

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, *et al.*,
Defendants-Appellants-Cross-Appellees.

On Appeal from the United States District Court
for the Northern District of Texas,
No. 4:20-CV-283-O, Hon. Reed C. O'Connor

**BRIEF FOR AMERICAN PUBLIC HEALTH ASSOCIATION,
PUBLIC HEALTH DEANS AND SCHOLARS, THE ROBERT
WOOD JOHNSON FOUNDATION, AND PUBLIC HEALTH
ADVOCATES AS *AMICI CURIAE*
IN SUPPORT OF CROSS-APPELLEES**

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**CORPORATE DISCLOSURE STATEMENT AND
SUPPLEMENTAL STATEMENT OF INTERESTED PARTIES**

**Case No. 23-10326, *Braidwood Management, Inc., et al.*
*v. Xavier Becerra, et al.***

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

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INTEREST OF *AMICI CURIAE*

The American Public Health Association (“APHA”), which was founded in 1872, is the leading professional organization for public health professionals in the United States. APHA shares the latest research and information, promotes best practices, and advocates for public health issues and policies grounded in scientific research. APHA represents more than 24,000 individual members and is the only organization that combines a 150-year perspective, a broad-based member community, and a focus on influencing federal policy to improve the public’s health.¹

The individual *amici* are a group of 107 distinguished deans and professors of public health and health law and policy with deep expertise in policies that promote population health and alleviate barriers to care. They are identified in Appendix A.

The Robert Wood Johnson Foundation (“RWJF”) is the nation’s largest philanthropic organization dedicated solely to health. It supports efforts to build a national Culture of Health rooted in equity that provides

¹ No counsel for a party authored this brief in whole or in part, and no person other than *amicus* or its counsel contributed money that was intended to fund the preparation or submission of this brief. See Fed. R. App. P. 29(a)(4)(E). All parties have consented to the filing of this brief.

every individual with a fair and just opportunity for health and wellbeing. As part of those efforts, RWJF has supported research demonstrating the benefits of comprehensive coverage for no-cost preventive health services.

Trust for America's Health ("TFAH") is a nonpartisan, nonprofit organization focused on public health research and policy. TFAH is committed to promoting optimal health for every person and community and making health equity foundational to policymaking at all levels. The organization's work is focused on the antecedents of poor health and on policies and programs to advance an evidence-based public health system that is ready to meet the challenges of the 21st century. TFAH develops reports and other resources and initiatives to educate the public and recommends policies to promote health and wellbeing and to make the prevention of illness and injury a national priority.

ChangeLab Solutions is an interdisciplinary team of lawyers, planners, policy analysts, public health practitioners, and other professionals who work across the nation to advance equitable laws and policies that ensure healthy lives for all. With more than two decades of experience in enacting policy, systems, and environmental changes at

local and state levels, ChangeLab Solutions focuses on eliminating health disparities by addressing the social determinants of health. It envisions healthy, equitable communities where every person is economically secure and can attain their full health potential.

APHA has a strong interest in ensuring the continued availability of cost-free coverage for preventive healthcare, given its mission to promote public health through evidence-based policies. The individual *amici*, RWJF, TFAH, and ChangeLab Solutions all share that interest. *Amici* file this brief to explain the importance of the cost-free preventive services requirements challenged on Plaintiffs' cross-appeal and the significant harm to public health that will result if the cross-appeal is successful.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Affordable Care Act (“ACA”) requires health insurance plans that cover more than 150 million Americans to provide cost-free access to four categories of life-saving preventive services. The district court’s decision eliminated this requirement with respect to one category of these services: those recommended by the U.S. Preventive Services Task Force (“USPSTF”) since the ACA’s enactment in 2010. *Amici* explained in their brief in support of the government’s appeal (Dkt. 187) that the lower court’s ruling, if permitted to stand, would result in serious illnesses and deaths that otherwise would have been prevented.

