No. 23-10326

United States Court of Appeals
for the
Fifth Circuit

Braidwood Management, Incorporated; John Scott Kelley; Kelley Orthodontics; Ashley Maxwell; Zach Maxwell; Joel Starnes,

Plaintiffs—Appellees/Cross-Appellants,

Joel Miller; Gregory Scheideman,

Plaintiffs—Cross-Appellants,

versus

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

BRIEF OF *AMICI CURIAE* HIV AND HEPATITIS POLICY INSTITUTE, AIDS ALABAMA, AIDS FOUNDATION OF CHICAGO, AIDS UNITED, AMERICAN ACADEMY OF HIV MEDICINE, *ET AL.*, IN SUPPORT OF APPELLANTS/CROSS-APPELLEES

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**U.S. Court of Appeals Fifth Circuit Admission Pending*
***Admitted to the Bar Under D.C. App. R. 46-A*

Counsel for Amici Curiae
June 23, 2023

ADDITIONAL AMICI LISTED ON INSIDE COVER

ASIAN AND PACIFIC ISLANDER WELLNESS CENTER, INC. DBA SAN FRANCISCO COMMUNITY HEALTH CENTER, CARING AMBASSADORS PROGRAM, INC., CENTER FOR HEALTH LAW POLICY AND INNOVATION, COMMUNITY EDUCATION GROUP, FENWAY COMMUNITY HEALTH CENTER, INC., FRANNIE PEABODY CENTER, GAY MEN'S HEALTH CRISIS, INC., GEORGIA AIDS COALITION, GLOBAL LIVER INSTITUTE, HEPATITIS B FOUNDATION, HEPATITIS EDUCATION PROJECT, HOUSING WORKS, INC., HUMAN RIGHTS CAMPAIGN FOUNDATION, LATINO COMMISSION ON AIDS, NATIONAL COALITION OF STD DIRECTORS, NATIONAL MINORITY AIDS COUNCIL, PREP4ALL, SOUTHERN AIDS COALITION, TREATMENT ACTION GROUP, AND WHITMAN-WALKER HEALTH

CERTIFICATE OF INTERESTED PERSONS

Amici Curiae certify that, in addition to those persons listed in the Parties' certificates of interested persons, the following is a complete supplemental list of interested persons as required by Federal Rule of Appellate Procedure 29(a)(4) and Fifth Circuit Rule 29.2:

HIV and Hepatitis Policy Institute
AIDS Alabama
AIDS Foundation of Chicago
AIDS United
American Academy of HIV Medicine
Asian and Pacific Islander Wellness Center, Inc. dba San Francisco Community Health Center
Caring Ambassadors Program, Inc.
Center for Health Law Policy and Innovation
Community Education Group
Fenway Community Health Center, Inc.
Frannie Peabody Center
Gay Men's Health Crisis, Inc.
Georgia AIDS Coalition
Global Liver Institute
Hepatitis B Foundation
Hepatitis Education Project
Housing Works, Inc.
Human Rights Campaign Foundation
Latino Commission on AIDS
National Coalition of STD Directors
National Minority AIDS Council
PrEP4All
Southern AIDS Coalition
Treatment Action Group
Whitman-Walker Health

As required by Federal Rule of Appellate Procedure 26.1, *Amici Curiae* certify that no publicly traded company or corporation—aside from any that may be identified in the Parties' certificates of interested persons—has an interest in the outcome of this case or appeal.

/s/ Richard H. Hughes IV
Richard H. Hughes IV

Counsel for Amici Curiae

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I. IDENTITY AND INTEREST OF *AMICI CURIAE*

Amicus Curiae HIV and Hepatitis Policy Institute is a non-profit advocacy organization that monitors policies that impact the prevention and treatment of human immunodeficiency virus ("HIV"), viral hepatitis, and other health conditions; communicates with patient communities on policy issues impacting their healthcare access; and educates policymakers about efforts to end HIV and hepatitis in the United States and improve access to quality and affordable healthcare.

The 24 other *amici curiae* are organizations that work globally, nationally, regionally, state-wide, and locally towards the elimination of HIV and/or viral hepatitis by providing or advocating for HIV testing, hepatitis B & C testing and/or HIV pre-exposure prophylaxis (PrEP). One is a global organization—Global Liver Institute—but many are national organizations—AIDS United, American Academy of HIV Medicine, Caring Ambassadors Program, Inc., Center for Health Law Policy and Innovation, Hepatitis B Foundation, Hepatitis Education Project, Human Rights Campaign Foundation, Latino Commission on AIDS, National Coalition of STD Directors, National Minority AIDS Council, PrEP4All, and Treatment Action Group—that advocate on behalf of

people and communities affected by HIV and viral hepatitis, including organizations focused on women, racial, ethnic, and other groups most impacted by these infectious diseases. Others are regional, state-based, or local organizations—AIDS Alabama, AIDS Foundation of Chicago, Asian and Pacific Islander Wellness Center, Inc. dba San Francisco Community Health Center, Community Education Group, Fenway Community Health Center, Inc., Frannie Peabody Center, Gay Men's Health Crisis, Inc., Georgia AIDS Coalition, Housing Works, Inc., Southern AIDS Coalition, and Whitman-Walker Health—that provide direct HIV and/or hepatitis services, including PrEP in states such as Alabama, Georgia, West Virginia, Pennsylvania, and Maine and in cities like Boston, Chicago, and San Francisco. All share an interest in the provision of HIV and hepatitis preventive services affected by this case, including PrEP.

