No. 23-10326

In the United States Court of Appeals for the Fifth Circuit

BRAIDWOOD MANAGEMENT, INCORPORATED; JOHN SCOTT KELLEY; KELLEY ORTHODONTICS; ASHLEY MAXWELL; ZACH MAXWELL; JOEL STARNES,
Plaintiff-Appellees/Cross-Appellants,

JOEL MILLER; GREGORY SCHEIDEMAN,
Plaintiff/Cross-Appellants,

v.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, in his official capacity as Secretary of Health and Human Services; UNITED STATES OF AMERICA; JANET YELLEN, SECRETARY, U.S. DEPARTMENT OF TREASURY, in her official capacity as Secretary of the Treasury; JULIE A. SU, ACTING SECRETARY, U.S. DEPARTMENT OF LABOR, in her official capacity as Secretary of Labor,
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 THE NATIONAL HEALTH LAW PROGRAM, ASIAN & PACIFIC ISLANDER AMERICAN HEALTH FORUM (APIAHF), CENTER FOR MEDICARE ADVOCACY, JUSTICE IN AGING, NATIONAL ASSOCIATION OF PEDIATRIC NURSE PRACTITIONERS, NATIONAL BLACK JUSTICE COALITION, TRANSHEALTH, ALABAMA DISABILITIES ADVOCACY PROGRAM, ARIZONA CENTER FOR LAW IN THE PUBLIC INTEREST, CENTER FOR CIVIL JUSTICE, COMMUNITY LEGAL AID SOCIETY, INC., FLORIDA HEALTH JUSTICE PROJECT, INDIANA JUSTICE PROJECT, KENTUCKY EQUAL JUSTICE CENTER, NEBRASKA APPLESEED CENTER FOR LAW IN THE PUBLIC INTEREST, NORTHWEST HEALTH LAW ADVOCATES, PUBLIC JUSTICE CENTER, AND TENNESSEE JUSTICE CENTER IN SUPPORT OF DEFENDANTS-APPELLANTS/CROSS-APPELLEES AND URGING REVERSAL

Martha Jane Perkins*
Wayne Turner
Sarah Grusin
NATIONAL HEALTH LAW PROGRAM
1512 E. Franklin St., Suite 110
Chapel Hill, North Carolina 27514
Tel: (919) 968-6308 (x101)
perkins@healthlaw.org
* *Counsel of Record for Amici Curiae*

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' 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.

1. National Health Law Program, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

2. Asian & Pacific Islander American Health Forum (APIAHF), *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

3. Center for Medicare Advocacy, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

4. Justice in Aging, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

5. National Association of Pediatric Nurse Practitioners, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

6. National Black Justice Coalition, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

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8. Alabama Disabilities Advocacy Program, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

9. Arizona Center for Law in the Public Interest, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

10. Center for Civil Justice, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

11. Community Legal Aid Society, Inc., *Amcius Curiae.* This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

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13. Indiana Justice Project, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

14. Kentucky Equal Justice Center, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

15. Nebraska Appleseed Center for Law in the Public Interest, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

16. Northwest Health Law Advocates, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

17. Public Justice Center, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

18. Tennessee Justice Center, *Amcius Curiae*. This organization is not a subsidiary of any other corporation and no publicly held corporation owns ten percent or more of the organization's stock.

19. Martha Jane Perkins is Counsel of Record for *Amici Curiae.*

Date: June 27, 2023

/s/ Martha Jane Perkins
Martha Jane Perkins

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INTEREST OF AMICI[1]

The *amici curiae* file this brief pursuant to Federal Rule of Appellate Procedure 29. All parties have consented to its filing. *Amici* are the National Health Law Program, Asian & Pacific Islander American Health Forum (APIAHF), Center for Medicare Advocacy, Justice in Aging, National Association of Pediatric Nurse Practitioners, National Black Justice Coalition, Transhealth, Alabama Disabilities Advocacy Program, Arizona Center for Law in the Public Interest, Center for Civil Justice, Community Legal Aid Society, Inc., Florida Health Justice Project, Indiana Justice Project, Kentucky Equal Justice Center, Nebraska Appleseed Center for Law in the Public Interest, Northwest Health Law Advocates, Public Justice Center, and Tennessee Justice Center.