Plaintiffs’ cross-appeal, if successful, would eliminate guaranteed cost-free access to preventive services in the other three statutory categories—immunizations; preventive treatments for infants, children, and adolescents; and preventive services for women, *see* 42 U.S.C. § 300gg-13(a)—that have been added by government experts since the ACA’s enactment. *Amici* submit this brief to explain the very serious harm to Americans’ health, and the significant increase in health care costs, that would result if Plaintiffs prevail on their cross-appeal.

Amici’s brief in support of the government’s appeal explained that:

- Congress in the ACA concluded that to prevent Americans from suffering from serious diseases, including diseases that can lead to death, it was necessary to remove barriers to Americans' use of preventive health services—and that requiring patients to pay part of the cost of these services was a key barrier to their use. Congress therefore included in the statute provisions mandating that insurers cover those services cost-free. Dkt. 187, at 7 & 19-20.
- The ACA's coverage guarantee and elimination of patient cost-sharing have increased Americans' access to and use of preventive services, Dkt. 187, at 15-19; and use of preventive services has lowered health care costs, *id.* at 15.
- If these statutory protections are eliminated, companies and insurers will re-impose cost sharing, and many Americans will not use these services. Dkt. 187 at 19-22.

The very same adverse consequences also will result if Plaintiffs' cross-appeal succeeds and Americans no longer have guaranteed cost-free access to the life-saving treatments recognized under the ACA's

three other preventive-service categories since the law's adoption more than 13 years ago. We will not repeat those arguments here.

Amici submit this brief to explain that—just as the district court's ruling eliminates statutory protection for critically important preventive services, Dkt. 187, at 8-14—upholding Plaintiffs' cross-appeal arguments would deprive Americans of access to additional life-saving treatments.

These additional treatments include vaccines that protect against deadly diseases such as influenza, RSV, and shingles; screening that tests newborns for more than seventy different genetic conditions and other diseases; testing women for post-pregnancy diabetes and annual doctor visits to enable women to access the full range of preventive services available under the ACA. Eliminating guaranteed cost-free coverage of these services will cause Americans to suffer serious illnesses, and deaths, that the services would have prevented.

This Court should affirm the district court's decision with respect to the issues raised on Plaintiffs' cross-appeal.

ARGUMENT

PLAINTIFFS' CROSS-APPEAL, IF SUCCESSFUL, WILL ELIMINATE COST-FREE COVERAGE OF NUMEROUS LIFE-SAVING SERVICES.

Plaintiffs' cross-appeal attacks three categories of preventive services: immunizations; “evidence-informed preventive care and screenings” for “infants, children, and adolescents”; and “preventive care and screenings” for women not adopted by the U.S. Preventive Services Task Force. 42 U.S.C. § 300gg-13(a)(2)-(4).

The government's brief demonstrates why Plaintiffs' cross-appeal arguments fail as a matter of law. *Amici* write separately to explain the serious harm to Americans' health that will be the inevitable consequence of eliminating guaranteed cost-free coverage for these preventive services.

A. Immunizations.

The life-saving immunizations that would lose guaranteed cost-free coverage under Plaintiffs' cross-appeal arguments include:

- Influenza. The formula for flu vaccine changes each year so that it targets the flu variants predicted to be prevalent in the United States—and therefore a different flu vaccine is

endorsed each year.² Accepting Plaintiffs’ arguments would mean that only flu vaccines endorsed before the ACA’s enactment in 2010 would receive guaranteed cost-free coverage.

Although “[m]ost persons who become ill after influenza virus infection recover without serious complications,” the disease “can be associated with serious illnesses, hospitalizations, and deaths, particularly among older adults, very young children, pregnant persons, and persons of all ages with certain chronic medical conditions.”³ One study found that “[d]uring each of the six influenza seasons from 2010–11 through 2015–16, influenza vaccination prevented an estimated 1.6–6.7 million illnesses, 790,000–3.1 million outpatient medical visits,

² Lisa A. Grohskopf, MD, *et al.*, *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023–24 Influenza Season* (Aug. 25, 2023), <https://bit.ly/3rGgp3v> (2023 Influenza Recommendation); see ACIP, *Influenza ACIP Vaccine Recommendations* (Aug. 23, 2023), <https://bit.ly/3ZGiYzb> (archiving annual flu vaccine recommendations).

