

## No. 23-10326

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

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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*.

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

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**BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION,  
AEROSPACE MEDICAL ASSOCIATION, AMERICAN ACADEMY OF  
OPHTHALMOLOGY, AMERICAN ACADEMY OF PEDIATRICS, 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 PSYCHIATRIC ASSOCIATION, AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY, AMERICAN SOCIETY FOR GASTROINTESTINAL  
ENDOSCOPY, AMERICAN SOCIETY OF NEPHROLOGY, GLMA: HEALTH  
PROFESSIONALS ADVANCING LGBTQ+ EQUALITY, NATIONAL  
HISPANIC MEDICAL ASSOCIATION, NATIONAL MEDICAL  
ASSOCIATION, RENAL PHYSICIANS ASSOCIATION, SOCIETY FOR  
MATERNAL-FETAL MEDICINE, AND SOCIETY OF LAPAROSCOPIC AND  
ROBOTIC SURGEONS IN SUPPORT OF DEFENDANTS  
APPELLANTS/CROSS-APPELLEES**

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## **CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT**

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 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 Psychiatric Association
- American Society of Clinical Oncology

- American Society for Gastrointestinal Endoscopy
- American Society of Nephrology
- GLMA: Health Professionals Advancing LGBTQ+ Equality
- National Hispanic Medical Association
- National Medical Association
- Renal Physicians Association
- Society for Maternal-Fetal Medicine
- Society of Laparoscopic and Robotic Surgeons

*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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s/ Carrie Y. Flaxman

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Dated: October 6, 2023

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## INTEREST OF *AMICI CURIAE*<sup>1</sup>

*Amici* include 20 associations representing hundreds of thousands of practicing physicians providing vital preventive healthcare services to millions of patients.

*Amici* submit this supplemental brief to explain how the district court's grant of summary judgment relating to the recommendations of the Advisory Committee on Immunization Practices ("ACIP") and the Health Resources and Services Administration ("HRSA") should be affirmed in order to maintain the no-cost coverage of vaccines and critical preventive healthcare services for women and children guaranteed by the Affordable Care Act ("ACA").<sup>2</sup>

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<sup>1</sup> 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.

<sup>2</sup> Consistent with the briefing schedule entered by this Court, *see* Briefing Schedule, ECF No. 156, this brief addresses only ACIP- and HRSA-recommended services—and the harms to patients should no-cost access to those services be undermined—the legality of which have been challenged in the cross-appeal.

## INTRODUCTION

For reasons that the government explains, the decision below regarding the ACA requirement that health insurance plans cover, without co-pay, co-insurance or deductible, the vaccines, women’s health care and pediatric health care services that are recommended by ACIP and HRSA should be affirmed. *Amici* write to illustrate the critical importance of those services and the grave harms that would occur should the Court invalidate that requirement, just as many of the same *amici* did in their initial brief relating to the recommendations for adult preventive services made by the U.S. Preventive Services Task Force (“USPSTF”), *see* Amicus Br., ECF No. 222. *Amici* urge this Court not to disrupt access to these no-cost services, such as vaccinations for diseases such as polio, the flu, and shingles; contraception and related care; and well visits for women and children, that their patients have relied on for more than a decade—which have enabled lifesaving and health-improving care for millions of people.

## ARGUMENT

- I. The preventive services requirement guarantees access to no-cost vaccines for most insureds as well as other vital preventive care for women and children that are critical to ensuring their health and well-being.**

As relevant to the cross appeal, the ACA requires most health insurers to provide free of charge services that are recommended by two entities affiliated with the U.S. Department of Health and Human Services.

### **A. ACIP-Recommended Services**

First, plans must cover immunizations that “have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.” 42 U.S.C. § 300gg-13(a)(2).