While each *amici* has particular interests, they collectively bring to the Court extensive experience working to obtain health insurance coverage or providing health care for low-income people, people with disabilities, and children. As such, the *amici* work extensively with the Medicaid Act and federal and state Medicaid programs. *Amici* also research and provide education on a range of policy and legal issues affecting low-income people, particularly when they involve Medicaid and

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[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), counsel for *amici curiae* states that no counsel for a party authored this brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

other health insurance coverage, and understand the vital importance of access to preventive services for Medicaid enrollees. As such, *amici* have an interest in the outcome of this case.

SUMMARY OF ARGUMENT

If successful, the Braidwood challenge could have repercussions far beyond the preventive services requirements for health plans sold in the private market. The Medicaid Act ties coverage of preventive services to the recommendations of the U.S. Preventive Services Task Force (PSTF) and the immunization recommendations of the Advisory Committee on Immunization Practices (ACIP). Millions of low-income people and people with disabilities depend on Medicaid coverage for these preventive care services, and this coverage has been shown to improve early detection of problems and improve health status.

ARGUMENT

I. MEDICAID COVERAGE PROVIDES A HEALTH CARE LIFELINE FOR MILLIONS OF LOW-INCOME CHILDREN AND ADULTS.

Medicaid is a federal-state partnership to furnish medical assistance to people whose income and resources are insufficient to meet the costs of necessary care. 42 U.S.C. § 1396-1. In exchange for generous federal funding—payment of half or more of the state's total expenditures—a participating state must operate its Medicaid program consistent with minimum federal requirements. Thereafter, states have flexibility in how they operate their programs. For example, the Medicaid Act

establishes the scope of benefits that states must offer to covered populations and includes cost sharing limits to ensure affordability. States can decide whether or not to extend the benefits package to additional services or to impose cost sharing. *See id.* §§ 1396-1396w-7. All states participate in Medicaid.

Medicaid is a lifeline for children and adults who qualify. More than 35 million children living in poverty receive their health coverage through Medicaid. *See* Ctr. for Medicaid & CHIP Servs., *February 2023 Medicaid and CHIP Enrollment Trends Snapshot*, Fig. 2, (Feb. 1, 2023) https://www.medicaid.gov/medicaid/national-medicaid-chip-program-information/downloads/february-2023-medicaid-chip-enrollment-trend-snapshot.pdf. Forty percent of all births in the United States are covered through Medicaid. Medicaid Access & Payment Comm'n, *Medicaid's Role in Maternal Health*, in Report to Congress on Medicaid and CHIP 99, 100 (2020), https://www.macpac.gov/publication/chapter-5-medicaids-role-in-maternal-health/. Children and youth in, and aging out of, foster care also qualify for Medicaid, including an increasing number removed from their homes due to abuse and neglect resulting from the opioid crisis. *See* Medicaid Access & Payment Comm'n, *The Intersection of Medicaid and Child Welfare*, in Report to Congress on Medicaid and CHIP 55, 57 (2015), https://www.macpac.gov/publication/the-intersection-of-medicaid-and-child-welfare/. In addition, 40 states have taken the option—

championed by President Reagan—to provide coverage to children with severe disabilities in their homes, thus helping them avoid living in institutions. *See* 42 U.S.C. § 1396a(e)(3); Kaiser Fam. Found., *State Adoption of Major Optional Pathways to Full Medicaid Eligibility Based on Old Age or Disability* (2022), https://www.kff.org/other/state-indicator/state-adoption-of-major-optional-pathways-to-full-medicaid-eligibility-based-on-old-age-or-disability/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

Medicaid is also a key provider of health coverage for adults. An estimated ten million people qualify for Medicaid on the basis of disability. Medicaid Access & Payment Comm'n, *People with Disabilities* https://www.macpac.gov/subtopic/people-with-disabilities/. Medicaid covers nearly 40 percent of nonelderly adults with HIV. *See* Lindsey Dawson et al., *Medicaid and People with HIV*, Kaiser Fam. Found. (Mar. 27, 2023), https://www.kff.org/hivaids/issue-brief/medicaid-and-people-with-hiv/. In 2010, Congress expanded Medicaid to include adults who are under 65 years of age, not pregnant, not entitled to Medicare or otherwise eligible for Medicaid, and whose incomes do not exceed 133 percent of the federal poverty level. 42 U.S.C. § 1396a(a)(10)(A)(i)(VIII).[2] Referred to as "Medicaid expansion,"

[2] *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) held that states could not be required to include this population group in their

40 states and the District of Columbia have taken up Medicaid expansion, and over 20 million adults, nationwide, have insurance coverage as a result. *See* Assistant Sec'y for Plan. & Evaluation Off. of Health Pol'y, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, 6 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf [hereinafter "ASPE, Access to Preventive Services"].