As such, *amicus* HIV and Hepatitis Policy Institute together with these 24 other *amici* have a crucial interest in maintaining patient access to clinical interventions that facilitate prevention and early detection of HIV, viral hepatitis, and other health conditions.

II. SUMMARY OF ARGUMENT

The United States Preventive Services Task Force ("USPSTF") and its recommendations have been essential to the prevention of HIV, hepatitis, and many other infectious and chronic diseases for millions of Americans. After the passage of the Affordable Care Act ("ACA"), USPSTF's recommendations became a critical first step in ensuring effective interventions are covered by health insurance. A wholesale invalidation of the coverage requirement for USPSTF's recommendations would strike a critical, unnecessary, and costly blow to the battle to end HIV, hepatitis, and other infectious diseases.

This brief details the impact of HIV and hepatitis in the U.S., emphasizing that these are infectious diseases spread by viruses which can and will spread to any person unless prevented from doing so. Removing access to evidence-based preventive measures will have a devastating impact, not only on those living with HIV and hepatitis, but also for those at risk for acquiring HIV and hepatitis and the population at-large.

We then contend that the district court's decision relied on fundamental misrepresentations about HIV transmission. If properly

understood, the district court could not have found that offering preventive services to protect people from acquiring HIV burdened Appellees'/Cross-Appellants' religious exercise, but rather, elimination of these services would threaten the health and livelihood of many who may share their same beliefs and many who do not. For these reasons, we urge this Court to reverse the lower court's decisions invalidating USPSTF's recommendations, and, in particular, USPSTF's requirement that health coverage include pre-exposure prophylaxis (PrEP) for HIV.

III. ARGUMENT

A. HIV and Hepatitis Impact Millions of Americans from All Walks of Life and Undermining Decades of Bipartisan Solutions Aimed at Ending Their Transmission Will Have Devastating Consequences

1. HIV and Hepatitis Are Viruses That Can Infect Any Person

HIV was first identified in 1981 when clusters of rare illnesses were reported in the U.S.[1] HIV attacks the immune system, and if left untreated, almost always progresses to acquired immunodeficiency syndrome (AIDS).[2] Once an individual is living with AIDS, they are

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[1] M.S. Gottlieb, *et al.*, *Pneumocystis Pneumonia - Los Angeles*, 30 MMWR 250, 250-52 (1981), https://stacks.cdc.gov/view/cdc/1261.
[2] *About HIV*, CDC, https://www.cdc.gov/hiv/basics/whatishiv.html (Jun. 30, 2022).

vulnerable to opportunistic infections or cancers that ravage the body.[3] Before adequate treatments were available, a positive HIV diagnosis was akin to a "death sentence." More than 700,000 people have died of HIV-related disease in the U.S., while more than 1.2 million people are living with HIV.[4] Despite progress in testing, treatment, and prevention, more than 32,000 new transmissions occur each year.[5]

People with HIV, including the gay community, have borne the brunt of stigma since the dawn of the epidemic, a stigma that haunts the memories of loved ones who were lost too young, ostracized by their families on their very deathbeds.[6] Since 1981, we have learned that HIV does not recognize geographic borders and can impact anyone no matter their gender, sexual behavior, occupation, age, race, ethnicity, or location. Yet, our society still struggles to move beyond the stigma of HIV. HIV is an opportunistic virus that has and will spread to those of all views,

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[3] These illnesses are considered AIDS-defining illnesses. *See AIDS-Defining Illnesses*, Merck Manual, https://www.merckmanuals.com/professional/multimedia/table/aids-defining-illnesses (last visited June 13, 2023).

[4] *The HIV/AIDS Epidemic in the United States: The Basics*, Kaiser Fam. Found. (June 7, 2021), https://www.kff.org/hivaids/fact-sheet/the-hivaids-epidemic-in-the-united-states-the-basics.

[5] *See id.*; *HIV and Women: HIV Diagnoses*, CDC (Aug. 18, 2022), https://www.cdc.gov/hiv/group/gender/women/diagnoses.html .

[6] Ruth Coker Burks & Kevin Carr O'Leary, *All the Young Men: A Memoir of Love, AIDS, and Chosen Family in the American South* 1 (2020).

orientations, and ideologies. Indeed, AIDS has taken the lives of authors, poets, actors, doctors, nurses, elected officials, lawyers, and judges.[7]

In the first two decades of the HIV epidemic, approximately half of the Americans with HIV were females or heterosexual males.[8] Globally, in 2021, 54% of those diagnosed with HIV were women and girls; most HIV transmission in this population occurs from heterosexual contact.[9] Today, in the U.S. approximately 20% of new diagnoses occur in women; 53% of those were in Black women which is double the rate of new diagnoses in white women.[10] HIV transmission can occur between the

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[7] Thessaly La Force, *Those We Lost to the AIDS Epidemic*, N.Y. Times Style Magazine (Apr. 14, 2018), https://www.nytimes.com/interactive/2018/04/17/t-magazine/aids-epidemic-deaths-new-york.html; The Associated Press, *Jon Hinson, 53, Congressman And Then Gay-Rights Advocate*, N.Y. Times (July 26, 1995), https://www.nytimes.com/1995/07/26/obituaries/jon-hinson-53-congressman-and-then-gay-rights-advocate.html; Albin Krebs, *Roy Cohn, Aide to McCarthy and Fiery Lawyer, Dies at 59*, N.Y. Times (Aug. 3, 1986), https://archive.nytimes.com/www.nytimes.com/library/national/science/aids/080386sci-aids.html; Bettina Boxall, *Rand Schrader, Judge and Gay Activist, Dies at 48 : Law: AIDS claims Municipal Court jurist. He is remembered for eloquence and tact in fight for equal rights*, L.A. TIMES (June 14, 1993), https://www.latimes.com/archives/la-xpm-1993-06-14-me-3011-story.html.

