

No. 23-10326

**In the United States Court of Appeals
for the Fifth Circuit**

BRAIDWOOD MANAGEMENT, INC., *et al.*,
Plaintiffs-Appellees / Cross-Appellants,

v.

XAVIER BECERRA, *in his official capacity as*
SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellants / Cross-Appellees.

On Appeal from the United States District Court
for the Northern District of Texas, Fort Worth Division
Case No. 4:20-cv-283

**BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL
ASSOCIATION, AEROSPACE MEDICAL ASSOCIATION,
AMERICAN ACADEMY OF OPHTHALMOLOGY, AMERICAN
ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF
CARDIOLOGY, AMERICAN COLLEGE OF CHEST PHYSICIANS,
AMERICAN COLLEGE OF LIFESTYLE MEDICINE, AMERICAN
COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS,
AMERICAN COLLEGE OF OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE, AMERICAN COLLEGE OF
PHYSICIANS, AMERICAN COLLEGE OF PREVENTIVE
MEDICINE, AMERICAN GASTROENTEROLOGICAL
ASSOCIATION, AMERICAN MEDICAL WOMEN'S
ASSOCIATION, AMERICAN OSTEOPATHIC ASSOCIATION,
AMERICAN PSYCHIATRIC ASSOCIATION, AMERICAN
SOCIETY OF CLINICAL ONCOLOGY, AMERICAN SOCIETY OF
ECHOCARDIOGRAPHY, AMERICAN SOCIETY FOR
GASTROINTESTINAL ENDOSCOPY, AMERICAN THORACIC
SOCIETY, AMERICAN SOCIETY OF NEPHROLOGY, GLMA:
HEALTH PROFESSIONALS ADVANCING LGBTQ+ EQUALITY,**

**INFECTIOUS DISEASES SOCIETY OF AMERICA, NATIONAL
HISPANIC MEDICAL ASSOCIATION, NATIONAL MEDICAL
ASSOCIATION, RENAL PHYSICIANS ASSOCIATION, SOCIETY
FOR MATERNAL-FETAL MEDICINE, SOCIETY OF
LAPAROSCOPIC AND ROBOTIC SURGEONS, AND UNDERSEA
AND HYPERBARIC MEDICAL SOCIETY, INC., IN SUPPORT OF
DEFENDANTS-APPELLANTS/CROSS-APPELLEES**

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CERTIFICATE OF INTERESTED PERSONS

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

Amici are:

- American Medical Association
- Aerospace Medical Association
- American Academy of Ophthalmology
- American Academy of Pediatrics
- American College of Cardiology
- American College of Chest Physicians
- American College of Lifestyle Medicine
- American College of Obstetricians and Gynecologists
- American College of Occupational and Environmental Medicine
- American College of Physicians
- American College of Preventive Medicine
- American Gastroenterological Association
- American Medical Women's Association

- American Osteopathic Association
- American Psychiatric Association
- American Society of Clinical Oncology
- American Society of Echocardiography
- American Society for Gastrointestinal Endoscopy
- American Thoracic Society
- American Society of Nephrology
- GLMA: Health Professionals Advancing LGBTQ+ Equality
- Infectious Diseases Society of America
- National Hispanic Medical Association
- National Medical Association
- Renal Physicians Association
- Society for Maternal-Fetal Medicine
- Society of Laparoscopic and Robotic Surgeons
- Undersea and Hyperbaric Medical Society, Inc.

Amici are non-profit, tax-exempt organizations. None has a parent company, and no publicly held company has any ownership interest of any kind in any of *amici*.

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INTEREST OF *AMICI CURIAE*¹

As set forth in the accompanying motion for leave, *amici* include 28 associations representing hundreds of thousands of practicing physicians providing vital preventive healthcare services to millions of patients. *Amici* submit this brief to explain how the decision below jeopardizes the coverage of preventive healthcare services and threatens to reverse positive trends in patient health.

¹ No party's counsel authored this brief in whole or in part, no party or party's counsel contributed money intended to fund this brief, and no person other than *amici*, their members, and their counsel contributed money to fund this brief. All parties consent to the filing of this brief.

INTRODUCTION

As professional organizations representing physicians across the country, *amici* know that no-cost preventive care saves lives, saves money, improves health outcomes, and enables healthier lifestyles. Ensuring that patients can receive these services without financial barriers is of the utmost importance to public health—and was one of the central features of the Affordable Care Act. The decision below threatens to gut the ACA’s preventive-care requirements and imperil access to vital healthcare services nationwide. *Amici* file this brief to explain the consequences the lower court’s decision could have on preventive-care access and to encourage this Court to reverse it.

