning & Eval., *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act*, 3, 6–7 (Jan. 11, 2022) (HHS, *Access to Preventive Services*), https://tinyurl.com/2p8r2rfy.

II. Absent a stay, lost access to cost-free preventive services could cause countless Americans to forgo necessary care, causing irreparable harm on a nationwide scale.

Following the district court's judgment, insurers may now impose cost-sharing requirements on preventive services that received "A" or "B" grades from the USPSTF after March 23, 2010, or decline to cover such services altogether. As a result, cost-free access to critical medical care is currently at risk for millions of American patients. Absent a stay, cost considerations may cause patients to forgo the preventive-care measures that enable them both to stay healthy and to identify and manage potentially life-threatening conditions at early stages when meaningful, cost-effective treatment is still possible.

The risk of irreparable harm on a nationwide scale is apparent from the vast breadth of critical preventive services threatened by the district court's ruling. The many USPSTF-recommended services that received

"A" or "B" ratings after March 23, 2010, will no longer be subject to the ACA's guarantee of cost-free coverage absent a stay. For example:

- Lung cancer screening for certain adults first received a qualifying rating in 2013. *See* USPSTF, *Lung Cancer: Screening* (Dec. 31, 2013), https://tinyurl.com/5bve6cts. Access to the screening is essential because early detection has a dramatic effect on health outcomes, with a 61 percent five-year survival rate for cases caught early falling to just 7 percent for cases caught later. Am. Lung Ass'n, *Lung Cancer Key Findings* (Nov. 17, 2022), https://tinyurl.com/yndkd8xr ("Early Diagnosis").
- Hepatitis B and C screenings received qualifying ratings in 2013 and 2014. *See* USPSTF, *Hepatitis B Virus Infection: Screening, 2014* (June 18, 2014), https://tinyurl.com/3rdba82k; USPSTF, *Hepatitis C: Screening* (June 15, 2013), https://tinyurl.com/4mjhrr9y. Both viruses are "major causes of acute and chronic liver disease," and early identification of those who are infected enables those individuals "to receive the necessary care and treatment to prevent or delay progression of

liver disease," while also reducing transmission rates and new infections. World Health Org., *Guidelines on Hepatitis B and C Testing* (Feb. 16, 2017), https://tinyurl.com/5n8ac8t6.

- Physical therapy for certain older adults to reduce the risk of falling first received a qualifying rating in 2012. *See* USPSTF, *Falls Prevention in Older Adults: Counseling and Preventive Medication* (May 15, 2012), https://tinyurl.com/47wt749a. Falls were the leading cause of injury-related mortality among older adults at the time the recommendation was last updated in 2018, causing an estimated 33,000 deaths in 2015 alone. *See* USPSTF, *Falls Prevention in Community-Dwelling Older Adults: Interventions* (Apr. 17, 2018), https://tinyurl.com/2p9asyxs ("Rationale").
- Behavioral counseling interventions aimed at enabling pregnant individuals to maintain a healthy body weight first received a qualifying rating in 2021. *See* USPSTF, *Healthy Weight and Weight Gain in Pregnancy: Behavioral Counseling Interventions* (May 25, 2021), https://tinyurl.com/yvude329. This recommendation addresses a pronounced increase in obesity

rates during pregnancy from 13 percent in 1993 to 24 percent in 2015, with particularly high obesity rates among Alaska Native/American Indian, Black, and Hispanic women. *Id.* ("Importance"). As the USPSTF explained, "[e]xcess weight at the beginning of pregnancy and excess gestational weight gain" are associated with "adverse … health outcomes" not only for the pregnant individual but also for the infant. *Id.*; *see also* Patrick M. Catalano, et al., *Obesity and Pregnancy: Mechanisms of Short Term and Long Term Adverse Consequences for Mother and Child*, Brit. Med. J. (Feb. 8, 2017), https://tinyurl.com/yc8yaanz (explaining that obesity increases the risk of spontaneous miscarriage and having a child with "congenital anomalies" such as neural tube defects, limb reductions, and cardiovascular anomalies).

Even among those services that had a qualifying rating from the USPSTF prior to March 23, 2010, many recommendations have since undergone important updates. For example:

- At the time the ACA went into effect, the USPSTF's preventive recommendations related to lipid disorders that could lead to

coronary heart disease were limited to screening for certain adults. *See* USPSTF, *Lipid Disorders in Adults (Cholesterol, Dyslipidemia): Screening* (Dec. 30, 2013), https://tinyurl.com/24sn6nvu (June 2008 recommendation). In 2016, the USPSTF updated the recommendation to include prescription of a statin. *See* USPSTF, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication* (Nov. 13, 2016), https://tinyurl.com/2p9f9mth. Statins are potentially life-saving medications that "[s]cientific studies and years of use all over the world have proven … [to] reduce a person's chances of having a heart attack or stroke" by up to 50 percent. CDC*, The Scoop on Statins: What Do You Need to Know?* (Sept. 27, 2021), https://tinyurl.com/3wab5skn.