[8] *CDC WONDER AIDS Public Use (Vintage 2002) Request*, CDC, http://wonder.cdc.gov/aids-v2002.html (last visited Jun. 13, 2023).

[9] *Global HIV & AIDS Statistics – Fact Sheet*, UNAIDS, https://www.unaids.org/en/resources/fact-sheet (last visited Jun. 1, 2023); CDC, "*HIV and Women*," *supra* note 5.

[10] CDC, "*HIV and Women*," *supra* note 5; Bisola O. Ojikutu & Kenneth Mayer, *HIV Prevention Among Black Women in the US—Time for Multimodal Integrated Strategies*, JAMA Network Open (Apr. 9, 2021); HIV.gov, *Impact on Racial and Ethnic Minorities*, https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities (Jan. 20, 2023).

members of a married, monogamous couple of any sexual orientation.[11] HIV can spread from mother to child during pregnancy, childbirth, or breastfeeding.[12]

Appellees'/Cross-Appellants' arguments against PrEP coverage rest on the flawed premise that *some* activities that may increase the likelihood of HIV transmission are the *only* activities through which HIV can be transmitted. Endorsing this logic and allowing refusal of PrEP coverage ignores those who acquired HIV as an infant, or someone who falls in love with a person who happens to be living with HIV, or countless other realities.

Further, adoption of the Appellees'/Cross-Appellants' claims would disrupt early detection and prevention of hepatitis, viral diseases that have impacted millions of people. Hepatitis B (HBV) and hepatitis C (HCV) are the most common forms of viral hepatitis in the U.S.[13]

As of 2020, approximately 880,000 adults in the U.S. have chronic HBV, with 14,000 estimated new infections that same year. HBV is a

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[11] Nicole Crepaz, *et al.*, *Examination of HIV Infection Through Heterosexual Contact with Partners Who Are Known to be HIV Infected in the United States, 2010–2015*, 31 AIDS 1641, 1642 (2017).
[12] *Prevent Perinatal Transmission*, CDC, https://www.cdc.gov/hiv/basics/hiv-prevention/mother-to-child.html (Feb. 2, 2023).
[13] *Viral Hepatitis*, CDC, https://www.cdc.gov/hepatitis/abc/index.htm (Mar. 9, 2023).

leading cause of liver cancer, and many HBV patients remain asymptomatic until this end stage.[14] Perinatal transmission of HBV disproportionally affects the Asian American Pacific Islander ("AAPI") community—8.9% of infants with a foreign-born AAPI mother are estimated to be HBV-positive.[15]

An estimated 2.2 million adults are living with HCV in the U.S.[16], and its impact on the health care system is hard to overstate. Since 2012, there have been more deaths due to HCV than all other sixty reportable infectious diseases — with the exception of COVID-19 — combined.[17] It can also remain asymptomatic until decades after infection.[18] Almost 40% of people with HCV are uninformed of their serostatus.[19]

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[14] Gadji Mahamat et al., *Global Prevalence of Hepatitis B Virus Serological Markers Among Healthcare Workers: A Systematic Review and Meta-analysis*, 13 World J. Hepatology 1190, 1192 (2021).

[15] *Hepatitis B Basic Information*, U.S. Dep't Health and Hum. Servs. (Mar. 31, 2023), https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-b-basics/index.html

[16] CDC, "*Viral Hepatitis*," *supra* note 13.

[17] *Viral Hepatitis in the United States: Data and Trends*, U.S. Dep't Health and Hum. Servs., https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/data-and-trends/index.html (June 7, 2016).

[18] *Q&As for Health Professionals*, CDC, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (Aug. 7, 2020).

[19] CDC, "*Viral Hepatitis*," *supra* note 13.

Concerningly, HCV cases are on the rise.[20] Cirrhosis due to chronic HCV is a leading indication for liver transplant, which is difficult and costly.[21] HCV is also one of the leading causes of liver cancer.[22] Unlike other forms of viral hepatitis, HCV can easily be cured.[23] However, failure to detect HCV forecloses the opportunity to cure it and can instead lead to further costs.

Approximately 15-30% of people in the U.S. with HIV are co-infected with HCV.[24] Hepatitis also affects people of all ages, genders, and ethnicities, and disproportionately impacts those with existing health conditions.[25] For both HIV and hepatitis, testing is crucial to early treatment and reducing transmission. For HCV, the opportunity for a cure is not possible if not first detected. With proper care, people with viral hepatitis can live healthy and fulfilling lives.

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[20] *Hepatitis C Basic Information*, U.S. Dep't Health and Hum. Servs., https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html (Nov. 30, 2020).

[21] Daniel Q. Huang et al., *Global Epidemiology of Cirrhosis — Aetiology, Trends and Predictions*, 20 Nature Rev's Gastroenterology & Hepatology 388, 389-395 (2023).

[22] CDC, "*Viral Hepatitis*," *supra* note 13.

[23] CDC, "*Q&As for Health,*" *supra* note 18.