As medical professionals, *amici* know that preventive care can mean the difference between kicking a smoking habit or living with a heightened risk of dozens of illnesses; between taking a statin or suffering a life-changing heart attack; between providing essential prenatal and postnatal care and screening or leaving pregnant people and children behind; and between catching a patient’s cancer early or catching it after it’s too late. Identifying and treating conditions before

they worsen, or before they present at all, yields better outcomes for patients and saves money for the health system overall.

By increasing access to insurance coverage, and by requiring insurance plans to cover preventive-health services without cost-sharing, such as copays and deductibles, the Affordable Care Act greatly expanded the availability of these services. In passing that statute, Congress incorporated the recommendations of the U.S. Preventive Services Task Force (“USPSTF” or “Task Force”), an objective, rigorous body of experts—a decision that ensures that insurers have to cover only the services that the available medical evidence demonstrates deliver high value to patients and the health system. The ACA’s preventive-care requirements have functioned for more than ten years, enabling millions of Americans to obtain no-cost preventive care and improving utilization of these vital services nationwide.

The district court’s holding regarding Task Force services will make it more difficult for Americans to access life-saving preventive care. In the face of copays and deductibles, not to mention uncertainty as to whether, for example, a cancer screening will be covered by

insurance, many Americans may forgo preventive services that could save or drastically improve their lives—to their detriment and to the detriment of our nation’s health system.

For the reasons that the government explains, the decision below regarding USPSTF services is wrong on the law and should be reversed on the merits. At minimum, this Court should reverse the nationwide injunction that the district court issued. *Amici* write to illustrate the grave harms that *amici*’s patients stand to face should the Court leave intact that expansive remedy. *Amici* urge this Court not to disrupt access to the no-cost preventive-care services that patients have enjoyed for more than a decade—services that have led to lifesaving and health-improving care for millions of people.²

² For the same reasons, *amici* urge the Court to affirm the district court’s holding with respect to the service recommendations of the Advisory Committee on Immunization Practices (“ACIP”) and the Health Resources and Services Administration (“HRSA”). Insofar as plaintiffs contest the district court’s holdings regarding ACIP and HRSA in their cross-appeal, *amici* may address ACIP and HRSA services—and the harms to patients should access to those services be undermined—in supplemental briefing, in accordance with the briefing schedule entered by this Court, *see* Dkt. 156 (5th Cir. June 13, 2023).

ARGUMENT

I. Encouraging patients to obtain preventive care improves health outcomes and the functioning of the health system overall.

Preventive care is an umbrella term that refers to “[r]outine health care that includes screenings, check-ups, and patient counseling to prevent illnesses, disease, or other health problems.”³ As medical professionals, *amici* have an obligation to ensure that our patients, and the public as a whole, receive medically indicated preventive services. As Principle VII of the AMA Principles of Medical Ethics states, “A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.”⁴ To that end, Opinion 8.11 of the AMA Code of Medical Ethics specifies that, “[w]hile a physician’s role tends to focus on diagnosing and treating illness once it occurs, physicians also have a

³ *Preventive Services*, HealthCare.gov, <https://www.healthcare.gov/glossary/preventive-services/> (last visited June 23, 2023).

⁴ *AMA Principles of Medical Ethics*, AMA Code Med. Ethics, <https://code-medical-ethics.ama-assn.org/principles> (last revised June 2001).

professional commitment to prevent disease and promote health and well-being for their patients and the community.”⁵

An extensive body of evidence demonstrates how preventive care can help patients live longer, healthier lives. Preventive services include both services aimed at the early detection and treatment of potentially fatal medical conditions and chronic diseases, as well as services aimed at encouraging people to adopt healthy lifestyles.

Preventive care can therefore “help people avoid acute illness, identify and treat chronic conditions, prevent cancer or lead to earlier detection, and improve health.”⁶ “When provided appropriately, these services can identify diseases at earlier stages when they are more treatable or may reduce a person’s risk for developing a disease.”⁷ Similarly, “[i]mproved access to prenatal care is a public health gain as late entry into

⁵ *Opinion 8.11, Health Promotion & Preventive Care*, AMA Code Med. Ethics, <https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/8.11.pdf> (last visited June 23, 2023).

⁶ *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, Ass’t Sec’y for Plan. & Evaluation, U.S. Dep’t of Health & Human Servs. 1 (Jan. 11, 2022), <https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf> [hereinafter 2022 ASPE Report].

