No. 23-10326

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT, INC., ET AL.,
Plaintiffs-Appellees/
Cross-Appellants,

JOEL MILLER; GREGORY SCHEIDEMAN,
Plaintiffs-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)
The Honorable Reed Charles O'Connor

BRIEF OF AMICI CURIAE ILLINOIS, ARIZONA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, MAINE, MARYLAND, MASSACHUSSETS, MICHIGAN, MINNESOTA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, PENNSYLVANIA, RHODE ISLAND, VERMONT, WASHINGTON, AND WISCONSIN IN SUPPORT OF DEFENDANTS-APPELLANTS AND PARTIAL REVERSAL

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CERTIFICATE OF INTERESTED PERSONS

A certificate of interested persons is not required, as amici curiae are all governmental entities. 5th Cir. R. 28.2.1.

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IDENTITY AND INTERESTS OF AMICI STATES

The States of Illinois, Arizona, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, Washington, and Wisconsin (collectively, the "amici States") submit this brief in support of Defendants-Appellants/Cross-Appellees Xavier Becerra, in his official capacity as Secretary of the Department of Health and Human Services; Janet Yellen, in her official capacity as Secretary of the Treasury; Julie Su, in her official capacity as Acting Secretary of Labor; and the United States of America pursuant to Federal Rule of Appellate Procedure 29(a)(2).[1]

The amici States have a substantial interest in safeguarding the public health and welfare of their citizens. This interest is substantially advanced by implementation and enforcement of the preventive services provision of the Patient Protection and Affordable Care Act ("ACA"), 42 U.S.C. §§ 300gg-13(a)(1)-(4), which has saved countless lives and

[1] No party's counsel authored this brief in whole or in part, and no fee has been or will be paid for its preparation.

mitigated the onset of debilitating illnesses by reducing financial barriers to preventive care. Plaintiffs' sweeping challenge to this provision—as well as the district court's order granting broad relief on two of their claims—interferes with this interest in several respects. First, enjoining the federal government from implementing and enforcing the preventive services provision, in whole or in part, will endanger the lives of countless state residents by obstructing their access to critical care. Second, any such order will deprive the States of a critical supplement to state protections for public health and burden their public health systems. The amici States thus urge this court to reverse the district court's judgment in favor of plaintiffs, but affirm the remainder of the judgment.

SUMMARY OF ARGUMENT

The ACA's preventive services provision requires most private insurance plans to cover certain preventive services and treatments without imposing cost sharing on patients. 42 U.S.C. §§ 300gg-13(a)(1)-(4). Specifically, private insurers must cover services recommended by the United States Preventive Services Task Force ("Task Force"), immunizations designated by the Advisory Committee on Immunization Practices ("ACIP"), and preventive care specified by the Health Resources and Services Administration ("HRSA") in its guidelines. *Id.* The covered care, which ranges from cancer screenings to cardiovascular disease behavior counseling, prevents and mitigates a broad variety of medical conditions from which large numbers of adult Americans suffer.[2] The covered care also includes preventive health care for children, such as well-child visits, screening for depression and anxiety, and routine immunizations.[3]

Plaintiffs challenge the preventive services provision on a range of constitutional and statutory grounds and seek broad relief, including a

[2] Laura Skopec & Jessica Banthin, *Free Preventive Services Improve Access to Care*, Urban Inst., 2 (July 2022), https://tinyurl.com/5ejun8ez;

permanent injunction restraining the federal government from "enforcing any coverage mandate based on an agency rating, recommendation, or guideline that issued after March 23, 2010," which is the date the ACA became law. ROA.244. In addition to their sweeping claims, plaintiffs raise specific concerns with the HRSA's guidelines requiring coverage of contraceptive methods approved by the Food and Drug Administration ("FDA"), and the Task Force's recommendation for preexposure prohylaxis ("PrEP") drugs, which are used to prevent human immunodeficiency virus ("HIV"). ROA.222-25.

The district court entered summary judgment for plaintiffs on their claims that the Task Force's composition violates the Appointments Clause and that the PrEP mandate violates their rights under the Religious Freedom Restoration Act. ROA.1820-21, 2129-30. The court entered summary judgment for the federal government on the remaining claims, including those challenging the HRSA's guidelines on contraceptive methods. ROA.1820-21, 2117-18, 2120-21, 2130. The

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A & B Recommendations, U.S. Preventive Servs. Task Force, https://tinyurl.com/y4ny8n93. All links were last visited on June 27, 2023.