ACIP is a federal committee comprised of immunization and public health experts that develops recommendations on how to use vaccines to control disease.<sup>3</sup> As a result, upon the CDC’s approval of these recommendations, infants, children and adults receive access (on a recommended schedule), without co-pay, to immunizations, such as for

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<sup>3</sup> ACIP, *Role of the Advisory Committee on Immunization Practices in CDC’s Vaccine Recommendations*, CDC, <https://www.cdc.gov/vaccines/acip/committee/role-vaccine-recommendations.html> (last visited Oct. 5, 2023).

influenza, meningitis, tetanus, HPV, hepatitis A and B, measles, mumps, rubella, varicella and COVID-19.<sup>4</sup> *Amici* can attest that “[f]ew measures in public health can compare with the impact of vaccines. Vaccinations have reduced disease, disability, and death from a variety of infectious diseases.”<sup>5</sup>

Importantly, ACIP regularly updates its recommendations according to the evidence base. By way of example, ACIP has recently recommended not only the latest COVID-19 vaccines for persons older than 6 months of age, but also newly developed immunizations for at risk populations for Respiratory Syncytial Virus, a highly contagious virus that causes potentially life-threatening lung infections. As a result of those recommendations, those immunizations are now available to most insured Americans without copay, coinsurance or deductibles.<sup>6</sup>

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<sup>4</sup> CDC, *For Healthcare Providers*, <https://www.cdc.gov/vaccines/schedules/hcp/index.html> (last visited Oct. 5, 2023); Kaiser Fam. Found., *Preventive Services Covered by Private Health Plans under the Affordable Care Act* (May 15, 2023), <https://www.kff.org/womens-health-policy/fact-sheet/preventive-services-covered-by-private-health-plans/>.

<sup>5</sup> Walter A. Orenstein & Rafi Ahmed, *Simply Put: Vaccination Saves Lives*, 114 Proc. Nat’l Acad. Sci. U.S.A., no. 16, Apr. 2017, at 4031, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5402432/pdf/pnas.201704507.pdf>.

<sup>6</sup> ACIP, *ACIP Recommendations*, CDC, <https://www.cdc.gov/vaccines/acip/recommendations.html> (last visited Oct. 5, 2023).

## **B. HRSA-Recommended Services**

The ACA also requires most insurance plans to cover two sets of recommended services, upon their adoption by HRSA. “[W]ith respect to infants, children, and adolescents,” plans must cover “evidence-informed preventive care and screenings provided for in the comprehensive guidelines,” and “with respect to women,” plans must cover “such additional preventive care and screenings” not covered by the USPSTF recommendations at issue in the appeal. 42 U.S.C. §§ 300gg-13(a)(3-4).

HRSA’s Bright Futures Project is charged with providing the recommendations for pediatric preventive care and screenings. Those recommendations are “age-specific” and “based on the best available scientific evidence” to “[h]elp increase the quality of primary and preventive care” for infants, children and adolescents.<sup>7</sup> *Amicus* American Academy of Pediatrics is the current lead grantee for the project. Those recommended services currently include well-child visits (on a schedule based on age), behavioral and developmental

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<sup>7</sup> HRSA, *Bright Futures* (last reviewed June 2022), <https://mchb.hrsa.gov/programs-impact/bright-futures>.

assessments, obesity screening, oral health assessments, newborn hearing screening; blood pressure screening, and vision screening.<sup>8</sup>

HRSA's Women's Preventive Services Initiative ("WPSI") is a national coalition of health professional organizations and patient advocates with expertise in women's health, led by *amicus* American College of Obstetricians and Gynecologists.<sup>9</sup> WPSI develops evidence-based clinical recommendations for preventive care for adolescents and women aged 13 years and older to "address health needs that are specific to women and fill gaps in other existing preventive care recommendations."<sup>10</sup> The recommended services currently include well women visits (which include prenatal, pre-pregnancy, postpartum, and intrapartum visits); breast and cervical cancer screenings;

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<sup>8</sup> Am. Acad. of Pediatrics, *Preventive Care/Periodicity Schedule* (last updated Mar. 1, 2023), <https://www.aap.org/periodicityschedule>; Bright Futures, *Recommendations for Preventive Pediatric Health Care*, Am. Acad. of Pediatrics (last updated Apr. 2023), [https://downloads.aap.org/AAP/PDF/periodicity\\_schedule.pdf](https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf).

<sup>9</sup> Women's Preventive Servs. Initiative, *About WPSI*, <https://www.womenspreventivehealth.org/about-wpsi/> (last visited Oct. 5, 2023).