[24] David H. Spach, *Hepatitis C Coinfection*, National HIV Curriculum (May 12, 2023), https://www.hiv.uw.edu/go/co-occurring-conditions/hepc-coinfection/core-concept/all#treatment-hcv-infection-persons-coinfected-hiv.

[25] CDC, "*Viral Hepatitis*," *supra* note 13.

2. The Federal Government Has a Bipartisan History of Implementing Programs Intended To Curb HIV

Due to its severe impact on our health care system and society, the federal government has worked across partisan lines to combat the spread of HIV. For example, the Ryan White Comprehensive AIDS Resources Emergency Act (Ryan White CARE Act), which helps low-income Americans living with HIV access medical care and support services, was signed by President George H.W. Bush after overwhelming bipartisan support in Congress.[26] In 2003, President George W. Bush created the President's Emergency Plan for AIDS Relief or PEPFAR, which provides countries across the world with HIV prevention, testing, and treatment.[27]

More recently, the Obama Administration developed, and the Trump and Biden Administrations continued, the National HIV/AIDS

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[26] Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (Ryan White CARE Act), Pub. L. No. 101–381, 104 Stat. 576 (1990); *Ryan White HIV/AIDS Program*, Health Res. & Serv. Admin, https://ryanwhite.hrsa.gov (last visited June 13, 2023).

[27] *Fact Sheet: The President's Emergency Plan for AIDS Relief*, White House Archives (Jan. 29, 2003), https://georgewbush-whitehouse.archives.gov/news/releases/2003/01/20030129-1.html.

Strategy.[28] The Strategy sets national goals to prevent the transmission of HIV, improves HIV-related health outcomes for people living with HIV, reduces treatment disparities and inequities, and coordinates efforts among those working to end the epidemic.[29]

In 2019, the Trump Administration launched the Ending the HIV Epidemic (EHE) initiative.[30] One of the initiative's four pillars is to diagnose people as soon as possible, while another is to increase PrEP uptake.[31] The same year, and somewhat synergistically, USPSTF carried out its role as delegated by Congress and made its evidence-based recommendation for PrEP.[32]

3. The Lower Court's Decision Threatens Progress Toward Ending HIV

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[28] The White House, *National HIV/AIDS Strategy: Federal Implementation Plan* 1 (2010); *Ending the HIV Epidemic Overview*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/(July 1, 2022); The White House, *National HIV/AIDS Strategy for the United States 2022-2025* 1 (2021).

[29] The White House, *National HIV/AIDS Strategy for the United States 2022-2025* 1 (2021).

[30] *What Is Ending the HIV Epidemic in the U.S.?*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview (July 1, 2022).

[31] *Key EHE Strategies*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/key-strategies (July 1, 2022).

[32] *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*, U.S. Preventive Servs. Task Force (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

The district court's decision to invalidate USPSTF's recommendations, including PrEP access, based on a fundamental misunderstanding of HIV transmission, risks upending decades of progress in the fight against a serious, life-threatening condition. In the 42 years since HIV was first identified, we have made near-miraculous strides in reducing deaths, severity of symptoms, and transmission. It is now possible for people living with HIV to live long, full lives due to improvements in the detection, treatment, and prevention of HIV. Collectively, these components represent a continuum of care.[33] When any one component is weakened, the risk of transmission increases.[34]

Studies show that people who know their HIV-positive status play an active role in reducing HIV transmission.[35] Testing is the only way to determine HIV status. To increase testing, in 1996, USPSTF began recommending screening for HIV for certain at-risk groups, including pregnant women.[36] Recognizing the broad impact of HIV, USPSTF

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[33] *HIV Care Continuum*, HIV.gov, https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum (Oct. 28, 2022).

[34] Zihao Li, *et al.*, *Vital Signs: HIV Transmission Along the Continuum of Care—United States, 2016*, 68 MMWR 267, 267 (2019).

[35] *HIV Testing in the United States*, Kaiser Family Found. (June 24, 2022), https://www.kff.org/hivaids/fact-sheet/hiv-testing-in-the-united-states/.

[36] *Human Immunodeficiency Virus (HIV) Infection: Screening, 1996*, U.S. Preventive Servs. Task Force (Jan. 1, 1996),

expanded that recommendation in 2013 to include adolescents and adults aged 15 to 65 years and younger adolescents and older adults at increased risk.[37] The USPSTF recommendation means that HIV screening is covered by health plans for these populations, which helps increase HIV screening. In fact, in 2017, nearly half of all women between the ages of 18-64 reported having an HIV test at some point, and 16% of women reported having a test within the past year.[38]

In 2021, among people estimated by CDC to be living with HIV, 87% were diagnosed, meaning that 13% of people did not know their HIV-positive status and continued to transmit it without access to proper care.[39] Of those who tested positive, 80% were connected to care within one month after their diagnosis.[40]

HIV treatment is the next step in the HIV care continuum after someone is diagnosed. The dire threat posed by HIV prompted the U.S.

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https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/human-immunodeficiency-virus-hiv-infection-screening-1996.

[37] *Id.*

[38] *Women and HIV in the United States*, Kaiser Family Found. (Mar. 9, 2020), https://www.kff.org/hivaids/fact-sheet/women-and-hivaids-in-the-united-states.

[39] *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections*, CDC, https://www.cdc.gov/media/releases/2023/p0523-hiv-declines-among-young-people.html (May 23, 2023).

[40] *HIV Surveillance Report Supplemental Report*, CDC, https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-4 (May 23, 2023).