Medicaid plays a key role in addressing health disparities, providing coverage to approximately three in ten Black, American Indian and Alaska Native and Native Hawaiian, and Other Pacific Islander nonelderly adults, as well as more than two in ten Hispanic nonelderly adults. *See* Madeline Guth et al., *Medicaid and Racial Health Equity*, Kaiser Fam. Found. (Mar. 17, 2022), https://www.kff.org/medicaid/issue-brief/medicaid-and-racial-health-equity/.

Medicaid's scope of benefits is designed to ensure that enrollees have coverage for critical health services. As noted, states must cover certain services and have the option to cover others. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a). Mandatory services include physician services; outpatient hospital services; tobacco cessation services for pregnant women; early and periodic well-child visits and

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Medicaid program. States electing to do so receive 90 percent federal funding for the coverage. *See* 42 U.S.C. § 1396d(y)(1).

ACIP-recommended vaccines for children and youth under age 21; and, as of 2023, ACIP-recommended immunizations for adults. *Id.* § 1396d(a). Optional services include prescription drugs (which all states cover). *Id.*

The Medicaid Act limits cost sharing to ensure that those who qualify can afford the coverage. For example, states choosing to impose copayments must ensure that they are nominal in amount, and ACIP-recommended immunizations must be covered with no costing. *Id*. §§ 1396o, 1396o-1.

Medicaid coverage of preventive services could be jeopardized if the Court affirms the lower court or upholds Braidwood's challenge to the PSTF's authority to recommend preventive services and ACIP's authority to recommend vaccines.

II. THIS CASE COULD HAVE NEGATIVE REPERCUSSIONS FOR MEDICAID COVERAGE OF THE PREVENTIVE SERVICES THAT LOW-INCOME ADULTS NEED.

A. Medicaid coverage of preventive services for adults is at risk.

Two separate Medicaid provisions address coverage of preventive services for adults. One concerns Medicaid expansion adults; the other, adults who qualify for Medicaid through other eligibility pathways because they are disabled or caring for a child. As discussed below, this coverage is tied to the recommendations of the PSTF and ACIP.

The Medicaid Act requires most Medicaid expansion adults to obtain services through an Alternative Benefits Plan (ABP). *See* 42 U.S.C. §§ 1396a(k)(1), 1396u-

7(b). ABPs must cover a minimum set of essential health benefits (EHBs), including preventive services. *Id.* §§ 1396u-7(b)(5), 18022(b)(1)(I). According to the Affordable Care Act (ACA), "the Secretary [of Health and Human Services] shall define the essential health benefits." *Id.* § 18022(b)(1). The Secretary has chosen to define EHBs by adopting PSTF, ACIP, and HRSA preventive services recommendations. *See* 42 C.F.R. § 440.347, 45 C.F.R. §§ 147.130, 156.115.[3]

Although coverage of preventive services is mandatory for the Medicaid expansion population, there is no such requirement for adults enrolled through other eligibility pathways—those with disabilities or caring for a child. States have the option to cover preventive services for these adults. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13).

Most states have opted to provide some preventive services. The coverage can be limited; for example, some states have excluded screening mammograms and Pap testing. ASPE, *Access to Preventive Services* at 6. Utilization of preventive services has also been a problem, particularly for people with disabilities. *See*, *e.g.*, Anna Marrocco & Helen Krouse, *Obstacles to Preventive Care for Individuals with*

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[3] Judge O'Connor held that "[t]he U.S. Preventive Services Task Force's (PSTF) recommendations operating *in conjunction with* 42 U.S.C. § 300gg-13(a)(1) violate Article II's Appointments Clause and are therefore unlawful." Final Judgment, *Braidwood Mgmt. v. Becerra*, No. 4:20-cv-00283-O, 2023 WL 2703229 (N.D. Tex. Mar. 30, 2023) (emphasis added). Coverage of preventive services in Medicaid ABPs relies only on the Secretary's designation pursuant to 42 U.S.C. § 18022(b)(1).

Disability: Implications for Nurse Practitioners, 29 J Am. Ass'n Nurse Practs. 282 (2017) (noting barriers associated with cost, transportation, and provider attitudes); Julie Williams Merten et al., *Barriers to Cancer Screening for People with Disabilities: A Literature Review,* 8 Disability Health J. 9 (2015).