⁷ *11th Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services*, U.S. Preventive Servs. Task Force 5 (2021), <https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/2021-uspstf-annual-report-to-congress.pdf>.

prenatal care or no prenatal care is known to contribute to poor birth outcomes, especially an increase in low birthweight and preterm babies.”⁸ Overall, a 2007 study by the National Commission on Prevention Priorities estimated that “[i]ncreasing the use of just 5 preventive services,” including several Task Force-recommended services, “would save more than 100,000 lives each year in the United States.”⁹

Preventive care also reduces overall spending on health care. By “reduc[ing] the amount of undiagnosed or untreated conditions,” preventive care “is expected to reduce costs through less invasive or complex treatment options.”¹⁰ For instance, cancer is cheaper to treat at the outset than after it has metastasized. While prevention does not always reduce medical costs in all instances, “[t]here are a number of preventive services that directly reduce costs,” including “childhood

⁸ Susan Gennaro et al., *Improving Prenatal Care for Minority Women*, 41 Am. J. Maternity Child Nursing 147, 148 (2016), https://journals.lww.com/mcnjournal/Abstract/2016/05000/Improving_Prenatal_Care_for_Minority_Women.3.aspx.

⁹ *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*, Partnership for Prevention 6 (2007).

¹⁰ Robert Brent Dixon & Attila J. Hertelendy, *Interrelation of Preventive Care Benefits & Shared Costs Under the Affordable Care Act*, 3 Int’l J. Health Pol’y & Mgmt. 145, 146 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154552/pdf/IJHPM-3-145.pdf>.

immunizations, risky behavior counseling (e.g. smoking cessation, illicit drug abstinence), . . . and certain cancer screens.”¹¹ Indeed, “[e]ighteen of the 25 preventive services evaluated by the [National Convention on Prevention Priorities] cost \$50,000 or less per quality-adjusted life year (QALY) and 10 of these cost less than \$15,000 per QALY, all well within the range of what is considered a favorable cost-effectiveness ratio.”¹²

But patients reap the many benefits of preventive care only if they access preventive-care services in the first place. That can be an uphill battle,¹³ and the cost of care is a core reason why.¹⁴ In particular, “[s]tudies have shown that out-of-pocket payments can be a barrier to the use of recommended preventive services, and reductions in cost sharing were found to be associated with increased use of preventive services.”¹⁵ Indeed, a 2012 meta-analysis of 47 separate studies found

¹¹ *Id.*

¹² P’ship for Prevention, *supra* note 9, at 12.

¹³ 2022 ASPE Report, *supra* note 6, at 7.

¹⁴ Amanda Borsky et al., *Few Americans Receive All High-Priority, Appropriate Clinical Preventive Services*, 37 *Health Affs.* 925, 927 (2018), <https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1248>.

¹⁵ Christine Leopold et al., *The Impact of the Affordable Care Act on Cancer Survivorship*, 23 *Cancer J.* 181, 184 (2017), https://journals.lww.com/journalppo/Fulltext/2017/05000/The_Impact_of_the_Affordable_Care_Act_on_Cancer.6.aspx; J. Frank Wharam et al., *Two-Year Trends in Cancer Screening Among Low Socioeconomic Status Women in an HMO-Based*

“strong[] support” for “the concept that cost sharing, as a financial barrier, decreases ... the use of preventive services.”¹⁶ Prior to the enactment of the Affordable Care Act, the majority of Americans either lacked health insurance or were enrolled in insurance plans that did not cover preventive care without cost-sharing¹⁷—creating a substantial barrier to widespread use of preventive care.

II. The Affordable Care Act significantly expanded access to no-cost preventive care.

Congress passed the Affordable Care Act in 2010 “to improve national health-insurance markets and extend coverage to millions of people without adequate (or any) health insurance.” *Me. Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1315 (2020). Increasing access to preventive care is a core component of the scheme that Congress designed. As then-Secretary of Health and Human Services Kathleen

High-Deductible Health Plan, 27 J. Gen. Internal Med. 1112, 1112 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3515008/pdf/11606_2012_Article_2057.pdf (“Previous research suggests that cost-sharing broadly reduces use of medical services, including cancer screening.”).

¹⁶ Reza Rezayatmand et al., *The Impact of Out-of-Pocket Payments on Prevention and Health-Related Lifestyle: A Systematic Literature Review*, 23 Eur. J. Pub. Health 74, 77 (2012), <https://pubmed.ncbi.nlm.nih.gov/22544911/>.