[3] Skopec, *supra* note 2, at 1; *A & B Recommendations*, *supra* note 2.

court's remedial order granted relief specific to plaintiffs, as well as far-reaching, nationwide relief—vacating all agency actions taken to implement or enforce required coverage based on the Task Force's recommendations issued on or after March 23, 2010, and enjoining the federal government from implementing and enforcing coverage requirements based on such recommendations in the future. ROA.2121, 2129-32.[4]

The amici States agree with the federal government that plaintiffs have not shown that they satisfy the standard for a permanent injunction on any of their claims. The amici States write separately to underscore that the equities and public interest counsel strongly against an injunction of any scope in at least two ways. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (consideration of public interest and equities merges when government is defendant).

To start, an injunction would directly harm state residents. For more than a decade, millions of state residents—particularly the most vulnerable populations—have relied on no-cost coverage to access

[4] In light of the parties' stipulation, this court has stayed pending appeal the portion of the district court's judgment entering nationwide relief. 6/13/23 Order, ECF No. 153-2.

critical preventive care that they would otherwise forego because of its substantial costs. This care has significantly improved health outcomes, as health care providers have been able to detect, treat, and even prevent severe illnesses. But if the financial barriers to preventive care were resurrected, many individuals would lose access to these crucial services.

The amici States, too, have depended on the federal preventive care mandate, which applies to insurance plans within their borders—including many plans that the States cannot regulate under federal law. And even when the amici States can mandate coverage for preventive care, they benefit greatly from the preventive services provision, which produces robust, science-backed federal recommendations that the States utilize. Without the federal mandate, the States will be limited in their ability to ensure comprehensive preventive care coverage for their residents, which will deprive their residents of important access to care and also threaten to strain public health systems more broadly.

Enjoining the federal government from implementing and enforcing the preventive services provision will thus carry harmful, and

even fatal, consequences nationwide. These drastic repercussions will be significant regardless of whether this court adopts the broad remedy entered by the district court or provides more narrow relief. The amici States thus urge this court to reverse the district court's judgment in favor of plaintiffs but affirm the remainder of the judgment.

ARGUMENT

I. The Preventive Services Provision Has Significantly Improved Public Health Outcomes For The Amici States' Residents.

When the ACA was enacted, the medical community widely agreed that several leading causes of death in America were largely avoidable.[5] Our nation's healthcare system included robust preventive care, such as screenings and vaccinations, through which medical professionals could identify, treat, and even prevent the illnesses causing these deaths.[6] But many Americans did not avail themselves of these critical services because the costs were significant and often

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[5] Jared B. Fox & Frederic E. Shaw, *Clinical Preventive Services Coverage and the Affordable Care Act*, 105(1) Am. J. Pub. Health 7, 7-8 (2015) (based on 2010 data, concluding 9 out of 10 leading causes of death preventable); Mark Mather & Paola Scommegna, *Up to Half of U.S. Premature Deaths are Preventable; Behavioral Factors Key*, Population Reference Bureau (Sept. 14, 2015), https://tinyurl.com/mpmhtbmv (48% of deaths before age 80 preventable in 2010); *Background: The Affordable Care Act's New Rules on Preventive Care*, Ctrs. for Medicare & Medicaid Servs. (July 14, 2010) (many deaths due to chronic illnesses, which cause 70% of deaths in America, preventable), https://tinyurl.com/mwhawnjr.

[6] Fox, *supra* note 5, at 7; *Background: The Affordable Care Act*, *supra* note 5.

prohibitive.[7] This was true even for people with insurance, because insurers did not cover preventive services at all or imposed significant out-of-pocket costs, like deductibles, copayments, and coinsurance, for those services.[8] And while these considerable expenses deterred individuals of all backgrounds from accessing preventive care, they were felt particularly strongly by the most marginalized and vulnerable communities, such as people of color, individuals living in poverty, and single parents.[9] By one estimate, more than 100,000 individuals lost their lives annually to conditions that could have been remediated by preventive care.[10]

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[7] Hope C. Norris, et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79(2) Medical Care Rsch. and Rev. 175, 175 (2022); Skopec, *supra* note 2, at 2.

[8] Sabrina Corlette, *A World Without the ACA's Preventive Services Protections: The Impact of the* Braidwood *Decision*, Georgetown Univ., Health Pol'y Inst. (Apr. 18, 2023), https://tinyurl.com/2p9xr6j2.

[9] Danielle Kilschenstein, et al., *Cost Barriers to Health Services in U.S. Adults Before and After the Implementation of the Affordable Care Act*, 14(2) Cureus 1, 12-14 (2022).

[10] *Background: The Affordable Care Act's New Rules*, *supra* note 5; *see also* Michael V. Maciosek, et al., *Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost*, 29(9) Health Affs. 1656, 1659 (2010) (greater use of preventive services could prevent loss of more than 2 million life-years annually).

