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
Trial Court No. 4:20-CV-283

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, SOCIETY FOR MATERNAL-FETAL MEDICINE, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN ACADEMY OF FAMILY PHYSICIANS, NATIONAL MEDICAL ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN THORACIC SOCIETY, NATIONAL HISPANIC MEDICAL ASSOCIATION, AND AMERICAN SOCIETY OF CLINICAL ONCOLOGY
IN SUPPORT OF DEFENDANTS-APPELLANTS' MOTION FOR A PARTIAL STAY OF FINAL JUDGMENT PENDING APPEAL

(*Counsel listed on following page*)

Madeline H. Gitomer
Counsel of Record
Jeffrey B. Dubner
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Telephone: (202) 448-9090

Counsel for Amici

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:

A. The **American Medical Association** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

B. The **American College of Obstetricians and Gynecologists** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

C. The **Society for Maternal-Fetal Medicine** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

D. The **American Academy of Pediatrics** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

E. The **American Medical Women's Association** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

F. The **American Academy of Family Physicians** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

G. The **National Medical Association** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

H. The **Infectious Diseases Society of America** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

I. The **American Thoracic Society** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

J. The **American College of Chest Physicians** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

K. The **National Hispanic Medical Association** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

L. The **American Society of Clinical Oncology** is a non-profit, tax-exempt organization. It has no parent company, and no publicly held company has any ownership interest in it of any kind.

Counsel for *amici curiae*:

Madeline H. Gitomer
Jeffrey B. Dubner
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, DC 20043

Dated: April 28, 2023

s/ Madeline H. Gitomer

Madeline H. Gitomer
Counsel of Record

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INTEREST OF *AMICI CURIAE*[1]

As set forth in the accompanying motion for leave, *Amici* include 12 associations representing hundreds of thousands of practicing physicians providing vital preventive health care services to millions of patients. *Amici* submit this brief to explain how the decision below jeopardizes the coverage of preventive health care 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 is of the utmost importance to public health. The district court's unprecedented decision imperils access to these services nationwide. *Amici* file this brief to inform this Court of the repercussions that decision could have on preventive care access.

The decision below will make it more difficult for Americans to access life-saving preventive services. Many Americans who go to their doctor in the coming months may no longer be sure that, for example, their cancer screenings are covered by their insurance. Many may instead decide not to receive care that could save or drastically improve their lives—to their detriment and to the detriment of our nation's health system.

Amici urge the Court, in evaluating whether to partially stay the district court's ruling pending appeal, to "pay particular regard for the public consequences" of restricting access to preventive care. *Winter v.*

Nat. Res. Def. Council, 555 U.S. 7, 24, 32 (2008) (citations omitted). This brief demonstrates how *Amici*'s patients could face severe and irreparable harm should the Court decline to partially stay the lower court's ruling. The preventive care services available to patients over the past ten years at no additional cost have led to lifesaving and health-improving care for millions of people. In balancing the equities, it is clear that any potential harm faced by Plaintiffs pales in comparison to the harm that patients and physicians will face should the court maintain these barriers to preventive care.

The Court should therefore partially stay the decision below.

ARGUMENT

I. Access to preventive care improves health outcomes and the health system overall.

Preventive care refers to "[r]outine health care that includes screenings, check-ups, and patient counseling to prevent illnesses, disease, or other health problems."[2] A 2007 Partnership for Prevention study estimated that "[i]ncreasing the use of just 5 preventive services," including several services recommended by the United States

[2] *Preventive Services*, HealthCare.gov, https://www.healthcare.gov/glossary/preventive-services/ (last visited Apr. 24, 2023).

Preventive Services Task Force ("Task Force"), "would save more than 100,000 lives each year in the United States."[3]

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."[4]

Despite the benefits of preventive care, it can be difficult to encourage patients to fully utilize these services. "Studies 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."[5] A 2012 meta-

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[3] *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*, P'ship for Prevention 6 (2007), *available at* https://studylib.net/doc/13757197/preventive-care---a-national-profile-on-use--disparities-....

[4] 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.

[5] 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 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.

analysis of 47 separate studies found "strong[] support" for "the concept that cost sharing, as a financial barrier, decreases … the use of preventive services."[6]

II. The Challenged Rules significantly expanded access to preventive care.

Increasing access to preventive care is central to the scheme that Congress designed when passing the Affordable Care Act.[7] 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 insurance plans that added coverage of preventive care after the statute's enactment.[8]

The number of Americans whose insurance covers preventive care without out-of-pocket costs has only grown. "In 2020, the most recent

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[6] 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/.

[7] 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.

[8] *Id.*

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."[9]

The Task Force requirements can also apply to Medicaid expansion enrollees, adding another 20 million adults,[10] 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.[11] In other words, approximately *233 million individuals* are currently enrolled in plans that must cover preventive services without cost-sharing.

This dramatic expansion of preventive coverage has generally increased the utilization of preventive services. A recent study found that "6 in 10 privately insured people (60%) received ACA preventive

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[9] *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act,* ASPE (Jan. 11, 2012), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf, at 3.

[10] *Id.* at 6.

[11] *Id.* at 7.

care in 2018," or roughly 100 million people.[12] Similarly, a 2022 review of 35 studies determined that "[t]he majority of findings in our literature conclude that cost-sharing elimination led to increases in utilization for select preventive services."[13]

ASPE's 2022 report 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."[14] 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

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[12] 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/.

[13] 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://journals.sagepub.com/doi/10.1177/10775587211027372.

[14] *2022 ASPE Report*, *supra* note 9, at 7, 8.

screenings) helped patients obtain recommended services."[15] Other studies have suggested that the ACA has made it more likely that pregnant persons will seek vital prenatal care.[16] These improvements mean that more Americans are now able to live healthier lives.