¹⁷ Xuesong Han et al., *Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing as Part of the Affordable Care Act in the United States?*, 78 Preventive Med. 85, 87 (2015), <https://www.sciencedirect.com/science/article/abs/pii/S0091743515002285?via%3Dihub>.

Sebelius noted, “Many of the 10 major titles in the law, especially Title IV, Prevention of Chronic Diseases and Improving Public Health, advance a prevention theme through a wide array of new initiatives and funding.”¹⁸

Specifically, Congress sought to eliminate cost-sharing requirements for accessing vital, evidence-backed preventive services.¹⁹ In doing so, “the ACA transforms the U.S.’s public and private health care financing systems into vehicles for promoting public health.”²⁰ As relevant here, 42 U.S.C. § 300gg-13 mandates:

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

- (1) evidence-based items or services that have in effect a rating of “A” or “B” in the current

¹⁸ Howard K. Koh & Kathleen G. Sebelius, *Promoting Prevention through the Affordable Care Act*, 363 N.E. J. Med. 1296, 1296 (2010), https://www.nejm.org/doi/10.1056/NEJMp1008560?url_ver=Z39.88-2003.

¹⁹ *See id.* (“A major strategy is to remove cost as a barrier to these services, potentially opening new avenues toward health.”).

²⁰ John Aloysius Cogan Jr., *The Affordable Care Act’s Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J.L. Med. & Ethics 355, 355 (2011), <https://journals.sagepub.com/doi/10.1111/j.1748-720X.2011.00605.x>.

recommendations of the United States Preventive Services Task Force²¹

“The [Task Force] is an internationally recognized, independent panel of nonfederal experts in primary care, prevention, and research methods that makes evidence-based recommendations to guide the delivery of clinical preventive services.”²² Some have even referred to the Task Force’s methodology as the “gold standard” for clinical practice recommendations.²³ An “A” or a “B” recommendation indicates moderate to high certainty that the net benefits of a given service are moderate to substantial; other grades include “C,” meaning that a service should be provided selectively, “D,” meaning that a service is

²¹ These requirements do not apply to so-called “grandfathered” plans, meaning plans that were in existence prior to 2010 and are therefore exempt from certain ACA provisions.

²² Janelle Guirguis-Blake et al., *Current Processes of the U.S. Preventive Services Task Force: Refining Evidence-Based Recommendation Development*, 147 *Annals Internal Med.* 117, 117 (2007), https://www.researchgate.net/publication/6260162_Current_Processes_of_the_US_Preventive_Services_Task_Force_Refining_Evidence-Based_Recommendation_Development.

²³ Doug Campos-Outcalt, *Practice Alert: US Preventive Services Task Force: The Gold Standard of Evidence-Based Prevention*, 54 *J. Fam. Pract.* 517, 517 (2005), https://cdn.mdedge.com/files/s3fs-public/Document/September-2017/5406JFP_PracticeAlert.pdf; Chyke A. Doubeni et al., *Viewpoint: Addressing Systemic Racism Through Clinical Preventive Service Recommendations from the US Preventive Services Task Force*, 325 *J. Am. Med. Ass’n* 627, 627 (2021), <https://jamanetwork.com/journals/jama/article-abstract/2775793> (citing *Inst. Med., Clinical Practice Guidelines We Can Trust* (Robin Graham et al. eds., 2011)); Guirguis-Blake et al., *supra* note 22, at 117.

discouraged, and “I,” meaning that there is insufficient evidence to assess the costs and benefits of a service.²⁴

The Task Force has assigned a grade of A or B to 46 services, which have become core components of preventive medicine. These services include:

- Screenings, genetic assessments, risk-reducing medications, and behavioral counseling for various cancers, including breast, colorectal, lung, skin, and various cancers of the female reproductive system.
- Preventive services for pregnant people and those who have recently given birth, including screening for aspirin use in those at high risk for preeclampsia, interventions to support breastfeeding, screenings for sexually transmitted diseases, folic acid supplements for neural tube defects, gestational diabetes screening, preventive medications for newborns, and blood testing.

²⁴ *Grade Definitions*, U.S. Preventive Servs. Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions> (last updated June 2018).