- At the time the ACA went into effect, the USPSTF recommended screening adults aged 50–75 for colorectal cancer. *See* USPSTF, *Colorectal Cancer: Screening* (Oct. 15, 2008), https://tinyurl.com/4xsveypy. Based on new evidence of "a recent trend for increasing risk of colorectal cancer in … adults younger than 50 years," the USPSTF updated its recommendation in

2021 to include adults aged 45–49. *See* USPSTF, *Colorectal Cancer: Screening* (May 18, 2021), https://tinyurl.com/54w9u4x2 ("Practice Considerations"). The USPSTF expects this update to "increase life-years gained and decrease colorectal cancer cases and deaths compared with beginning screening at age 50 years."[2] *Id.*

- At the time the ACA went into effect, the USPSTF recommended screening for type 2 diabetes only for certain adults with elevated blood pressure. *See* USPSTF, *Diabetes Mellitus (Type 2) in Adults: Screening* (June 15, 2008), https://tinyurl.com/mr23xvz6.

[2] In their opposition to the government's stay motion in the district court, plaintiffs cited a single study concerning one form of colorectal cancer screening—the colonoscopy—to question the efficacy of *all* preventive care. D. Ct. Dkt. No. 127 at 7–8. A single study of colonoscopies, however, cannot call into question the entire body of scientific literature upon which the USPSTF and its partner organizations have relied in crafting their recommendations as to numerous preventive services. Moreover, the study on which plaintiffs relied is inapt. It concerned the effect of an *invitation* to receive a colonoscopy in four European countries where citizens *already have access* to free preventive care. *See* Michael Bretthauer, et al., *Effect of Colonoscopy Screening on Risks of Colorectal Cancer and Related Death*, N. Engl. J. Med. (Oct. 27, 2022), https://tinyurl.com/yc6uw8yy (abstract). Even then, the study concluded that "the risk of colorectal cancer at 10 years was lower among participants who were invited to undergo screening." *Id.*

Since then, the USPSTF has reviewed a series of "new lifestyle intervention studies" and updated its recommendation to include screening for abnormal blood glucose levels in overweight or obese adults irrespective of their blood pressure, explaining that the "new body of evidence" gave it "increased confidence" that such measures would be effective. USPSTF, *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening* (Oct. 26, 2015), https://tinyurl.com/2p8z43u6 ("Update of Previous USPSTF Recommendation").

- At the time the ACA went into effect, the USPSTF recommended HIV screening only for pregnant women and for adolescents and adults at increased risk of infection. *See* USPSTF, *Human Immunodeficiency Virus (HIV) Infection: Screening, 2005* (July 5, 2005), https://tinyurl.com/yeyp28zv. But "based on studies … address[ing] previous evidence gaps," the USPSTF later updated its recommendation to cover screening for all people ages 15–65. USPSTF, *Human Immunodeficiency Virus (HIV) Infection: Screening* (Apr. 15, 2013), https://tinyurl.com/ysscnfpu ("Update of Previous USPSTF

Recommendation"). This "expanded HIV screening could identify a substantial number of persons with previously undiagnosed HIV infection," *id.*, enabling them to begin life-saving treatment and to take measures that will "substantially decrease[] risk for transmission," *id.* ("Rationale").

Absent a stay, insurers may now eliminate coverage, or impose cost-sharing, for these and numerous other vital preventive services. The risk that insurers will do so is real. Congress, after all, required coverage under the ACA precisely because substantial numbers of Americans lacked adequate coverage for preventive services. *See supra* at 7–8 (explaining that the ACA expanded access for 76 million Americans and that as many as 100 million Americans utilized cost-free preventive services in 2018 alone). The self-funded employer health plans that cover around 65 percent of American workers "can make benefit changes at any time," so long as they provide sixty days' notice, and "[a]ny savings generated from reducing benefits go directly to employers' bottom lines, an attractive prospect as many companies face pressure to reduce labor

costs and maintain profit levels."[3] Sabrina Corlette, *A World Without the ACA's Preventive Services Protections: The Impact of the* Braidwood *Decision*, Health Affs. (Apr. 11, 2023), https://tinyurl.com/3wfzrfk6.