Congress passed the preventive services provision to avert these easily preventable losses.[11] Within four years after the ACA's passage, approximately 76 million Americans gained expanded coverage to one or more preventive services.[12] This number has grown steadily: as of 2020, an estimated 151.6 million people are enrolled in private insurance plans that cover preventive services at no cost to patients.[13] And as Congress anticipated, individuals who do not face significant financial barriers to preventive services use them.[14] Numerous studies confirm that, after the preventive services provision was enacted, the utilization of preventive care increased across the board—from flu vaccinations to blood pressure checks to cholesterol screenings.[15]

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[11] Norris, *supra* note 7, at 175-76.

[12] *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, Off. of the Assistant Sec'y for Plan. and Evaluation, at 1 (June 27, 2014), https://tinyurl.com/4h5yynnr.

[13] *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act*, Off. of the Assistant Sec'y for Plan. and Evaluation, at 3 (Jan. 11, 2022), https://tinyurl.com/5a8bducj.

[14] Norris, *supra* note 7, at 192.

[15] 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, 90-91 (2015); *see* Josephine S. Lau, et al., *Improvement in Preventive Care of Young Adults After the Affordable Care Act*, 168(12) JAMA Ped. 1101, 1105

These services improve public health outcomes by enabling medical professionals to identify and treat illnesses earlier, and, in some cases, entirely prevent them.[16] For instance, colorectal cancer—the second leading cause of cancer fatalities in America—is considered largely preventable with screening, which allows doctors to identify and then remove cancerous pregrowths.[17] When the ACA was enacted, however, a colorectal cancer screening could cost patients $1,600 out of pocket, which was often financially prohibitive, and the number of colorectal screenings was declining.[18] But when this financial barrier was removed following the Task Force's recommendation, colorectal

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(2014) (significant increase in routine examinations, blood pressure and cholesterol screenings, and dental visits by young adults following no-cost coverage).

[16] *Preventive Services Covered by Private Health Plans Under the Affordable Care Act*, Kaiser Fam. Found. (May 15, 2023), https://tinyurl.com/3tka45ff.

[17] *Access to Preventive Services*, *supra* note 13, at 7-8; *see* Michelle R. Xu, et al., *Impact of the Affordable Care Act on Colorectal Cancer Outcomes: A Systematic Review*, 58(4) Am. J. Prev. Med. 1, 2 (2020) (screening for colorectal cancer can decrease incidence and mortality by 30 to 60%).

[18] Djenaba A. Joseph, et al., *Prevalence of Colorectal Cancer Screening Among Adults—Behavioral Risk Factor Surveillance System, United States, 2010*, Ctrs. for Disease Control and Prevention ("CDC") (June 15, 2012), https://tinyurl.com/nv5kt994.

cancer screening rates increased for many populations—according to one study of United Healthcare beneficiaries, for instance, the number of colorectal cancer screenings increased by 9.1% in the two years following the ACA's enactment.[19] As predicted, this increase in screening has been associated with decreased incidence of colorectal cancer, as well as resulting deaths.[20]

Beyond the positive impact on the general population, the preventive services provision has had a considerable impact on populations traditionally underserved by the healthcare system. Women, for example, typically interact more often with the healthcare system than men, particularly given the greater health care needs associated with women's reproductive care.[21] Before the ACA was passed, being a woman was considered a pre-existing condition that

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[19] Xu, *supra* note 17, at 6.

[20] *Access to Preventive Services*, *supra* note 13, at 8. The number of lives saved is likely to increase, as the Task Force recently updated its recommendation to require insurers to also cover certain follow-up tests for colorectal cancer. *FAQs About Affordable Care Implementation Part 51*, Dep't of Lab., at 12 (Jan. 10, 2022), https://tinyurl.com/282nxzk2.

[21] Munira Z. Gunja, et al., *How the Affordable Care Act Has Helped Women Gain Insurance and Improved Their Ability to Get Health Care*, The Commonwealth Fund (Aug. 10, 2017), https://tinyurl.com/cfazjvw9.