Food and Drug Administration ("FDA") to create the "accelerated approval pathway" in 1992, expediting access to new drugs for serious diseases.[41] Since then, over 40 drugs have been approved to treat HIV.[42]

While there still is no cure for HIV, these transformative developments have substantially reduced HIV-related morbidity and mortality and improved long-term outcomes for persons living with HIV.[43] The average age of death for a person living with HIV has steadily increased from 37.9 years in 1987 to 77 years in 2016.[44] Moreover, an individual with HIV who, through successful treatment, has achieved a consistently undetectable viral load cannot transmit the virus to others.[45]

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[41] Kylie Stengel, *Understanding the History and Use of the Accelerated Approval Pathway*, Avalere Health (Jan. 4, 2022), https://avalere.com/insights/understanding-the-history-and-use-of-the-accelerated-approval-pathway.

[42] *FDA-Approved HIV Medicines*, HIVinfo.NIH.gov, https://hivinfo.nih.gov/understanding-hiv/fact-sheets/fda-approved-hiv-medicines (Mar. 23, 2023).

[43] Hayden E. Klein, *Earlier ART Linked to Better Long-term HIV Outcomes*, Am. J. Managed Care (Nov. 3, 2022) https://www.ajmc.com/view/earlier-art-linked-to-better-long-term-hiv-outcomes.

[44] Jiaquan Xu, *QuickStats: Average Age at Death from HIV Disease, by Sex—United States, 1987–2013*, 64 MMWR 1228, 1228 (2015); Mark Mascolini, *Increased Overall Life Expectancy but not Comorbidity-free Years for People with HIV*, Conference on Retroviruses and Opportunistic Infection (Mar. 2020), https://www.natap.org/2020/CROI/croi_134.htm.

[45] *Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV*, CDC, https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html#anchor_1562942347 (June 17, 2022).

Advancements in treatment also led to highly effective HIV prevention medication. FDA approved the first PrEP product in 2012 and today PrEP comes in the form of a daily pill or long-acting injection.[46] PrEP has evolved into an extremely effective and accepted tool for the prevention of HIV, [47] reducing the risk of acquiring HIV by over 99%.[48]

In 2019, USPSTF issued a Grade A recommendation for PrEP, in turn eliminating copays for those with commercial health insurance. In 2022, approximately 31.4% of the people for whom PrEP is recommended were prescribed it, a marked increase from approximately 3% in 2015.[49] A principal aim of the Trump Administration's EHE initiative was to increase this number to 50% by 2030.[50] Of the 1.2 million people eligible for PrEP, an estimated 665,472, or just over half, are privately insured.[51]

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[46] *CDC Statement on FDA Approval of Drug for HIV Prevention*, CDC (July 16, 2012), https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html; *About PrEP*, CDC, https://www.cdc.gov/hiv/basics/prep/about-prep.html (June 30, 2022).

[47] *PrEP for HIV Prevention in the U.S.*, CDC, https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html (Nov. 23, 2021).

[48] *PrEP Effectiveness*, CDC, https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html (Jun. 6, 2022); CDC, "HIV Surveillance Report," *supra* note 40.

[49] *Charts*, CDC, https://gis.cdc.gov/grasp/nchhstpatlas/charts.html (last visited June 13, 2023).

[50] CDC, *"PrEP for HIV Prevention*," *supra* note 47.

[51] Amanda Honeycutt, *et al.*, HIV+Hepatitis Policy Inst., *U.S. PrEP Cost Analysis* 6 (2022).

USPSTF also recommends testing to prevent and reduce transmission of other sexually transmitted infections (STIs). Specifically for people with HIV, USPSTF recommends more frequent screenings for chlamydia, gonorrhea, syphilis, herpes, trichomoniasis, cervical cancer, anal cancer, as well as HCV and HBV.[52]

HIV screening and prevention is also synergistic with prevention of other sexually transmitted infections (STIs). A person with an STI is up to five times more likely to acquire HIV and is at increased risk of transmitting HIV to others.[53] In 2018, lifetime medical costs for the 1,896 new HIV transmissions attributed to chlamydia, gonorrhea, and syphilis totaled $800 million. [54]

The PrEP regimen includes not only the drug itself but also a host of essential support services including regular HIV testing; testing for kidney function, HBV, HCV, STIs and pregnancy; and adherence

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[52] *A & B Recommendations*, U.S. Preventive Servs. Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations (last visited June 8, 2023); *FAQs About Affordable Care Act Implementation Part 47*, Ctrs. for Medicare & Medicaid Servs. (July 19, 2021).

[53] CDC, *Reversing the Rise in STIs: Integrating Services to Address the Syndemic of STIs, HIV, Substance Use, and Viral Hepatitis*, https://www.cdc.gov/std/statistics/2019/syndemic-infographic.pdf (last visited June 5, 2023).

[54] *Id.*

counseling.[55] These services assure that PrEP is administered safely and effectively. They would be cost-prohibitive without no-cost coverage for the vast majority of those eligible for PrEP. The Kaiser Family Foundation found that approximately 40% of Americans have delayed or foregone medical care "due to cost."[56] The Commonwealth Fund found that a copayment as low as $5 lowers utilization.[57] Cost-sharing for PrEP and related services would discourage PrEP uptake, leading to increased risk of HIV transmission.