- Precautionary screenings for certain population-wide diseases and conditions, including hepatitis, human immunodeficiency virus (HIV), and hypertension.
- Services for populations at high risk for certain conditions, including aneurysm screening in men aged 65 to 75 who have a history of smoking, cardiovascular disease screening among at-risk populations, tuberculosis screening, screening for osteoporosis in women aged 65 and older, screening for prediabetes and Type 2 Diabetes in adults aged 35 to 70 who are overweight or have obesity, and statin use in adults aged 40 to 75 years with cardiovascular risk factors.
- Preventive mental health screenings, including anxiety and depression screening in children and adults.
- General, population-wide services aimed at encouraging healthy lifestyles, including obesity screening and weight loss programs, tobacco cessation programs, and screening for unhealthy drug and alcohol use.²⁵

²⁵ *A & B Recommendations*, U.S. Preventive Servs. Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations> (last visited June 23, 2023).

In enacting the ACA, Congress sought to guarantee access to services like these regardless of financial constraints.

The ACA's preventive-care requirements have generally been successful in expanding access to preventive care, and, for that reason, have proven to be one of the most popular parts of the statute.²⁶ “While some plans already covered the full costs of these services prior to the Affordable Care Act, millions of Americans were enrolled in health plans that did not.”²⁷ In 2014, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services estimated that *76 million* individuals gained access to preventive care without cost-sharing as a result of the ACA, either by newly enrolling in private insurance or by having already enrolled in

²⁶ See Ashley Kirzinger et al., *5 Charts About Public Opinion on the Affordable Care Act*, Kaiser Fam. Found. (Apr. 14, 2022), <https://www.kff.org/health-reform/poll-finding/5-charts-about-public-opinion-on-the-affordable-care-act-and-the-supreme-court/> (finding that 62% of Americans saw it as “very important” that preventive care requirements be kept in place).

²⁷ Amy Burke & Adelle Simmons, *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 2 (June 27, 2014), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//44251/ib_PreventiveServices.pdf.

insurance plans that added coverage of preventive care after the ACA's enactment.²⁸

The number of Americans with insurance that covers preventive care with no out-of-pocket costs has continued to grow over the subsequent decade. “In 2020, the most recent year of data available,” statistics indicate that “151.6 million individuals currently have private health coverage that covers preventive services with zero cost-sharing,” including “approximately 58 million women, 57 million men, and 37 million children.”²⁹ The ACA's preventive-care requirements can also apply to Medicaid expansion enrollees, adding another 20 million adults,³⁰ and to Medicare enrollees, if HHS has determined that a given service is appropriate for inclusion in the program, adding 61.5 million individuals more.³¹ In other words, approximately *233 million people* are currently enrolled in health plans that must cover preventive services without cost-sharing.

²⁸ *Id.*

²⁹ 2022 ASPE Report, *supra* note 6, at 3.

³⁰ *Id.* at 6.

³¹ *Id.* at 7.

This dramatic expansion of preventive coverage has generally increased the utilization of preventive services. A recent study found, for example, that “6 in 10 privately insured people (60%) received ACA preventive care in 2018,” or roughly 100 million people.³² A 2022 literature review of 35 separate studies conducted by the University of Michigan Center for Value-Based Insurance Design determined that “[t]he majority of findings in our literature conclude that cost-sharing elimination led to increases in utilization for select preventive services.”³³ “Changes in utilization may be localized or augmented among specific populations, including low-income individuals, Medicare beneficiaries lacking supplemental insurance, and those with high levels of cost-sharing for a service pre-elimination,” which “suggest that low-socioeconomic groups and those who experience the greatest financial barriers to care appear to benefit the most from cost-sharing

³² Krutika Amin et al., *Preventive Services Use Among People with Private Insurance Coverage*, Peterson-KFF Health Sys. Tracker (Mar. 20, 2023), <https://www.healthsystemtracker.org/brief/preventive-services-use-among-people-with-private-insurance-coverage/>.

³³ Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 *Med. Care. Rsch. & Rev.* 175, 192 (2022), <https://www.deepdyve.com/lp/sage/utilization-impact-of-cost-sharing-elimination-for-preventive-care-bpUvb2r4Lr?key=sage>.

elimination.”³⁴ To the extent preventive services remain under-utilized, it is because of additional barriers like lack of awareness of particular services or the benefits of preventive care.³⁵

So, for example, a study of 64,000 adults with different insurance profiles found that in the two years after the ACA’s preventive-care mandate eliminated cost-sharing for many health plans, “the rate of uptake increased for some” services, including “[b]lood pressure check, cholesterol check, and flu vaccination.”³⁶ The study’s authors concluded that there were “some positive benefits of the provisions,” even in the face of “limited overall awareness and understanding of the ACA during the early days.”³⁷