Recognizing the importance of preventive services, the ACA amended the Medicaid Act to provide states an incentive: states offering coverage of preventive services, with no cost sharing, to adults in all Medicaid eligibility categories are entitled to receive enhanced federal Medicaid funding. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4106, 124 Stat. 119, 559 (2010) (codified as amended at 42 U.S.C. § 1396d(b)(5)). At least 16 states have opted to provide this coverage. *See* Lindsey Dawson et al., *Medicaid and HIV*, Kaiser Fam. Found. (Mar. 27, 2023), https://www.kff.org/hivaids/issue-brief/medicaid-and-people-with-hiv/ (listing California, Colorado, Delaware, Hawaii, Kentucky, Louisiana, Massachusetts, Montana, New Hampshire, New Jersey, Nevada, New York, Ohio, Oregon, Washington State, and Wisconsin). When adding this provision, Congress defined preventive services to include:

> (A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force;
>
> (B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration.

42 U.S.C. § 1396d(a)(13). *Compare id.* § 300gg-13(a)(1) (requiring coverage of preventive services that have "a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force").

Finally, in 2022, Congress amended the Medicaid Act to require all state Medicaid programs to provide immunizations recommended by ACIP, without cost sharing, for adults in all Medicaid eligibility categories beginning in 2023. *See* Inflation Reduction Act of 2022, Pub. L. No. 117–169, § 11405, 136 Stat. 1818, 1900 (2022) (codified as amended at 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(10)(C)(iv), 1396o-1(b)(3)(B)). The statute includes an increase in federal funding to states to help pay for the new coverage requirement. 42 U.S.C. § 1396d(b). Before this amendment was enacted, at least 19 states had coverage gaps or cost sharing for key adult immunizations. *See Adult Vaccine Coverage in Medicaid: Assessing Existing Gaps and Looking Ahead to Implementation of the Inflation Reduction Act*, Avalere (Dec. 5, 2022), https://avalere.com/insights/ira-policy-will-fill-gaps-in-medicaid-vaccine-coverage-for-adults.

Medicaid Act coverage of adults' preventive services and vaccines is tied to PSTF and ACIP recommendations. Thus, the Court's decision could affect this coverage in the future, leading states to reduce coverage or charge cost sharing for preventive services that, as discussed below, are unquestionably benefiting low-income adults.

B. Adult enrollees benefit from receiving preventive care.

Access to preventive services without cost sharing is a game changer for low-income adults. This is confirmed by numerous studies that compare the experiences of adults in Medicaid expansion states with adults in states that have not expanded. Medicaid expansion adults have experienced increased utilization of a variety of preventive services, and in turn, benefitted from increased early diagnoses and treatment of diseases and health conditions. *See, e.g.*, Madeline Guth & Meghana Ammula, *Building on the Evidence Base: Studies on the Effects of Medicaid Expansion, February 2020 to March 2021*, Kaiser Fam. Found. (2021), https://files.kff.org/attachment/Report-Building-on-the-Evidence-Base-Studies-on-the-Effects-of-Medicaid-Expansion.pdf (compiling studies); Madeline Guth et al., *The Effects of Medicaid Expansion Under the ACA: Studies from January 2014 to January 2020*, Kaiser Fam. Found., 8-9 (2020), https://files.kff.org/attachment/Report-The-Effects-of-Medicaid-Expansion-under-the-ACA-Updated-Findings-from-a-Literature-Review.pdf (same).

In one study, the improvement in screening rates for colorectal cancer translated to an additional 236,573 Medicaid expansion adults receiving a screening in 2016. *See* Stacey A. Fedewa et al., *Changes in Breast and Colorectal Cancer Screening After Medicaid Expansion Under the Affordable Care Act*, 57 Am. J. Preventive Med. 1, 3 (2019). Compared with adults living in states that have not

taken up Medicaid expansion, adults living in Medicaid expansion states saw greater improvements in breast cancer screening, detection, and treatment rates among lower-income women. *See, e.g.,* Yoshiko Toyoda et al., *Affordable Care Act State-Specific Medicaid Expansion: Impact on Health Insurance Coverage and Breast Cancer Screening Rates*, 230 J. Am. Coll. Surgeons 5 (2020), *available at* https://www.journalacs.org/article/S1072-7515(20)30213-1/fulltext; *see also, e.g.*, Nicolas Ajkay et al., *Early Impact of Medicaid Expansion and Quality of Breast Cancer Care in Kentucky*, 226 J. Am. Coll. Surgeons 498 (2018), *available at* https://doi.org/10.1016/j.jamcollsurg.2017.12.041; Xu Ji et al., *Association of Medicaid Expansion with Cancer Stage and Disparities in Newly Diagnosed Young Adults*, 113 J. Nat'l Cancer Inst. 1723, 1728 (2021), *available at* https://academic.oup.com/jnci/advance-article-abstract/doi/10.1093/jnci/djab105/6280550?redirectedFrom=fulltext (finding Medicaid coverage of preventive services resulted in a narrowing of rural-urban and Black-white disparities among young adults diagnosed with cancer).