USPSTF recommendations have been indispensable in the fight to eliminate HIV. Together, the preventive services coverage requirement and USPSTF recommendations facilitate access to HIV screening and PrEP without any cost-sharing, including copays and deductibles. Lessened coverage of USPTSF-recommended services or allowing cost-sharing for these services can result in new HIV diagnoses, treatment-

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[55] Ctrs. for Medicare & Medicaid Servs, *supra* note 52.

[56] Alex Montero et al., *Americans' Challenges with Health Care Costs*, Kaiser Fam. Found. (July 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs.

[57] Brian Schilling, *Hitting the Copay Sweet Spot*, The Commonwealth Fund, https://www.commonwealthfund.org/publications/newsletter-article/hitting-copay-sweet-spot (last visited June 5, 2023).

resistant HIV, and delays in diagnosis and treatment, resulting in increased incidence of HIV/AIDS and worse societal health outcomes.[58]

4. The Lower Court's Ruling Risks Ending Hepatitis Prevention for Millions

Like HIV, hepatitis requires a complex continuum of care targeting detection and treatment of the virus and preventing transmission. The Trump Administration increased the federal government's commitment to ending hepatitis transmission with the January 2021 release of its Viral Hepatitis National Strategic Plan.[59] Hepatitis screening is broadly recommended for HBV and HCV to reduce morbidity and mortality, and transmission of the disease.[60] Beginning in 2009, USPSTF issued a Grade A recommendation for HBV screening among all pregnant women.[61] In 2014, USPSTF issued a Grade B recommendation for HBV

[58] *Early HIV Diagnosis and Treatment Important for Better Long-term Health Outcomes*, HIV.gov, https://www.hiv.gov/blog/early-hiv-diagnosis-treatment-important-better-long-term-health-outcomes (Nov. 2, 2022).
[59] U.S. Dep't Health and Hum. Servs., *Viral Hepatitis National Strategic Plan: A Roadmap to Elimination for the United States* (2021).
[60] Colleen Moriarty, *Hepatitis C: Why Screening Is Important for Baby Boomers and Millennials*, YaleMedicine (Oct. 5, 2020), https://www.yalemedicine.org/news/hepatitis-c-screening.
[61] *Hepatitis B in Pregnant Women: Screening*, U.S. Preventive Servs. Task Force (June 15, 2009), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-in-pregnant-women-screening-2009.

screening for all adolescents and adults at increased risk.[62] In 2020, USPSTF expanded its Grade B screening recommendation for HBV to include all adults aged 18 to 79 at increased risk.[63] In 2020, USPSTF expanded its prior recommendation to encourage HCV screening for all adults aged 18 to 79.[64] These recommendations facilitate coverage for hepatitis screening without cost-sharing, which is critical to early detection and treatment of hepatitis.[65] Because of the asymptomatic nature of HBV and HCV, without routine testing, people would not know of their hepatitis infection until it is too late.[66] Moreover, concurrent HBV, HCV, and HIV viruses are also associated with higher mortality

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[62] *Hepatitis B Virus Infection: Screening, 2014*, U.S. Preventive Servs. Task Force (June 18, 2014), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-screening-nonpregnant-adolescents-adults-may-2014.

[63] *Hepatitis B Virus Infection in Adolescents and Adults: Screening*, U.S. Preventive Servs. Task Force (Dec. 15, 2020), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-screening.

[64] *Hepatitis C Virus Infection in Adolescents and Adults: Screening*, U.S. Preventive Servs. Task Force (Mar. 2, 2020), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening.

[65] National Alliance of State and Territorial AIDS Directors, *Frequently Asked Questions: Insurance Coverage for Viral Hepatitis Treatment and Preventive Services* 4 (2022).

[66] *Viral Hepatitis Preventive Services Coverage*, CDC, https://www.cdc.gov/nchhstp/highqualitycare/preventiveservices/hepatitis.html (May 5, 2020); *Viral Hepatitis and the Affordable Care Act*, U.S. Dep't Health and Hum. Servs., https://www.hhs.gov/hepatitis/policies-and-guidelines/affordable-care-act/index.html (May 13, 2016).

risk than any of these respective diseases alone.[67] USPSTF's recommendations are critical to reducing transmission of HIV and hepatitis, and should not be undermined.

B. The Preventive Services Coverage Requirement to Cover PrEP Does Not Violate RFRA

1. Coverage of HIV Prevention Does Not Substantially Burden Appellees'/Cross-Appellants' Religious Exercise

The ACA's requirement to cover preventive services, including PrEP for HIV, does not substantially burden Appellees'/Cross-Appellants' religious exercise. The district court erred in accepting their claim that this requirement would force complicity in several behaviors,[68] including homosexual behavior, drug use, and "sexual activity outside of marriage between one man and one woman."[69] No research demonstrates that having access to PrEP causes individuals to engage in said behaviors. In fact, research has shown the opposite – that negative stigmatization of PrEP discourages PrEP use among those who most

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[67] Zahid A. Butt, *et al.*, *Concurrent Hepatitis C and B Virus and Human Immunodeficiency Virus Infections Are Associated With Higher Mortality Risk Illustrating the Impact of Syndemics on Health Outcomes*, 7 Open Forum Infectious Diseases 3 (2020).
[68] ROA.1816.
[69] ROA.2112.

need it, including HIV-negative partners in monogamous, heterosexual relationships.[70]

Rather than evaluate the sincerity of Appellees'/Cross-Appellants' religious beliefs, this Court has the "narrow function . . . to determine" whether the line [the plaintiffs have] drawn reflects "an honest conviction[.]"[71] Thus, courts must still gauge whether a law substantially burdens religious exercise – whether there is in fact a line or nexus between plaintiffs' sincere conviction and the activity that will occur.