"signaled the potential for higher health care use and higher costs" to insurers, and thus many insurers protected themselves from perceived risks by charging women higher rates and excluding many services from coverage.[22] By requiring no-cost coverage for services specific to women's health, the preventive services provision has expanded women's access to critical care in multiple ways, ranging from increased cholesterol checks to earlier detection of breast cancer.[23]

The preventive services provision's positive impact on women's health is particularly pronounced in the area of contraceptive care. The HRSA's guidelines requiring no-cost coverage of FDA-approved contraceptives has significantly reduced out-of-pocket spending for contraceptives.[24] According to one study, this coverage has saved women $1.4 billion annually on birth control.[25] Given that cost was a

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[22] *Id.*

[23] *Id.*; *see* Amy Pason, Letter to Nevada Health and Human Services Committee in Support of Senate Bill 233 (May 21, 2017) (on file with author) (explaining that, before ACA's enactment, many female teachers at rural public school forewent breast cancer screenings due to cost and subsequently developed breast cancer).

[24] *Preventive Services Covered*, *supra* note 16.

[25] Nicole Rapfogel, et al., *10 Ways the ACA Has Improved Health Care in the Past Decade*, Ctr. for Am. Progress (May 23, 2020), https://tinyurl.com/3wshcamt.

major barrier to contraceptive use, it is unsurprising that no-cost coverage has led women to utilize both short-term (*e.g.*, birth control pills) and long-term (*e.g.*, intrauterine devices) birth control methods at higher rates.[26] Nor is it surprising that the greatest increases have been experienced by women who faced the highest out-of-pocket costs before the ACA was enacted.[27] And the increased usage of contraceptives has improved women's health and economic outcomes by decreasing unwanted pregnancies and abortions and reducing the rate of entry into poverty, while at the same time increasing wages and rates of entry into professional school and the labor force.[28]

Women are not the only population traditionally underserved by the healthcare system to have benefited greatly from the preventive services provision. Studies have confirmed that those with socioeconomical disadvantages have benefited the most from this provision, as the coverage has enabled them to utilize preventive care at higher rates and has thereby reduced disparities in access to health

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[26] *Access to Preventive Services*, *supra* note 13, at 9; *Preventive Services Covered*, *supra* note 16.

[27] Norris, *supra* note 7, at 186.

[28] *Access to Preventive Services*, *supra* note 13, at 9.

care.[29] For instance, community health centers, which serve individuals with limited financial means, received increasing visits for a variety of treatments after the ACA was enacted, including for cervical and colorectal cancer screenings.[30] No-cost coverage has also reduced racial and ethnic disparities in accessing health care by expanding access to a variety of preventive services across racial groups and immigration statuses.[31] For instance, Hispanic and Black women have the highest rates of cervical cancer in the general population, and they increased their utilization of cervical cancer screening following the enactment of the preventive services provision.[32]

Finally, in addition to improving health outcomes for specific individuals, the preventive services provision has promoted the public

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[29] Norris, *supra* note 7, at 192, 194. Women with lower economic statutes have also utilized preventive care, such as mammograms and contraceptives, at higher rates than those with more extensive financial means. *Id.* at 180, 186; Gregory S. Cooper, et al., *Cancer Preventive Services, Socioeconomic Status, and the Affordable Care Act*, 123(9) Cancer 1585, 1588 (Jan. 9, 2017).

[30] Nathalie Huguet, et al., *Cervical and Colorectal Cancer Screening Prevalence Before and After Affordable Care Act Medicaid Expansion*, 124 Prev. Med. J. 91, 96 (2019).

[31] *Access to Preventive Services*, *supra* note 13, at 7.

[32] Huguet, *supra* note 30.

health more broadly by reducing the spread of highly infectious diseases. As one example, PrEP medication reduces the risk of contracting HIV from sex by 99% and from intravenous drugs by 74%.[33] There is currently no effective cure for HIV, nor is there a meaningfully viable alternative to PrEP medication; the other commonly used treatment, antiretroviral therapy, is useful in managing HIV after it is contracted but costs nearly double the amount of PrEP medication.[34] PrEP medication is thus an invaluable tool in preventing the spread of this highly contagious, and lifelong, infection.[35] In fact, according to a computer simulation, increased PrEP medication usage will be the

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[33] *How Effective is PrEP?*, CDC (June 6, 2022), https://tinyurl.com/2s3k6w9z. CDC guidelines require those who receive PrEP medication to undergo comprehensive and frequent testing for sexually transmitted infections, so the receipt of PrEP medication also reduces the spread of other infections. *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update, A Clinical Practice Guideline*, CDC, at 43 (2021), https://tinyurl.com/bddaxcd8.

[34] *What is HIV Treatment?*, CDC (July 14, 2022), https://tinyurl.com/2s3vvapj; Nicole McCann, et al., *HIV Antiretroviral Therapy Costs in the United States, 2012-2018*, 180(4) JAMA Intern. Med. 601, 603 (2020).