³ *2023 Influenza Recommendation*.

39,000–87,000 hospitalizations, and 3,000–10,000 respiratory and circulatory deaths each season in the United States.”⁴

- RSV. Respiratory syncytial virus, commonly known as RSV, is “a common respiratory virus that usually causes mild, cold-like symptoms.” But the disease poses serious risks to older adults and infants. Thus, RSV each year “causes substantial morbidity and mortality in older adults, including lower respiratory tract disease (LRTD), hospitalization, and death. . . . Most adult RSV disease cases occur among older adults with an estimated 60,000–160,000 hospitalizations and 6,000–10,000 deaths annually among adults aged ≥ 65 years.”⁵ Also, “RSV infection is the leading cause of hospitalization among U.S. infants”; “[a]pproximately 50,000–80,000 RSV-associated hospitalizations and 100–300 RSV-associated deaths occur annually among U.S. infants

⁴ *Id.*

⁵ Michael Melgar, MD, *et al.*, *Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023* (July 21, 2023), <https://bit.ly/48JkR24>.

and children aged <5 years.”⁶ CDC accordingly has recommended vaccinations for older adults and infants and young children.⁷

- Shingles. One in three Americans will suffer from herpes zoster, which is commonly known as shingles. The incidence of the disease increases with age, and older adults can suffer serious debilitating symptoms—in particular, persistent pain, which can last for three months or more. The government in 2018 recommended a new, more effective vaccine for older Americans.⁸ (The prior vaccine, recommended in 2008, is no longer available in the United States.⁹)

⁶ Jefferson M. Jones MD, *et al.*, *Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023* (Aug. 25, 2023), <https://bit.ly/46Dctzu> .

⁷ See notes 5 and 6.

⁸ Kathleen L. Dooling, MD, *et al.*, *Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines* (Jan. 26, 2018), <https://bit.ly/3ZHiJ6O> ; see also Tara C. Anderson, DVM, PhD, *et al.*, *Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022* (Jan. 21, 2022), <https://bit.ly/3rHJXxN>.

⁹ CDC, *Shingles Vaccination* (May 8, 2023), <https://bit.ly/48K4v9p>.

- Pneumococcal Disease. There are a number of different types of pneumococcal diseases of which pneumonia is the most common. These diseases are especially serious for children and older adults. For example, during 2008–2014 the proportion of cases that resulted in hospitalization “rang[ed] from 8.5% among adults aged 18–49 years to 38.6% among adults aged ≥ 85 years.”; an analysis of studies based on data collected 2010–2016, found the incidence of hospitalization to be “126–422 per 100,000 adults aged < 65 years and 847–3,365 per 100,000 adults aged ≥ 65 years.”¹⁰ Similarly, studies found that “among persons aged < 18 years, 1,280 to 3,990 episodes of health care utilization per 100,000 person-years occurred in 2014 for all-cause pneumonia” and “during 2018–2019, 87 to 680 hospitalizations per 100,000 population occurred for all-cause pneumonia.”¹¹ New, safer and more effective vaccines

¹⁰ Miwako Kobayashi, MD, *et al.*, *Pneumococcal Vaccine for Adults Aged ≥ 19 Years: Recommendations of the Advisory Committee on Immunization Practices, United States, 2023* (Sept. 8, 2023), <https://bit.ly/3PRpwGS> (2023 Adult Pneumococcal Recommendations).