The Supreme Court provides a basis for this narrow analysis in *Burwell v. Hobby Lobby Stores, Inc.*[72] and *Thomas v. Review Board of Indiana Employment Security Division*,[73] where both plaintiffs drew a line that reflected the undisputed, factual circumstance to which they objected to protect the religious beliefs they believed were violated. For example, plaintiffs in *Hobby Lobby* objected to the ACA's requirement to provide insurance coverage for contraceptives, believing certain

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[70] Lisa A. Eaton, Seth C. Kalichman et al., *Stigma and Conspiracy Beliefs Related to Pre-exposure Prophylaxis (PrEP) and Interest in Using PrEP Among Black and White Men and Transgender Women Who Have Sex with Men*, 21 AIDS Behav.1236, 1236 (2017).
[71] *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 725 (2014).
[72] *Id.*
[73] 450 U.S. 707, 716 (1981).

contraceptives would cause embryo destruction—a fact the government did not contradict.[74] Plaintiffs argued that the medication's function of embryo destruction was the moral wrong, rather than sexual activity itself.[75]

In *Thomas*, a plaintiff employed to make multi-use sheet steel was transferred to a job making turrets for tanks.[76] He was then denied unemployment insurance when he left his job because he was unwilling to participate in building weapons, which would have facilitated war or conflict.[77] In both cases, all parties agreed upon the underlying facts – contraceptives acted on the human body in a particular manner and manipulation of steel into a turret was an element of building a weapon for war.

There is no such nexus here. Appellees/Cross-Appellants do not contend that interrupting the spread of HIV is a moral wrong, and thus, the line they draw against providing PrEP does not reflect the true object of their sincerely held religious convictions. Refusing coverage for PrEP in spite of this non-existent nexus will reduce access to PrEP and

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[74] *See generally, Hobby Lobby*, 573 U.S. at 682; *Id.* at 697.
[75] *Id.* at 701.
[76] *Thomas,* 450 U.S. at 709.
[77] *Id.*

ultimately facilitate transmission of HIV to people who engage in heterosexual activity within a marital relationship as well as people who are at risk of acquiring HIV from the specific activities they oppose. It will not have an impact on furthering or restricting the behaviors to which they sincerely object.

Simply put, PrEP is for people who do not have HIV and do not wish to acquire HIV. PrEP will work in the same manner regardless of whether a person is in a heterosexual or same-sex relationship. HIV can be transmitted in a monogamous or non-monogamous relationship. It can be transmitted by methods that do not involve sexual contact or needle sharing, such as childbirth and breastfeeding. If an HIV-negative person wishes to marry someone living with HIV – known as a serodiscordant couple – and to have an intimate relationship in the privacy of their marriage, that person would be a good candidate for PrEP, because they know that they would be at a heightened risk for exposure and do not wish to acquire HIV or risk transmitting it to their children.

2. Health Coverage for HIV Prevention is a Compelling Governmental Interest

Appellees/Cross-Appellants have not disputed the government's compelling interest "in preventing the spread of infectious disease, the

severity of HIV, or the effectiveness of PrEP."[78] Similarly, the Supreme Court has permitted the assumption in decisions involving coverage for contraceptives that the government has a compelling interest in requiring coverage.[79] The lower court here did not concede to a similar assumption, casting the requirement to cover PrEP as a "generalized policy" without connection to employers such as Braidwood.[80]

In fact, the government has two compelling interests – both economic and public health – in assuring coverage of HIV preventive services, including PrEP, for millions of Americans through health insurance, including employer-sponsored coverage.

(a) Congress Had a Compelling Interest in Stabilizing Insurance Markets with Reforms That Included the Preventive Coverage Requirement

As best expressed by Chief Justice John Roberts, "Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them."[81] Indeed, the Supreme Court has consistently recognized

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[78] ROA.1818.
[79] *See, generally, Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682 (2014).
[80] ROA.1812.
[81] *See King v. Burwell*, 576 U.S. 473, 498 (2015).

the delicate nature of health insurance regulation.[82] After the "death spirals" of the health insurance market in the early 1990s, Congress made incremental reforms, first through the Health Insurance Portability and Accountability Act, and ultimately through the ACA, to shore up the highly complex, multi-market U.S. health insurance system.[83]

The Court has recognized what is commonly referred to as the "three-legged stool" of health insurance coverage: (1) the individual mandate and minimum essential coverage; (2) guaranteed issue; and (3) and subsidies to ensure access.[84] The first leg of this stool ensures that the vast majority of Americans receive health insurance containing minimum essential coverage, including cost-free preventive care.

Ensuring this coverage achieves many goals of the insurance regulation Congress undertook, including promotion of good health

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[82] *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 521-22 (2012) (determining the fate of the act's individual mandate and Medicaid expansion provisions; *see also id.* (upholding the ACA's tax credits); *California v. Texas,* 141 S. Ct. 2104, 2120 (2021) (finding that the ACA's tax penalty was severable, thus upholding the ACA in its entirety).

[83] *See*, Timothy Stoltzfus Jost and John E. McDonough, in The Trillion Dollar Revolution: How the Affordable Care Act Transformed Politics, Law, and Health Care in America, 32-33 (Ezekiel J. Emanuel & Abbe R. Gluck eds., 1st ed. 2020).