[35] *How Effective is PrEP?*, *supra* note 33.

largest contributor to reducing further HIV infections in New York, which has the second highest HIV rate in the United States.[36]

But the high cost of PrEP medication deters usage.[37] In 2018, when insurers were not required to cover PrEP medication, 87% of surveyed District of Columbia residents who inject drugs and are at high risk for HIV stated that they were not taking the medication but would be very or somewhat likely to do so if it were free.[38] The Task Force has since recommended the use of PrEP medication, and private insurers have been required to cover the medication without cost

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[36] Rona Vail, et al., *PrEP to Prevent HIV and Promote Sexual Health*, John Hopkins Univ. (May 2022), https://tinyurl.com/5efhe8dk.

[37] Karishma Srikanth, et al., *Associated Costs Are a Barrier to HIV Preexposure Prophylaxis Access in the United States*, 112(6) Am. J. Pub. Health 834, 835 (2022) (30-day supply costs $2,000). The PrEP manufacturer sought to encourage usage of the medication by instituting a copay assistance program (discounts for individuals living far below the poverty line), but insurers still passed on costs to the patient by refusing to apply the amount covered by the manufacturer towards the individual's deductible. Katie Keith, *USPSTF Recommends Access Without Cost Sharing to HIV Prevention*, Health Affs. (June 13, 2019), https://tinyurl.com/2t5tm254; *Paying for Pre-Exposure Prohylaxis (PrEP): Gilead Medication Assistance Program*, CDC (Mar. 9, 2022), https://tinyurl.com/34zkxxym.

[38] *Annual Epidemiology and Surveillance Report: Data Through December 2019*, D.C. Dep't of Health, at 31, https://tinyurl.com/bdhtyz2u.

sharing since 2021.[39] That year, 30% of the 1.2 million individuals who could benefit from PrEP were prescribed the medication—as compared to 13% of such individuals in 2017.[40] As the CDC recently explained in a May 2023 release, this treatment has been a key contributor in preventing the spread of HIV, particularly among young gay and bisexual men.[41] Without no-cost coverage, however, the country will backtrack in the progress it has made in combatting the spread of HIV.[42]

In short, the preventive services provision has reduced a barrier to equal access to health care faced by many—financial cost. Enjoining

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[39] Keith, *supra* note 37.

[40] Press Release, CDC, *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections* (May 23, 2023), https://tinyurl.com/yh76ap9r.

[41] *Id.*

[42] Meredithe McNamara, et al., Braidwood *Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community*, Yale L. (Feb. 13, 2023), https://tinyurl.com/ynzce8da (Harvard and Yale study estimating that if PrEP medication coverage is reduced by just 10%, there will be 2,083 additional HIV infections).

implementation and enforcement of this provision would reinstate this significant deterrent to the use of vital health care.[43]

II. Enjoining The Federal Government From Implementing And Enforcing All Or Part Of The Preventive Services Provision Will Harm The Amici States' Ability To Protect Their Residents.

In addition to directly harming millions of state residents by reviving financial barriers to obtaining preventive care, an injunction enjoining all or part of the preventive services provision would hamstring the amici States' ability to protect their residents' health and welfare. The States play an important role in ensuring access to health care for their residents by, among other things, operating public health agencies and regulating insurance markets within their borders. But federal regulation of insurance coverage is a critical supplement to these state efforts because the States cannot, under federal law, mandate insurance requirements for a large category of insurance plans and because the States rely on federal guidance even when they are

[43] According to a recent survey published by Morning Consult in January 2023, many individuals remain unlikely to utilize preventive care if it is not covered by insurance. Ricky Zipp, *Many Americans Are Likely to Skip Preventive Care if ACA Coverage Falls Through*, Morning Consult (Mar. 8, 2023), https://tinyurl.com/56th946x.

able to mandate specific coverage. Eliminating the preventive services provision would thus deprive the States of an important mechanism for facilitating uniform and comprehensive access to preventive care. This would not only endanger the lives of those whose illnesses could be prevented, but it would also burden state public health systems—thereby frustrating the States' ability to safeguard the public health more broadly.

A. Federal law prevents the States from mandating specific insurance coverage for many of their residents.

The States' authority to act on their own to ensure continuous access to no-cost preventive care for their residents is greatly constrained by the Employee Retirement Income Security Act of 1974 ("ERISA"), which limits the ways in which the States can regulate employer-sponsored health plans. 29 U.S.C. §§ 1003(a), 1144(a), 1144(b)(2)(A). As a result, a decision enjoining the federal government from implementing all or part of the preventive services provision would leave significant gaps in coverage that the States would be unable to fill.