¹¹ Miwako Kobayashi, MD, *et al.*, *Use of 15-Valent Pneumococcal Conjugate Vaccine Among U.S. Children: Updated Recommendations of the Advisory Committee on Immunization Practices — United States*,

for these diseases have been recommended for adults and for children after enactment of the ACA.¹²

Other diseases for which vaccines would no longer receive guaranteed cost-free coverage include meningitis (for which new vaccines have become available and recommendations for various age groups have changed since enactment of the ACA)¹³ and hepatitis B (for low-risk individuals ages 19-59).¹⁴

Finally, vaccine studies confirm that “patient out-of-pocket costs” are “the most significant predictor” of failure to use preventive services¹⁵; unvaccinated individuals inflict huge costs on the health care system—

2022 (Sept. 16, 2022), <https://bit.ly/3Q4IUkQ> (2022 *Children Pneumococcal Recommendations*).

¹² 2023 *Adult Pneumococcal Recommendations* (summarizing history of approvals); 2022 *Children Pneumococcal Recommendations* (same).

¹³ Sarah A. Mbaeyi, MD, *et al.*, *Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020* at Box 1 & Box 2 (Sept. 25, 2022), <https://bit.ly/3tloX0i>.

¹⁴ Mark K. Weng, MD, *et al.*, *Universal Hepatitis B Vaccination in Adults Aged 19–59 Years: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022* (Apr. 1, 2022), <https://bit.ly/48ImJbC>.

¹⁵ Osayl E. Akinbosye, PhD, PAHM, *et al.*, *Factors Associated with Zostavax Abandonment*, 8 *Amer. J. of Pharmacy Benefits* 84, 89 (July/Aug. 2016) (study of use of Shingles vaccine).

in one study, \$7.1 billion in one year, which was 80% of the cost of vaccine-preventable disease¹⁶; and greater vaccine take-up reduces illness and health care costs.¹⁷

B. Preventive services for infants, children, and adolescents.

Critical services for infants, children, and adolescents also would lose guaranteed cost-free coverage:

- Uniform screening panel for newborns. Provides for screening of newborns for more than seventy different serious adverse conditions, including particularly genetic conditions. They include, for example, cystic fibrosis, sickle cell anemia, congenital heart disease, hearing loss, and numerous other diseases and conditions.¹⁸

¹⁶ Sachiko Ozawa, *et al.*, *Modeling the Economic Burden of Adult Vaccine-Preventable Diseases in the United States*, 35 *Health Affairs* 1 (Nov. 2016). Another study found that four adult vaccine-preventable diseases (influenza, pneumococcal disease, shingles, and pertussis) produced \$26.5 billion in health costs. John M. McLaughlin, *et al.*, *Estimated Human and Economic Burden of Four Major Adult Vaccine-Preventable Diseases in the United States*, 36 *J. Primary Prevent.* 259 (2015).

¹⁷ CDC, *2021–2022 Estimated Flu Illnesses, Medical Visits, Hospitalizations, and Deaths Prevented by Flu Vaccination* (Jan. 25, 2023), <https://bit.ly/3Q2UtZU>.

¹⁸ See HRSA, *Recommended Uniform Screening Panel* (Jan. 2023), <https://bit.ly/45myod7> (listing conditions); HRSA, *Newborn Screening –*

- Anemia screening. Screening in infants, children, and adolescents can identify iron deficiencies that can produce developmental delays and cognitive impairment.¹⁹

In addition, some important preventive services for children included in the U.S. Preventive Services Task Force recommendations are also included in the recommendations focused on infants and children—such as screening for depression in adolescents,²⁰ which is especially important in light of the post-pandemic increase in mental health issues. If the court upholds the district court’s ruling and Plaintiffs prevail on their cross-appeal, that result would eliminate guaranteed cost-free coverage of those services.