Finally, the availability of no-cost preventive care has improved utilization and health outcomes among populations that have historically faced difficulty accessing health care. In particular, 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."[17] Other studies have also found increases in cancer screening

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[15] 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.

[16] Yhenneko 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.

[17] 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 e126, e131 (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.

rates and improvements in blood pressure and glucose rates among members of historically marginalized communities.[18]

Eliminating coverage requirements would impose further barriers, making it even harder to ensure that patients receive the requisite care.

III. The decision below imperils access to preventive care for millions of Americans.

The district court's decision allows insurers nationwide to reimpose cost-sharing requirements on millions of Americans. In other words, the effect of the court's decision is to 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 Research Institute survey suggests that between eight and 20 percent of respondents may impose cost sharing for some preventive services.[19]

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[18] *See, e.g.*, *2022 ASPE Report*, *supra* note 9, at 8, 10; Cagdas Agirdas & Jordan Holding, *Effects of the ACA on Preventive Care Disparities*, 16 Applied Health Econ. & Health Pol'y 859, 869, https://link.springer.com/article/10.1007/s40258-018-0423-5.

[19] *Will Employers Introduce Cost Sharing for Preventive Services? Finding from EBRI's First Employer Pulse Survey*, EBRI Fast Facts (Oct. 27, 2002),

Further, "[a]ccording 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."[20] If even ten percent of those workers' plans reverted to excluding preventive care or requiring cost-sharing, more than *six million Americans* could, at some point, lose access to no-cost preventive services.

Patients who fall within that category would 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 unhealthy drug use."[21] 38% of the

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https://www.ebri.org/docs/default-source/fast-facts/ff-445-pssurvey-27oct22.pdf?sfvrsn=52f4382f_2.

[20] Amy Burke & Adelle Simmons, *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, ASPE (June 27, 2014), at 2, https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//44251/ib_PreventiveServices.pdf.

[21] 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/.

adults in the survey responded that they would not even pay for cancer screenings.[22]

In other words, imposing cost-sharing requirements could deter at-risk patients—and, in particular, those of limited means—from scheduling services like mammograms, colonoscopies, and screening tests for osteoporosis, hypertension, diabetes, lung cancer, and other conditions that could shorten their lives if undetected and untreated.[23] And many pregnant persons and children could suffer from missing screenings and treatments during critical phases of pregnancy and early childhood. Deterring patients from receiving these vital services will result in worse health outcomes, and impose higher costs on the health system to treat maladies as they emerge and/or worsen.

All Americans, moreover, will be affected by the confusion that emerges from gutting the ACA's decade-old preventive-care

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[22] *Id.*

[23] *See* Harris Meyer, *Court Ruling May Spur Competitive Health Plans to Bring Back Copays for Preventive Services*, Orlando Medical News (Sept. 20, 2022), https://www.orlandomedicalnews.com/article/6131/court-ruling-may-spur-competitive-health-plans-to-bring-back-copays-for-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.'").

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."[24] 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.[25] The confusion and harm that will likely follow the lower court's decision must be given consideration in evaluating whether a stay benefits the public interest, particularly given "the disruptive consequences of an interim change that may itself

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[24] *Id.*

[25] *See, e.g.*, Hope Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 Med. Rsch. & Rev. 1, 19 (2021), https://journals.sagepub.com/doi/10.1177/10775587211027372 (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.

be changed." *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) (quotation omitted).

Insurers may also alter their plans in ways that could distort the functioning of the insurance system. Insurers would likely lower their costs by designing their preventive services benefits to attract healthier customers, or use cost-sharing requirements to lower premiums, forcing other insurers to follow suit to compete.[26] 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."[27] Put simply, the decision below could trigger a far-reaching "race to the bottom."[28]

For these reasons a partial stay pending appeal is warranted, even if the Court might ultimately affirm the district court's decision.

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[26] Meyer, *Court Ruling*, *supra* note 23; *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*].

[27] Meyer, *What Will Payers Do*, *supra* note 26.

[28] *Id.*

Courts must "pay particular regard for the public consequences" of imposing an injunction. *Winter,* 555 U.S. at 32 (citations omitted). The public interest weighs heavily against jeopardizing Americans' access to vital preventive services while this litigation continues—particularly given that the Task Force's role in recommending specific services has been the status quo for ten years.

Ultimately, if the decision below invalidating the Task Force's recommendations nationwide is not partially stayed, *amici* will struggle to encourage their patients to accept services that they know will save lives and to help their patients navigate a new and confusing insurance situation. *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, and *Amici* ask that the Court avoid upsetting that substantial progress while the case proceeds.

CONCLUSION

For these reasons, *Amici* request that the Court partially stay the decision below and protect millions of Americans from losing access to vital preventive services.

Respectfully submitted,

Dated: April 28, 2023

s/ Madeline H. Gitomer

Madeline H. Gitomer
Jeffrey B. Dubner
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
Telephone: (202) 448-9090
mgitomer@democracyforward.org

Counsel for *Amici*

CERTIFICATE OF COMPLIANCE

With Type-Volume Limit, Typeface Requirements,
and Type-Style Requirements

I certify that this filing complies with the type-volume limitation of 32(a)(7)(B) because it contains 2591 words, excluding the parts exempted by Fed. R. App. P. 32(f).

This filing also complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and Fifth Circuit Rule 32.1 and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in proportionally spaced typeface using Microsoft Word for Windows, version 2016 in Century Schoolbook 14-point font typeface, with 12-point font typeface for footnotes.

s/ Madeline H. Gitomer

Madeline H. Gitomer

Date: April 28, 2023

CERTIFICATE OF SERVICE

I, Madeline H. Gitomer, counsel for *Amici*, certify that on April 28, 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

Madeline H. Gitomer

Date: April 28, 2023