<sup>10</sup> Amy Burke & Adelle Simmons, *Increased Coverage of Preventive Services with Zero Cost Sharing under the Affordable Care Act*, Assistant Sec'y for Plan. & Evaluation, at 2 (June 24, 2014), [https://aspe.hhs.gov/sites/default/files/migrated\\_legacy\\_files//44251/ib\\_PreventiveServices.pdf](https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//44251/ib_PreventiveServices.pdf); Kimberly D. Gregory et al., *Screening for Anxiety in Adolescent and Adult Women: A Recommendation from the Women's Preventive Services Initiative*, 117 *Annals Internal Med.* 48 (2020), <https://www.acpjournals.org/action/showCitFormats?doi=10.7326%2FM20-0580>.

contraception and related services<sup>11</sup>; breastfeeding support and supplies, postpartum diabetes screenings; and screening and counseling for concerns including intimate partner violence and urinary incontinence.<sup>12</sup> As with the other bodies charged with making recommendations, WPSI updates the guidance with the evidence base: recently, HRSA adopted a WPSI recommendation on screening for anxiety in adolescents and adult women “to improve detection; achieve earlier diagnosis and treatment; and improve health, function, and well-being.”<sup>13</sup>

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<sup>11</sup> With respect to contraception, plans must cover at least one product within each FDA-approved, granted, or cleared contraceptive method, as well as the related counseling, insertion, removal and follow-up services. See HRSA, *Women’s Preventive Services Guidelines* (last reviewed Dec. 2022), <https://www.hrsa.gov/womens-guidelines>; Dep’t of Health & Hum. Servs., *Health Benefits & Coverage*, [https://www.healthcare.gov/coverage/birth-control-benefits/#:~:text=Plans%20in%20the%20Health%20Insurance,by%20a%20health%20care%20provider.&text=A%20fixed%20amount%20\(%2420,to%20glossary%20for%20more%20details](https://www.healthcare.gov/coverage/birth-control-benefits/#:~:text=Plans%20in%20the%20Health%20Insurance,by%20a%20health%20care%20provider.&text=A%20fixed%20amount%20(%2420,to%20glossary%20for%20more%20details) (last visited Oct. 5, 2023). As *amicus* ACOG has noted, contraception is critical preventive care, the benefits of which include “improved health and well-being, reduced global maternal mortality, health benefits of pregnancy spacing for maternal and child health, female engagement in the work force, and economic self-sufficiency for women.” Am. Coll. of Obstetricians & Gynecologists, *Access to Contraception*, Committee Opinion No. 615, at 2 (Jan. 2015), <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2015/01/access-to-contraception>.

<sup>12</sup> HRSA, *Women’s Preventive Services Guidelines* (last reviewed Dec. 2022), <https://www.hrsa.gov/womens-guidelines>.

<sup>13</sup> Kimberly D. Gregory et al., *Screening for Anxiety in Adolescent and Adult Women: A Recommendation from the Women’s Preventive Services Initiative*, 117 *Annals Internal Med.* 48 (2020).

**II. The ACA’s preventive services requirement has increased access to ACIP- and HRSA-recommended services, and affirming that part of the district court’s decision is vital to preserving and improving public health.**

As set forth in the brief filed by many of the same *amici* in support of the government’s appeal, because of the success of the ACA, as of 2020, approximately *233 million people* are currently enrolled in health plans that must cover preventive services without cost-sharing.<sup>14</sup> That means that, in addition to the preventive services for adults covered by the USPSTF recommendations that are addressed in *amici*’s earlier brief, Amicus Br., 12-13, ECF No. 222, millions of people now have access to no-copay vaccinations. And women and children have access to the specific preventive care recommended for their populations, allowing these individuals to avoid acute illness, identify and obtain treatment for chronic conditions, and improve their health.

These recommendations have been critical to improving public health. For example, one study showed that “after the elimination of cost-sharing requirements began in 2010, the receipt of . . . flu

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<sup>14</sup> Assistant Sec’y for Plan. & Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, Issue Brief No. HP-2022-01, at 1 (Jan. 11, 2022), <https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf>.

vaccination significantly increased from 2009 to 2011/2012, primarily among privately insured populations aged 18-64 years.”<sup>15</sup> Indeed, this is not surprising as a study of Medicaid patients showed that “[e]ach additional dollar of copayment [paid] for vaccination decreased influenza vaccination coverage 1-6 percentage points.”<sup>16</sup> Similarly, a study of claims from 2009 to 2015 showed that the ACA’s guarantees were associated with a significant increase in completion by females and males of the vaccine series for human papillomavirus (“HPV”), critical for protecting against cervical and other cancers.<sup>17</sup>

The HRSA WPSI recommendations have also been essential in improving access to preventive care. Studies have shown increases in contraception use since the contraception coverage requirement took

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<sup>15</sup> 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).