Compared to states that have expanded Medicaid, non-expansion states see greater underutilization of pre-exposure prophylaxis (PrEP) that prevents HIV transmission. *See, e.g.,* Dimitris Karletsos et al., *Impact of Medicaid Expansion on PrEP Utilization in the U.S.: 2012–2018*, 25 AIDS & Behav. 1103, 1106 (2021). HIV transmission rates are of particular concern in low-income communities of

color, which are overrepresented among new yearly HIV diagnoses. *See* Chris Breyer et al., *Call to Action: How Can the US Ending the HIV Epidemic Initiative Succeed?*, 397 Lancet 1151, 1153 (2021); *see also* André Dailey et al., *Diagnoses of HIV Infection in the United States and Dependent Areas, 2020,* 33 HIV Surveillance Rep. 1, 21–22 (2022) (noting disproportionate HIV infection rates among Black women in the southern United States). Texas, a non-expansion state, accounted for most of the nation's new HIV diagnoses in 2021. *See* Ctrs. for Disease Control & Prevention, *Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas, 2021* (May 23, 2023), https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-34/index.html.

III. THIS CASE COULD HAVE NEGATIVE REPERCUSSIONS FOR MEDICAID COVERAGE OF THE PREVENTIVE SERVICES THAT LOW-INCOME CHILDREN NEED.

A. Medicaid coverage of preventive vaccines for children is at risk.

The Medicaid Act requires participating states to provide coverage of Early and Periodic Screening, Diagnostic and Treatment (EPSDT) services, including immunizations, for Medicaid-eligible children and youth under age 21. *See* 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r). The statute requires states to arrange for these services, not just pay for them, thus recognizing that prevention and early detection and treatment can avoid more serious medical

conditions later in life. *See generally* Ctrs. for Medicare & Medicaid Servs., EPSDT - *A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents,* 4 (2014), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/epsdt_coverage_guide_127.pdf ("The goal of EPSDT is to assure that individual children get the health care they need when they need it—the right care to the right child at the right time in the right setting."). EPSDT screens must be provided according to periodicity schedules set by the state Medicaid agency in consultation with child health experts, and at other times as needed to determine whether a child has a condition that needs care. 42 U.S.C. § 1396d(r)(1)-(4). To help ensure access to EPSDT, states are prohibited from charging cost sharing for services provided to persons under age 18. *See* 42 U.S.C. § 1396o(a)(2) (also providing states the option to exempt from cost sharing individuals under 21, 20, or 19 years of age).

Congress expanded childhood immunization coverage in 1993 by establishing the Vaccines for Children (VFC) program and including not only Medicaid-eligible children but any child who is uninsured, as well as children of Native American descent. *See* Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13631, 107 Stat. 312, 636–45 (1993) (codified as amended at 42 U.S.C. §§ 1396a(a)(62), 1396s). VFC coverage is determined by the ACIP-recommendations, as established and periodically revised, for the periodicity, dosage

and contraindications for vaccines and in delivery and administration of the vaccines. *See* 42 U.S.C. §§ 1396a(a)(62), 1396d(r)(1)(A)(i), (B)(iii), 1396s(e).

HHS's authority to purchase and negotiate discounted prices from manufacturers for current and new vaccines is also tied to ACIP-recommended immunizations. *See id.* §§ 1396s(d), (h)(6).[4] The bulk purchase of children's vaccines yields an average discount of about 30 percent off the list price. *See* Karyn Schwartz et al., *Vaccine Coverage, Pricing, and Reimbursement in the U.S.*, Kaiser Fam. Found. Table 3, (Nov. 18, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/vaccine-coverage-pricing-and-reimbursement-in-the-u-s/.