In addition, insurers have a financial incentive to cut coverage for preventive services used disproportionately by people who have or are at higher risk of developing costly medical conditions, as a means of discouraging them from enrolling in a health plan. *See* Elizabeth Guo, et al., *Eliminating Coverage Discrimination Through the Essential Health Benefit's Anti-Discrimination Provisions*, 107 Am. J. Pub. Health 253, 253 (2017), https://tinyurl.com/4uep53rj (describing discriminatory practices whereby insurers "design benefits to discourage enrollment of individuals with significant health needs" or "prevent these patients from receiving appropriate care, thus saving the insurer money"). Many insurers, in short, may spy an advantage in capitalizing on the district

[3] While a handful of states have legal provisions that mirror the ACA's coverage protections, the Employee Retirement Income Security Act largely preempts application of these state-law requirements to employer-funded plans. *See* 29 U.S.C. § 1144(a).

court's judgment by doing away with cost-free access to certain preventive services.

The district court dismissed these concerns on the basis of a letter from a number of business and insurer associations that expressed the "sense" that the majority of their members "d[id] not anticipate making changes" to their coverage while this case is pending. Letter from James A. Klein, President, Am. Benefits Council, et al., to Rep. Ron Wyden, Chairman, Sen. Fin. Comm., et al., 1–2 (Apr. 19, 2023), https://tinyurl.com/62ff2a9u, *cited in* D. Ct. Dkt. No. 129 at 2. The letter, however, offers scant reassurance. Most obviously, an association's "sense" of what members "anticipate" doing is an inadequate response to the historical reality that prompted Congress to direct cost-free coverage for preventive care. Moreover, even if many big insurers do not diminish coverage, large numbers of people could be affected if even a handful of insurers take a different course. *See, e.g.*, UnitedHealth Grp., *UnitedHealthcare: Health Care Coverage and Benefits*, https://tinyurl.com/8xer9eze (noting coverage for 26.7 million people). And of course, the letter cited by the district court says nothing about coverage for the many individuals who receive healthcare benefits

through small or midsized self-funding employers that do not belong to the signatory organizations. *See* Paul Fronstin, Emp'ee Ben. Res. Inst., *Trends in Self-Insured Health Plans Since the ACA*, 4 (Sept. 30, 2021), https://tinyurl.com/52yxt99m (reporting that 31.7 percent of employers with 100–499 employees and 16.1 percent of employers with fewer than 100 employees offered self-insured plans in 2020); Small Business & Entrepreneurship Council, *Facts & Data on Small Business and Entrepreneurship*, https://tinyurl.com/2s4345h9 (citing U.S. Census Bureau data showing that 46.4 percent of private-sector employees worked for firms with fewer than 500 employees in 2018).

If preventive care costs increase even for "just" a few million Americans, the health consequences could be serious. To take an example based on just one of the many preventive services threatened by the district court's judgment, statins used to reduce the risk of stroke and cardiac arrest first received a qualifying rating from the USPSTF in 2016. If insurers now respond to the district court's judgment by imposing cost-sharing requirements for patients to receive these life-saving medications, research suggests that patients could discontinue use despite the risks to their health. *See, e.g.*, Teresa B. Gibson, et al., *The*

Effects of Prescription Drug Copayments on Statin Adherence, Am. J. of Managed Care (Sept. 1, 2006), https://tinyurl.com/mv6ucnpz (explaining that "higher prescription drug copayments are associated with lower statin adherence"). One "natural experiment" study examined what happened when an insurance plan covering all British Columbia residents over the age of 65 moved from (1) providing cost-free coverage for statins to (2) requiring $10–$25 copayments to (3) requiring 25 percent coinsurance payments. Sebastian Schneeweiss, et al., *Adherence to Statin Therapy Under Drug Cost Sharing in Patients with and Without Acute Myocardial Infarction*, 115 Circulation 2128, 2128 (2007), https://tinyurl.com/yc3u6ttc. The study found that, "[r]elative to full-coverage policies, adherence to new statin therapy was significantly reduced … under a fixed copayment policy … and the subsequent coinsurance policy." *Id.* Significantly, "[s]udden changes to full out-of-pocket spending … almost doubled the risk of stopping statins." *Id.*

More broadly, according to a recent survey, 40 percent of American adults would be unable or unwilling to pay out of pocket for the majority of the evidence-backed preventive services affected by the district court's judgment. Ricky Zipp, *Many Americans Are Likely to Skip Preventive*