<sup>16</sup> Charles Stoecker et al., *The Cost of Cost-Sharing: The Impact of Medicaid Benefit Design on Influenza Vaccination Uptake*, 5 *Vaccines*, no. 1, 2007, at 1.

<sup>17</sup> Summer Sherburne Hawkins et al., *Associations Between Insurance-Related Affordable Care Act Policy Changes with HPV Vaccine Completion*, 21 *BMC Pub. Health*, no. 1, Feb. 2021, at 4-5, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7866643/pdf/12889\\_2021\\_Article\\_10328.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7866643/pdf/12889_2021_Article_10328.pdf); see also Brandy J. Lipton & Sandra L. Decker, *ACA Provisions Associated with Increase in Percentage of Young Adult Women Initiating and Completing the HPV Vaccine*, 43 *Health Affs.*, no. 5, 2015, at 1 (“we estimated that the 2010 policy implementation increased the likelihood of HPV vaccine initiation and completion by 7.7 and 5.8 percentage points, respectively, for women ages 19-25 relative to a control group of women age 18 or 26”).

effect, both of short-term birth control methods, such as birth control pills, patches and diaphragms, and in particular, of highly effective long-acting contraceptives (“LARCs”) like intrauterine devices (“IUDs”).<sup>18</sup> On average, women saved \$255 on oral contraception and \$248 on IUDs annually between 2010 and 2013.<sup>19</sup>

Affirming the decision below with respect to the HRSA- and ACIP-recommended services is necessary to avoid risking no-cost coverage of those services. As explained in *amici*’s previous brief, that decision ensures that insurers nationwide cannot reimpose cost-sharing requirements on *amici*’s patients, which would result in confusion and could prevent patients, particularly those of more limited means, from obtaining critically necessary vaccines and other preventive care for themselves and their families, Amicus Br. 21-26, ECF No. 222.

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<sup>18</sup> Assistant Sec’y for Plan. & Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, *supra* note 14, at 9-10; Nora V. Becker et al., *ACA Mandate Led to Substantial Increase in Contraceptive Use Among Women Enrolled in High-Deductible Health Plans*, 40 *Health Affs.*, no. 4, Apr. 2021; Caroline S. Carlin et al., *Affordable Care Act’s Mandate Eliminating Contraceptive Cost Sharing Influenced Choices of Women with Employer Coverage*, 35 *Health Affs.*, no. 9, Sept. 2016.

<sup>19</sup> Nora V. Becker & Daniel Polsky, *Women Saw Large Decrease in Out-of-Pocket Spending for Contraceptives After ACA Mandate Removed Cost Sharing*, 34 *Health Affs.*, no. 7, July 2015. This study estimated that the contraceptive coverage requirement led to savings to patients using contraceptive pills of approximately \$1.4 billion between 2012 and 2013.

Deterring patients from receiving these vital services will result in worse health outcomes and impose higher costs on the health system.

### CONCLUSION

The Court should reverse the judgment of the lower court with respect to the USPSTF services, reverse the nationwide injunction, and affirm paragraphs 2 and 4 of the district court judgment with respect to the ACIP and HRSA services.

Respectfully submitted,

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Dated: October 6, 2023

## **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 Fed. R. App. P. 32(a)(7)(B) because, excluding the parts exempted by Fed. R. App. P. 32(f), it contains 2,826 words.

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 a proportionally spaced typeface using Microsoft Word 365 in 14-point Century Schoolbook font, with 12-point font for footnotes.

s/ Carrie Y. Flaxman

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Dated: October 6, 2023

**CERTIFICATE OF SERVICE**

I, Carrie Y. Flaxman, counsel for *amici*, certify that on October 6, 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/ Carrie Y. Flaxman

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Dated: October 6, 2023