³⁴ *Id.* at 193; *see also* Lindsay M. Sabik & Georges Adunlin, *The ACA and Cancer Screening and Diagnosis*, 23 *Cancer J.* 151, 161 (2017), https://journals.lww.com/journalppo/Fulltext/2017/05000/The_ACA_and_Cancer_Screening_and_Diagnosis.2.aspx (“Despite mixed findings, evidence to date suggests that impacts on screening were greatest among those with lower education and income, as well as groups that faced the highest cost-barriers to screening prior to the ACA. Thus, key populations targeted by the ACA’s provisions appear to have benefited the most in terms of access to cancer screening.”)

³⁵ Norris et al., *supra* note 33, at 193.

³⁶ Han et al., *supra* note 17, at 86–87.

³⁷ *Id.* at 89; *see also* Heidi D. Nelson et al., *Mammography Screening in a Large Health System Following the U.S. Preventive Services Task Force Recommendations and the Affordable Care Act*, 10 *PLOS One* (June 2015), at 2, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4487998/pdf/pone.0131903.pdf> (“Mammography screening volumes in a large community health system decreased among women age <50 and ≥75 in association with new U.S. Preventive Services

More recent studies have found significant increases in cancer screening rates. ASPE's 2022 report on preventive care utilization found that "[s]tudies examining changes in cancer screening among privately insured individuals after the ACA eliminated cost-sharing show an overall increase in colorectal cancer screening tests," as well as "increase[d] cervical cancer screening rates among Latinas and Chinese-American women."³⁸ And a study of improvements in cancer screenings in community health centers found that "both increased insurance options (Medicaid expansion and subsidized exchange coverage) and preventive service coverage requirements (ensuring no out-of-pocket cost to patients for these screenings) helped patients obtain recommended services."³⁹

Studies have also confirmed that the ACA's preventive care requirements increased the use of general wellness services. A 2014 study found that the expansion of insurance "accounted for the increase

Task Force practice recommendations, while insurance coverage changes under the Affordable Care Act were associated with increased screening volumes among women age 50-74.").

³⁸ 2022 ASPE Report, *supra* note 6, at 7, 8.

³⁹ Nathalie Huguet et al., *Cervical and Colorectal Cancer Screening Prevalence Before and After Affordable Care Act Medicaid Expansion*, 124 *Preventive Med.* 91, 95 (2019), <https://www.sciencedirect.com/science/article/pii/S0091743519301719>.

in young adults' receipt of a routine examination" in the preceding year, which "suggests that young adults will take initiative to seek a routine examination when financial barriers are removed."⁴⁰ It also found that "insurance accounted for the increase in receiving a blood pressure screening and accounted for part of the increases in receiving a cholesterol screening."⁴¹ Similarly, "the percentage of Medicare beneficiaries utilizing annual wellness visits increased 14.9 percentage points between 2011 (the first year when such visits were covered) and 2016, rising from 8.1 percent to 23.0 percent."⁴² Other studies have suggested that the ACA has made it more likely that pregnant persons will seek vital prenatal care.⁴³

These improvements mean that more Americans, including pregnant persons and children, are now able to take steps toward living healthier lives as a result of the requirement that insurers cover

⁴⁰ Josephine S. Lau et al., *Improvement in Preventive Care of Young Adults After the Affordable Care Act: The Affordable Care Act Is Helping*, 168 J. Am. Med. Ass'n 1101, 1105 (2014), <https://jamanetwork.com/journals/jamapediatrics/fullarticle/1913624>.

⁴¹ *Id.*

⁴² 2022 ASPE Report, *supra* note 6, at 8.

⁴³ Yheneko J. Taylor et al., *Insurance Differences in Preventive Care Use and Adverse Birth Outcomes Among Pregnant Women in a Medicaid Nonexpansion State: A Retrospective Cohort Study*, 29 J. Women's Health 29, 30 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6983742/pdf/jwh.2019.7658.pdf>.

preventive services. The availability of no-cost preventive care has also improved utilization and health outcomes among populations that have historically been subjected to discrimination. Racial and ethnic disparities in health outcomes persist “even when access-related factors, such as patients’ insurance status and income, are controlled.”⁴⁴ In particular, “[r]acial and ethnic disparities in utilization of preventive care services are well-documented.”⁴⁵ However, a recent study concluded that “[g]iven the large differences in the share of uninsured and the use of clinical preventive services among Black and Hispanic adults relative to White adults pre-ACA, the ACA does appear to have reduced the differences between minority adults and White adults.”⁴⁶ To take one example, “[t]he growth in the use of mammography (Hispanic women) and colonoscopy screening ... increased at a higher

⁴⁴ *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Inst. of Med. 1 (Brian D. Smedley et al. eds., 2003), <https://nap.nationalacademies.org/catalog/10260/unequal-treatment-confronting-racial-and-ethnic-disparities-in-health-care>; see also Shirley A. Hill, *Inequality and African-American Health: How Racial Disparities Create Sickness* 11, 60 (2016).