Employer-sponsored health plans are generally funded in one of two ways. The first type are "fully insured" plans, where the employer purchases an insurance contract to cover risks associated with employee health plans.[44] The second are "self-funded," which means that the employer uses its own funds to cover such costs.[45] Self-funded plans are increasingly common for a variety of reasons. For instance, many employers choose these plans because then they need only pay for actual bills presented by employees instead of pre-paying a large premium to an insurance carrier.[46] But ERISA preempts the States from directly regulating self-funded employer health plans. 29 U.S.C. §§ 1003(a), 1144(a), 1144(b)(2)(A); *see FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990) (States cannot directly regulate "self-funded employee benefit plans" under ERISA).

Accordingly, if the federal preventive care mandate cannot be enforced, the States would not be able to respond by enacting similar

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[44] Paul Fronstin, *Trends in Self-Insured Health Plans Since the ACA*, Emp. Benefit Rsch. Inst. (Sept. 30, 2021), https://tinyurl.com/2a4fd7eu.

[45] *Id.*

[46] *What is Self Funding?*, Health Care Adm'rs Assoc.., https://tinyurl.com/2zfnsbkz.

mandates to protect their residents enrolled in self-funded plans. And there are many such residents: In 2022, 65% of employees with employer-sponsored coverage were enrolled in self-funded plans.[47] This percentage is even higher in some States; for example, as of 2022, 70% of workers in Delaware, 73% in Nebraska, 73% in North Carolina, and 70% in Ohio were enrolled in self-funded employer plans.[48] And these rates are increasing.[49]

In the absence of a federal preventive care mandate, then, it would be up to employers with self-funded plans to decide whether to continue covering preventive services. But, as explained, before the ACA, many employer-sponsored plans did not cover preventive care without cost to patients, despite the medical consensus on the many—and even life-saving—benefits of such care. *See supra* p. 9; *see also Skyline Wesleyan Church v. Cal. Dep't of Managed Health Care*, 968 F.3d 738, 750 (9th Cir. 2020) (that insurers offered restricted coverage

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[47] *2022 Employer Health Benefits Survey*, Kaiser Fam. Found. (Oct. 27, 2022), https://tinyurl.com/5awsexbb.

[48] *Employer-Provided Health Coverage: State-to-State 2022*, Am.'s Health Ins. Plans, at 11, 30, 36, 38 (2022), https://tinyurl.com/ycx36sna.

[49] Fronstin, *supra* note 44.

before California imposed coverage requirements was "strong evidence" that insurers would revert to original plans absent state regulation). Without a mandate, employers with self-funded plans are free to revert to this practice. This will result in a patchwork of coverage within state borders, with many state residents left without access to preventive care. And experience teaches that the gaps in covered care will likely be felt the strongest by those least able to afford services,[50] including historically disadvantaged minorities, who took particular advantage of preventive care following the ACA's enactment, *see supra* pp. 14-15.[51]

B. The States benefit from federal mandates and implementing agency action when issuing their own mandates.

Notwithstanding ERISA preemption, the States remain important regulators of insurance markets. They retain the authority to regulate many plans other than self-funded employee plans, including fully insured employee plans, plans purchased directly from the insurance

[50] Skopec, *supra* note 2, at 3.

[51] *A World Without the ACA's Preventive Services Provision*, *supra* note 8.

market, and state and local government plans.[52] To this end, the States have long enacted a variety of insurance mandates.[53]

If the federal preventive care mandate were enjoined, the States may choose to enact their own mandates to ensure that at least some of their residents receive continued access to no-cost preventive care. Most States currently lack mandates that are co-extensive with the preventive services provision's requirements, although some States have begun the process of enacting similar mandates in the wake of the district court's decision.[54]

But when enacting insurance mandates, the States benefit greatly from federal mandates and guidance. They often base their insurance

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[52] Catherine Stamm, et al., *A Primer on ERISA's Preemption of State Laws*, Mercer (Mar. 22, 2022), https://tinyurl.com/25f8658d; Justin Giovanelli, et al., *The ACA's Preventive Services Benefit is in Jeopardy: What Can States Do to Preserve Access?*, The Commonwealth Fund (Nov. 21, 2022), https://tinyurl.com/2t68c2um.

[53] Giovanelli, *supra* note 52.

[54] Michigan, for example does not mandate coverage of any of the preventive services affected by the district court's decision, but its governor has "call[ed] on" the state legislature to "take swift action to pass laws to ensure that Michiganders can continue to have access to these critical services without having to worry about whether they can afford it." Letter from Governor Gretchen Whitmer to Michigan Department of Insurance Director Anita Fox (Apr. 3, 2023), https://tinyurl.com/mpjerj84.

requirements on federal requirements, rather than starting from scratch, while retaining the flexibility to exceed these requirements. Absent the federal preventive care mandate and implementing action, the States will have to invest significant resources and time in enacting and implementing their own mandates, and their different approaches could result in a patchwork of coverage nationwide.