B. Children benefit from receiving vaccine coverage.

Medicaid coverage of childhood vaccines has dramatically reduced morbidity, mortality, and disability for the targeted diseases. *See, e.g.,* Sandra E. Talbird et al., *Impact of Routine Childhood Immunization in Reducing Vaccine-Preventable Diseases in the United States*, 150 Pediatrics 1 (2022), *available at* https://publications.aap.org/pediatrics/article/150/3/e2021056013/188495/Impact-of-Routine-Childhood-Immunization-in. Researchers at the U.S. Centers for Disease

[4] Vaccines are excluded from the Medicaid Drug Rebate Program, in which state Medicaid programs receive generous rebates on covered outpatient prescription drugs. *See* 42 U.S.C. § 1396r-8(k)(2)(B). Without federal authority to negotiate and purchase discounted vaccines, states would need to purchase pediatric vaccines at prices set by manufacturers.

Control and Prevention found that in its first ten years, the Medicaid VFC program prevented an estimated 322 million illnesses, 21 million hospitalizations, and 732,000 deaths. *See* Cynthia G. Whitney et al., *Benefits from Immunization During the Vaccines for Children Program Era — United States, 1994–2013*, 63 Morbidity & Mortality Wkly. Rep. 341, 352 (Apr. 25, 2014), https://www.cdc.gov/mmwr/pdf/wk/mm6316.pdf#page=12. Eighty-six percent of the nation's pediatricians participate in the VFC program. *See* Sean T. O'Leary et al., *Pediatricians' Experiences With and Perceptions of the Vaccines for Children Program*, 145 Pediatrics 1 (March 1, 2020), *available at* https://www.publications.aap.org/pediatrics/article/145/3/e20191207/36852/Pediatricians-Experiences-With-and-Perceptions-of. The VFC program has been widely recognized as a success. *See, e.g.*, Sara Rosenbaum, *A Twenty-First Century Vaccines For Children Program*, Health Affs. (Jul. 12, 2022), https://www.healthaffairs.org/content/forefront/twenty-first-century-vaccines-children-program ("Today, VFC is regarded as one of this nation's most effective public health policy achievements.").

However, the lockdowns associated with COVID-19 led to a significant decrease in the number of children receiving childhood immunizations. *See* Jeanne M. Santoli et al., *Effects of the COVID-19 Pandemic on Routine Pediatric Vaccine Ordering and Administration — United States, 2020*, 69 Morbidity & Mortality

Wkly. Rep. 591, 592 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6919e2.htm?s_cid=mm6919e2_w. Recent outbreaks in Texas and Ohio of preventable childhood diseases, attributed to lower vaccination rates, offer a glimpse of what can be expected if families have reduced access to childhood vaccines through the VFC program. *See, e.g.*, Tasmiah Nuzhath et al., *Childhood Immunization During the COVID-19 Pandemic in Texas*, 39 Vaccine 3333 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8078904/; Ciara McCarthy, *Risk of Measles Outbreak in Tarrant County Increases as Vaccinations Fall in Kids*, Forth Worth Star-Telegram (Jan. 25, 2023), https://www.star-telegram.com/news/local/crossroads-lab/article271609062.html.

If Braidwood's claim to nullify ACIP-recommended vaccines succeeds, it could lead to coverage disruptions for children in low-income families who have health coverage through Medicaid and no other means of obtaining potentially life-saving immunizations.

CONCLUSION

WHEREFORE, *Amici* ask that the Court reverse the opinion of the district court with respect to the PSTF and PrEP access and reject Braidwood's appeal seeking to invalidate the recommendations of PSTF, ACIP, and HRSA.

Dated: June 27, 2023

Respectfully submitted,

/s/ Martha Jane Perkins
Martha Jane Perkins*
Wayne Turner
Sarah Grusin
National Health Law Program
1512 East Franklin St., Ste. 110
Chapel Hill, NC 27514
(919) 968-6308
perkins@healthlaw.org
** Counsel of Record for Amici Curiae*

CERTIFICATE OF SERVICE

I certify that on this day, June 27, 2023, I electronically filed the forgoing brief with the Clerk of the Court by using the CM/ECF system.

Date: June 27, 2023

/s/ Martha Jane Perkins
Martha Jane Perkins

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I certify that the foregoing brief complies with the requirements of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5), and that the total number of words in this brief is 3,240 according to the count of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

Date: June 27, 2023

/s/ Martha Jane Perkins
Martha Jane Perkins

CERTIFICATE OF DIGITAL SUBMISSION

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 (SentinelOne 22-34-612) and is free of viruses.

Date: June 27, 2023

/s/ Martha Jane Perkins
Martha Jane Perkins