⁴⁵ Cagdas Agirdas & Jordan G. Holding, *Effects of the ACA on Preventive Care Disparities*, 16 *Applied Health Econ. & Health Pol’y* 859, 860 (2018), <https://link.springer.com/article/10.1007/s40258-018-0423-5>.

⁴⁶ 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* (Apr. 2022), <https://www.ajmc.com/view/racial-trends-in-clinical-preventive-services-use-chronic-disease-prevalence-and-lack-of-insurance-before-and-after-the-affordable-care-act>.

percentage point rate among both Hispanic and Black adults compared with White adults with the implementation of the ACA.”⁴⁷ Other studies have also found increases in cancer screening rates and improvements in blood pressure and glucose levels among members of historically marginalized communities.⁴⁸

III. Affirming the judgment below would imperil access to preventive care for millions of Americans.

The district court’s holding with respect to Task Force services—and, crucially, its imposition of a nationwide injunction rather than plaintiff-specific relief—jeopardizes coverage of preventive services that plaintiffs never suggested injure them in any way. Such a decision would allow insurers nationwide to reimpose cost-sharing requirements on millions of Americans. In other words, it would allow insurers to charge their enrollees—*amici*’s patients—for mammograms, colonoscopies, and other services at will.

That decision jeopardizes preventive care for tens of millions of Americans. Although it is difficult to know exactly how many plans will cease covering no-cost preventive services, a 2022 Employee Benefit

⁴⁷ *Id.*

⁴⁸ *See, e.g.*, 2022 ASPE Report, *supra* note 6, at 8, 10; Agirdas & Holding, *supra* note 45, at 869.

Research Institute survey of employers found that between 8 and 20 percent of respondents may impose cost-sharing for some preventive services.⁴⁹ “According to the Kaiser Family Foundation’s Employer Health Benefits Survey in 2012, 41 percent of all workers were covered by employer-sponsored group health plans that expanded their list of covered preventive services due to the Affordable Care Act.”⁵⁰ If even ten percent of those workers’ plans reverted to excluding preventive care or requiring cost-sharing—at the low end of the survey’s findings—more than six million Americans could lose access to no-cost preventive services.

Patients who fall within that category could therefore face substantial out-of-pocket costs for obtaining preventive services—costs that could deter many of them from seeking necessary care. A recent Morning Consult survey found that “at least half [of survey respondents] said they would not pay out of pocket for preventive services such as tobacco cessation or screenings for HIV, depression and

⁴⁹ *Will Employers Introduce Cost Sharing for Preventive Services? Finding from EBRI’s First Employer Pulse Survey*, EBRI Fast Facts (Oct. 27, 2022), https://www.ebri.org/docs/default-source/fast-facts/ff-445-pssurvey-27oct22.pdf?sfvrsn=52f4382f_4.

⁵⁰ Burke & Simmons, *supra* note 27, at 2.

unhealthy drug use.”⁵¹ Thirty-eight percent of the adults in the survey responded that they would not even pay for cancer screenings.⁵²

In other words, subjecting patients to a copay or deductible to access preventive services will deter some of them—and, in particular, those of limited means—from scheduling mammograms, colonoscopies, and screening tests for osteoporosis, hypertension, diabetes, lung cancer, depression, and other conditions that could shorten their lives if undetected and untreated.⁵³ Millions of patients could lose first-dollar coverage for cholesterol treatment, tobacco and alcohol cessation, and diet and obesity counseling. And pregnant persons and children will suffer from missing screenings and treatments during critical phases of pregnancy and early childhood. Deterring patients from receiving these

⁵¹ Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through*, Morning Consult (Mar. 8, 2023), <https://morningconsult.com/2023/03/08/affordable-care-act-polling-data/>.