Condition Information (July 2023), <https://bit.ly/3ZKQ9l7> (describing conditions and reasons for inclusion in uniform panel); HRSA, *Preventive Guidelines and Screenings for Women, Children, and Youth* (July 2022), <https://bit.ly/46ELXpe> (stating that “[r]ecommendations for preventive pediatric care” are set forth in Bright Futures/American Academy of Pediatrics, *Recommendations for Preventive Pediatric Health Care* (2023), <https://bit.ly/46dggDI> (*Pediatric Preventive Care Recommendations*); *Pediatric Preventive Care Recommendations* at note 18 (incorporating Recommended Uniform Screening Panel).

¹⁹ Joseph F. Hagan, *et al.*, American Academy of Pediatrics, *Guidelines for Health Supervision of Infants, Children, and Adolescents* 278-79 (4th ed. 2017), <https://bit.ly/3rHL3tp> (*Infant/Children Preventive Services Guidelines*).

²⁰ *Infant/Children Preventive Services Guidelines* at 283.

C. Preventive services for women.

Finally, Plaintiffs' cross-appeal arguments would eliminate guaranteed cost-free coverage for important preventive services for women, including:

- Screening for post-pregnancy diabetes.²¹ Women who experience diabetes during pregnancy have a greater risk of developing post-pregnancy diabetes. Periodic post-pregnancy screening “provides early detection of continued glucose abnormalities, allowing for timely interventions to prevent progression and diabetes-related complications.”²²
- Screening for urinary incontinence. Annual screening to “assess whether women experience urinary incontinence and whether it impacts their activities and quality of life.”²³ Urinary incontinence is experienced by large numbers of women: it is a “common and sometimes debilitating condition,

²¹ HRSA, *Women's Preventive Services Guidelines* (Dec. 2022), <https://bit.ly/3rKAOnZ> (*Women's Preventive Services Guidelines*).

²² Heidi D. Nelson, MD, MPH, *et al.*, *Screening for Type 2 Diabetes After Pregnancy* 3 (Dec. 1, 2022), <https://bit.ly/3t1pKhM>.

²³ *Women's Preventive Services Guidelines*.

yet it is often not addressed during routine health care.”²⁴

“Early identification and intervention could reduce progression of symptoms and the need for more complex and costly treatments later. Treatment could improve social and physical function and reduce complications of incontinence such as urinary tract infections, skin ulceration, falls and fractures.”²⁵

- Well-Women Preventive Visits. One preventive care visit per year “to ensure the provision of all recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.”²⁶
- Contraceptives. Access to “the full range of female-controlled contraceptives to prevent unintended pregnancy and improve

²⁴ Heidi D. Nelson, MD, MPH, *et al.*, *Screening for Urinary Incontinence* 6 (Dec. 2017), <https://bit.ly/3F3grWn>.

²⁵ *Id.*

²⁶ *Women’s Preventive Services Guidelines*.

birth outcomes.”²⁷ Adopted pursuant to a recommendation by the Institute of Medicine, which is part of the National Academy of Sciences.²⁸

²⁷ *Id.*

²⁸ Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps* 10, 102-110 (2011).

CONCLUSION

With respect to Plaintiffs' cross-appeal, the Court should affirm paragraphs 2 and 4 of the district court's judgment.

Dated: October 6, 2023

Respectfully submitted,

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APPENDIX A

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the above document was filed and served on October 6, 2023, via ECF upon counsel of record for the parties. I further certify that a copy of this brief was served on Christopher M. Lynch, counsel for U.S. Department of Justice, via United States mail.

/s/ Andrew J. Pincus

Andrew J. Pincus

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Pursuant to paragraph A(6) of this Court's ECF Filing Standards, I hereby certify that (1) required privacy redactions have been made, 5th Cir. R. 25.2.13; (2) the electronic submission is an exact copy of the paper document, 5th Cir. R. 25.2.1; and (3) the document has been scanned for viruses with the most recent version of a commercial virus scanning program and is free of viruses.

/s/ Andrew J. Pincus
Andrew J. Pincus

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1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 2755 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Century Schoolbook font.

Dated: October 6, 2023

/s/ Andrew J. Pincus

Andrew J. Pincus