Care If ACA Coverage Falls Through, Morning Consult (Mar. 8, 2023), https://tinyurl.com/5xu5fvf8. This figure underscores the well-established principle that cost-sharing requirements can prevent or deter patients from utilizing medical services. *See* Rajender Agarwal, et al., *High-Deductible Health Plans Reduce Health Care Cost and Utilization, Including Use of Needed Preventive Services*, 36 Health Affs. 1762, 1766 (2017), https://tinyurl.com/mrekw95f (reporting, "consistent with a large body of evidence on cost sharing," that deductibles can cause patients to "forgo needed care," including preventive care, "to save money"); Mitchell D. Wong, et al., *Effects of Cost Sharing on Care Seeking and Health Status: Results from the Medical Outcomes Study*, Am. J. Pub. Health (2001), https://tinyurl.com/2p8ftt4s ("Requiring patients to pay a portion of their medical bill out of pocket[] … sharply reduces their use of health care resources."); *cf.* Karishma Srikanth, et al., *Associated Costs Are a Barrier to HIV Preexposure Prophylaxis Access in the United States*, 112 Am. J. Pub. Health 834, 835 (2022), https://tinyurl.com/mr2skuye (explaining the role of "actual and perceived cost barrier[s]" in inhibiting use of prophylactic HIV medications and increasing the "transmission and prevalence of HIV").

Plaintiffs' argument that it is improper to "presume[] that rational people will decline to purchase valuable items," D. Ct. Dkt. No. 127 at 9, overlooks that the ACA's requirement of full coverage for preventive care is targeted to benefit precisely those patients who lack the means to absorb the cost themselves. *See, e.g.*, Hope C. Norris, et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, Med. Care Res. & Rev., 20 (2021), https://tinyurl.com/nha6we29 (explaining that "those who [are] financially vulnerable incur[] substantial increases in utilization" of preventive services when cost-sharing is eliminated). Even as to patients for whom the cost of preventive care does not impose a direct financial burden, behavioral economics teaches that consumers routinely fail to accurately appraise the value of "incurring costs today to produce future benefits." Nat'l Bur. of Econ. Res., *Lessons for Health Care from Behavioral Economics*, Bull. on Aging & Health (2008), https://tinyurl.com/3exfj6ur.

Plaintiffs' citation to one document describing equivocal uptake of a handful of preventive services in the immediate aftermath of the ACA's passage fails to support their broad contention that "the preventive care

mandates imposed by the ACA did *not* lead to increased consumption of the relevant services." D. Ct. Dkt. No. 127 at 6 (citing HHS, *Access to Preventive Services* at 7–8). The cited document expressly noted the relative dearth of studies "specifically examining the effects of eliminating cost-sharing for preventive services among individuals who already had health coverage" prior to the ACA. HHS, *Access to Preventive Services* at 7. Plaintiffs offer no reason to doubt that those effects were consistent with the vast body of research confirming the commonsense idea that lifting cost barriers to preventive services increases utilization, particularly among the most economically vulnerable communities.

III. No countervailing harms to plaintiffs or to the public interest counsel against a stay.

As against the considerable risk of irreparable harm to the health of millions of Americans absent a stay, plaintiffs here will suffer no harm—let alone irreparable harm—if this Court stays the district court's judgment. As for plaintiffs that supply health insurance, the government's requested stay does not encompass them, and they will remain free to withhold cost-free coverage of USPSTF-recommended preventive services from their employees during this appeal. As for plaintiffs that consume health insurance, they have not shown that the

inability to purchase a health-insurance plan that provides less coverage is an injury at all. *See* D. Ct. Dkt. No. 113 at 13–14. Although the district court held that four individual plaintiffs are injured by the lack of market access to health plans that exclude coverage for certain preventive services they find objectionable on religious grounds, *id.*, the balance of harms does not favor upending the entire national health insurance market on the off chance that an insurance option that is tailored to the specific convictions of these four individuals will emerge from the resulting market upheaval while this appeal is pending.

Cost-free coverage of USPSTF-recommended services has been the law for thirteen years, and that coverage has given countless Americans access to potentially life-saving care. In contrast to plaintiffs' speculation about beneficial hypothetical market impacts of the district court's judgment for the uninsured, *see* D. Ct. Dkt. No. 127 at 8, the risk that the judgment poses to the continuity of medical care for vast numbers of Americans is direct and immediate. This Court should step in to prevent this result until it has had the chance to consider whether the law demands such disruption.

CONCLUSION

This Court should stay the district court's judgment during the pendency of this appeal.

Respectfully submitted,

/s/ Nicolas A. Sansone
Nicolas A. Sansone
Allison M. Zieve
Public Citizen Litigation Group
1600 20th Street NW
Washington, DC 20009
(202) 588-1000

Attorneys for Amici Curiae American Lung Association, et al.

April 27, 2023

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B)(i) because, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and the Rules of this Court, it contains 4,774 words.

This brief also complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 29(a)(4), 32(a)(5), and 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook.

/s/ Nicolas A. Sansone
Nicolas A. Sansone
Attorney for Amici Curiae
American Lung Association, et al.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Brief of Amici Curiae with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit on April 27, 2023, using the Appellate Electronic Filing system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Nicolas A. Sansone
Nicolas A. Sansone
Attorney for Amici Curiae
American Lung Association, et al.