⁵² *Id.*

⁵³ See Harris Meyer, *Court Ruling May Spur Competitive Health Plans to Bring Back Copays for Preventive Services*, Kaiser Health News (Sept. 15, 2022), <https://khn.org/news/article/court-ruling-health-plans-copays-preventive-services/> (“Tom York, 57, said he appreciates the law’s mandate because until this year the deductible on his plan was \$5,000, meaning that without that ACA provision, he and his wife would have had to pay full price for those services until the deductible was met. ‘A colonoscopy could cost \$4,000,’ he said. ‘I can’t say I would have skipped it, but I would have had to think hard about it.’”).

vital services will result in worse health outcomes and impose higher costs on the health system to treat the maladies that emerge or worsen.

All Americans, moreover, will be affected by the confusion that would emerge from gutting the ACA's decade-old preventive-care requirements. Doing so would yield a "confusing patchwork of health plan benefit designs offered in various industries and in different parts of the country," making it difficult for "[p]atients who have serious medical conditions or are at high risk for such conditions" to "find[] a plan that fully covers preventive and screening services."⁵⁴ Patients will, for the first time in ten years, have to scrutinize insurance plans to determine what preventive services they cover, and at what out-of-pocket cost. And they will have to do so *both* when deciding which plan to select during enrollment, and then *again* when deciding whether to obtain a particular service. Many will instead decide to forgo basic preventive services entirely.⁵⁵

⁵⁴ *Id.*

⁵⁵ *See, e.g.,* Norris et al., *supra* note 33, at 193 (identifying "patients' unawareness of what services are exempt from cost-share" and "misperceptions of the importance of preventive care" as reasons patients decline to obtain preventive care); Stacey A. Fedewa et al., *Elimination of Cost-Sharing and Receipt of Screening for Colorectal and Breast Cancer*, 121 *Cancer* 3272, 3278 (2015), <https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.29494>.

Insurers may also alter their plans in ways that distort the functioning of the insurance system. Insurers would likely design their preventive-services benefits to attract healthier customers, reducing their overall costs, or use cost-sharing requirements to lower premiums, forcing other insurers to follow suit to compete.⁵⁶ Even plans that hold out and “keep a zero-cost policy for preventive services such as HIV prevention, diabetes screening, and lung cancer screening for smokers may gain a higher-risk population, forcing them to eventually add cost sharing to survive financially.”⁵⁷ Put simply, “[y]ou end up with a race to the bottom”⁵⁸—the precise opposite of what Congress sought to achieve in enacting the Affordable Care Act. Although some states might impose no-cost preventive care requirements by state law, only six states have done so thus far, and their authority to do so is limited

⁵⁶ Meyer, *Court Ruling*, *supra* note 53; see also Harris Meyer, *What Will Payers Do If Courts Strike Down the ACA’s No-Cost Requirement for Preventive Services?*, Managed Healthcare Exec. (Sept. 7, 2022), <https://www.managedhealthcareexecutive.com/view/what-will-payers-do-if-courts-strike-down-the-aca-s-no-cost-requirement-for-preventive-services-> [hereinafter Meyer, *What Will Payers Do*].

⁵⁷ Meyer, *What Will Payers Do*, *supra* note 56.

⁵⁸ *Id.*

to individual and small business health plans, not large employer plans.⁵⁹

If the decision below invalidating the Task Force's recommendations nationwide is not reversed, *amici* know from experience that their patients will be less likely to accept services that will save lives. Patients will struggle to navigate new and confusing insurance schemes. Ultimately, *amici* will see many of their patients, including some of their most vulnerable, turn down medically indicated services because of the very financial barriers that Congress sought to remove. The past ten years have shown the benefits of no-cost preventive coverage. *Amici* ask the Court to preserve those benefits by reversing the expansive injunctive relief that imperils access to no-cost preventive care nationwide.

CONCLUSION

The Court should reverse the judgment of the lower court with respect to Task Force services and reverse the nationwide injunction.

⁵⁹ Michael Ollove, *Lawsuit Could End Free Preventive Health Checkups*, Stateline, Pew Charitable Trusts (Aug. 9, 2022), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/08/09/lawsuit-could-end-free-preventive-health-checkups>.

Respectfully submitted,

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s/ Madeline H. Gitomer

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Dated: June 27, 2023

CERTIFICATE OF SERVICE

I, Madeline H. Gitomer, counsel for *amici*, certify that on June 27, 2023, a copy of the foregoing brief was filed electronically through the appellate CM/ECF system with the Clerk of the Court. I further certify that all parties required to be served have been served.

s/ Madeline H. Gitomer

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