Generally, establishing mandates is a multi-step and resource- and time-intensive process. Among other things, the State must define qualifying coverage, set penalties for noncompliance, determine any exemptions, establish regulations for implementing the mandates, and provide guidance to a range of stakeholders (*e.g.*, employers and insurers) on the mandate's requirements.[55] Although costs can vary from State to State, the process can be expensive and onerous.[56] But when a federal mandate is in effect, the States can minimize costs by

[55] *See* Press Release, Cal. Dep't of Ins., *New Insurance Laws for 2022 Will Protect Californians' Health and Safety* (Jan. 4, 2022), https://tinyurl.com/mrzyrud3 (describing steps taken to implement California mandate); Jason A. Levitis, *State Individual Mandates*, Brookings Inst., at 18 (Oct. 2018), https://tinyurl.com/37c6f8vm.

[56] *See* Levitis, *supra* note 55, at 16.

adapting federal regulatory and statutory language, guidance, forms, instructions, and educational materials, rather than starting anew.[57]

As one example, federal guidance is particularly beneficial for the States when determining which services to cover. With the federal mandate in place, medical experts across the Task Force, ACIP, and HRSA provide and update science-backed recommendations for such services. The States, in turn, can adopt these recommendations, rather than conducting their own research and analysis. Indeed, a number of States have chosen to do so.[58] Illinois, for example, has promulgated a regulation providing that covered insurers must provide no-cost coverage for all services recommended by the federal government pursuant to the preventive services provision.[59]

But if the federal government were enjoined from implementing the preventive services provision, Illinois and other States would have to conduct their own reviews of which services to cover (and for which

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[57] *See id.* at 19-21.

[58] *See, e.g.*, Cal. Health & Saf. Code § 1367.002(a); D.C. Code § 31-3834.02(a)(2); 18 Del. Code § 3558(b); Md. Code Ann., Ins. § 15-1A-10; N.H. Stat. § 173B:26-2mm; N.Y. Ins. Law § 3216(g)(17)(E); Va. Code Ann. § 38.2-3438-3442.

[59] 50 Ill. Admin. Code § 2001.8(a)(1).

populations) as medical knowledge and social needs evolve. Legislators, however, do not always possess the necessary expertise—or bandwidth—to gather this information. To remediate this information gap, more than half of the States enacted state mandate benefit review laws in the years preceding the ACA's enactment.[60] These statutes designated specific reviewers for deciding which services would be covered by preventive care mandates, and thus ensured more information in the decision-making process.[61] At the same time, however, these individual state processes were not as comprehensive as a uniform, national approach. Only a few States required recommendations to be evidence-based (a process that requires significant resources, including the collection of data and input from medical experts).[62] Moreover, the state processes varied greatly in other aspects, such as criteria and time for review.[63] As a result of

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[60] Nicole M. Bellows, *State-Mandated Benefit Review Laws*, 41 Health Serv. Res. 1104, 1109 (June 2006).

[61] *Id.*

[62] *Id.* at 1116-21; John V. Jacobi et. al., *Health Insurer Market Behavior After the Affordable Care Act: Assessing the Need for Monitoring, Targeted Enforcement, and Regulatory Reform*, 120 Penn St. L. Rev. 109, 117 (2015).

[63] Bellows, *supra* note 60, at 1116-21.

these variances, there was inadequate and inconsistent coverage nationwide, producing confusion and deterring the use of preventive services.[64] For instance, an individual who worked for an out-of-state employer would need to resolve whether her coverage was determined by the laws of the State in which she resided or in which the employer was headquartered.[65] To remediate these concerns, many States will have to invest significant resources to enhance existing (or establish new) review processes and provide guidance to their residents.

In short, although state preventive care mandates are an important tool for protecting the public health, the States benefit significantly from federal guidance and resources when enacting their own mandates. If implementation of the preventive services provision were enjoined, the States would have to invest a substantial portion of their limited resources toward enacting and implementing their own mandates, which could still leave gaps in coverage across the country.

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[64] *Id.*

[65] *See* Melissa Stuart, *Autism Insurance Reform: A Comparison of State Initiatives*, 8 Ind. Health L. Rev. 497, 524 (2011).

C. An injunction could strain state-operated public health systems.

Given ERISA preemption and practical constraints, the States will not be able to fully close the gaps left in preventive care coverage if the implementation and enforcement of the preventive services provision were enjoined in any respect. As explained, the costs of that decision will be borne by state residents—exacerbating inequities in access to critical care and needlessly risking lives. *See supra* Section I. But an injunction would also affect the States' ability to safeguard the public health more broadly because it could burden public health systems in multiple respects.

For one, an injunction could strain state programs aimed at helping individuals access preventive care. Despite the federal mandate, some individuals still struggle to access no-cost preventive care. This is in part because insurance companies may mistakenly bill individuals for covered preventive care—one study found that 1 in 4 patients who are entitled to no-cost preventive care under their employer-sponsored insurance plans received such bills in 2018, with an

estimated aggregate of $219 million erroneously billed.[66] Other individuals (an estimated 19.1 million in 2021) cannot enjoy no-cost preventive care because their insurance plans were grandfathered by the ACA and are thus exempt from compliance with the preventive services provision.[67]

The States have created state-funded programs to ensure that these individuals, too, can access preventive care without incurring significant expenses. Massachusetts, for example, has established a PrEP Drug Assistance Program, which aids individuals in navigating erroneous insurance bills for PrEP medication and covers out-of-pocket costs for individuals living in poverty who lack insurance or whose insurance does not cover this medication.[68] This program served almost 300 clients in fiscal year 2022, but Massachusetts anticipates that its program capacity would be strained if the PrEP mandate were

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[66] Jillian McKoy, *Patients Billed up to $219 Million in One Year for Preventive Services that Should Be Free*, Boston Univ. Sch. of Pub. Health (July 20, 2021), https://tinyurl.com/46bv9vu2.

[67] Katie Keith, *Final Rule on Grandfathered Health Plans Will Allow Higher Consumer Costs*, Health Affs. (Dec. 14, 2020), https://tinyurl.com/2p8rtswm.

[68] *How Can AccessHealth MA's PrEPDAP Help?*, Access Health MA, https://tinyurl.com/2p9fn2dy.

eliminated, as significantly more individuals would require the program's assistance. And several other States and the District of Columbia have implemented similar PrEP financial assistance programs that could be financially stretched if no-cost coverage of PrEP ended.[69]

Additionally, an injunction could encumber public health systems because it will require the States to re-allocate limited resources to ensure access to preventive care. As explained, passing and implementing state preventive care mandates will demand significant time and resources. *See supra* Section II.B. In addition, the federal mandate has conserved state resources because, as public health providers, the States operate medical facilities that have relied on the preventive services provision to bill insurance providers directly for preventive services.[70] These facilities have then redirected funds that

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[69] *Pre Exposure Prophylaxis Drug Assistance Program (PrEP DAP)*, D.C. Health, https://tinyurl.com/3cytf8cv; Erin Kim & Lyndsay Sanborn, *How Can States Stop HIV Transmission? Increase Access to Pre-Exposure Prophylaxis (PrEP)*, Nat'l Acad. for State Health Pol'y (Oct. 2018), https://tinyurl.com/2uf3t7at.

[70] Nadia Chait & Sherry Glied, *Promoting Prevention Under the Affordable Care Act*, 39 Ann. Rev. Pub. Health 507, 514 (2018).

they would have spent on preventive services to other pressing public needs. As one example, several States with additional public health funds were able to respond quickly to the Covid-19 pandemic, including by establishing robust contract-tracing programs.[71] Invalidating the preventive services provision will deprive the States of this additional flexibility, which has proven vital in recent years.

* * *

Expanded access to preventive care saves lives. But an injunction of any scope would force many individuals to choose between making ends meet and obtaining preventive care. And it would frustrate the States' ability to safeguard the public health by limiting their options for ensuring access to this critical care and by straining public health systems. The equities and public interest thus preclude an injunction here.

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[71] Sandra C. Melvin et al., *The Role of Public Health in Covid-19 Emergency Response Efforts from a Rural Perspective,* 17 Preventing Chronic Disease 1, 3 (2020).

CONCLUSION

For these reasons, this court should reverse the portions of the district court judgment in plaintiffs' favor, and affirm the remainder of the judgment.

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because it contains 5,927 words, excluding the parts of the brief exempted by Rule 32(f). This brief complies with the typeface requirement of Rule 32(a)(5) because it has been prepared in a proportionally spaced typeface (14-point Century Schoolbook) using Microsoft Word 365.

/s/ Sarah A. Hunger
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June 27, 2023

CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2023, I electronically filed the foregoing Brief of Amici Curiae Illinois, et al. with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit using the CM/ECF system. I further certify that all participants in this case are registered CM/ECF users and service will be accomplished by the CM/ECF System.

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