[84] *See, e.g.*, Sabrina Corlette et al., *The ACA's Effect on the Individual Insurance Market*, 39 Health Affairs 436, 437 (2020), https://www.healthaffairs.org/doi/10.1377/hlthaff.2019.01363.

outcomes, achieving robust risk pools, and reducing health care costs overall. The Supreme Court has consistently declined to dismantle the stool,[85] but district court's decision in this case would begin to whittle away at the leg that ensures minimum essential coverage. The wobblier the stool becomes, the greater the "spike in medical costs for a few participants has a greater influence on overall health plan costs for a small risk pool compared to a large risk pool."[86]

Preventive services protect beneficiaries, payors, and employers from costlier care in the future. Treatment for preventable conditions is generally more costly than prevention, particularly treatment for chronic conditions.[87] For example, HIV anti-retroviral therapy costs between $2,000 to $9,000 per month and approximately $510,000 over an individual's lifetime.[88] Direct expenditure related to HIV care and treatment between 2002 and 2011 was estimated to be between 800% and

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[85] *See, generally, Nat'l Fed'n of Indep. Bus.*, 567 U.S. at 589; *King v. Burwell*, 576 U.S. 473 (2015); *California v. Texas*, 141 S. Ct. 2104 (2021).
[86] *Id.*
[87] *Health and Economic Costs of Chronic Diseases*, CDC, https://www.cdc.gov/chronicdisease/about/costs/index.htm (Mar. 23, 2023, 12:00 AM).
[88] *How Much Does HIV Treatment Cost?*, WebMD, https://www.webmd.com/hiv-aids/hiv-treatment-cost (Aug. 3, 2022); *Summary of Information on the Safety and Effectiveness of Syringe Services Programs (SSPS)*, CDC, https://www.cdc.gov/ssp/syringe-services-programs-summary.html (Jan. 11, 2023).

900% higher than spending for other chronic health conditions.[89] Therefore, if employers were allowed broad exemptions fewer of those at-risk would have access to PrEP and more people will require costly HIV treatment. If a sufficient number of employers and other individuals were to request and be granted similar exemptions, insurance markets would be imperiled. Moreover, this directly contradicts the Appellees'/Cross-Appellants' argument that premiums would be lower if they did not have to provide coverage that includes PrEP.

(b) Congress's Delegation to USPSTF Does Not Alter Its Compelling Interest

The district court erred in its determination that the government did not express a "compelling interest in forcing employers to cover PrEP drugs in their insurance policies" because "Congress did not reflect that interest in the ACA" but rather "reflected an interest in compelling coverage for whatever [USPSTF] happens to recommend as having an "A" or "B" rating."[90] It likewise erred in its determination that requiring

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[89] *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with* HIV, HIV.gov, https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/antiretroviral-therapy-cost-considerations#:~:text=However%2C%20HIV%20treatment%20with%20ART,the%20costs%20attributable%20to%20ART (Mar. 23, 2023).
[90] ROA.1818.

PrEP coverage does not achieve a compelling interest, such as preventing HIV and lowering health care costs.

3. Congress was Deliberate in Selecting USPSTF's Recommendation Process to Serve as the Basis for Which Services Employers Should Be Required to Cover in Order to Ensure That Those Who Would Benefit Have Access to Appropriate Preventive Services.

The district court found fault with the government's argument that requiring employer-sponsored coverage without cost sharing for PrEP was the least restrictive means because it opined that instead, the government could provide PrEP for individuals whose employers received religious exemptions.[91] The lower court drew this suggested alternative from *Burwell v. Hobby Lobby Stores, Inc.*[92] that the government could simply provide the four objectionable contraceptive methods to employees.

First, the facts in *Hobby Lobby* and this case are not analogous. In *Hobby Lobby*, the plaintiffs objected to four out of twenty types of contraceptives.[93] Thus, even if the employer refused to cover these four, the plan beneficiaries would still have access to sixteen options for

[91] ROA.1819 – 1820.
[92] 573 U.S. 682, 692 (2014).
[93] *Hobby Lobby,* 573 U.S. at 683.

contraceptive access. Here, the Appellees/Cross-Appellants do not object to one type of PrEP– they do not wish to cover PrEP at all.

Under the status quo, the individuals who need PrEP have better access. If Appellees/Cross-Appellants or similarly situated employers object to *facilitating* employee access to PrEP, it would be unrealistic to then expect an employer's cooperation in securing alternative access to PrEP. For example, an employer requesting an exemption could object to a government requirement to communicate to beneficiaries that they have requested an exemption and thus, PrEP would remain out of reach, because this aid could be perceived as complicity. Instead, the government would bear the onus of somehow gaining access to the employers' plan information, which it may not be willing to provide, to send a notice or otherwise make it known to employees that they would qualify for separate government coverage.

Meanwhile, the employer's requested exemption would then shift the burden of securing health insurance coverage to the employee or plan beneficiary, who may not have the time or resources to navigate a separate program. Moreover, understanding plan coverage limitations can be confusing to patients. For example, if the employee is not aware

that their employer has declined to cover PrEP, they may not immediately understand why coverage is denied and face the frustration and exhaustion of futile appeals.

Further, these scenarios are bound to heighten the already pervasive stigma surrounding HIV. Indeed, it would convey to the employee that his or her employer not only does not approve of but finds the employee's behavior morally objectionable. Worse still, the government has endorsed this disapproval by allowing an exemption that will, ultimately, shift the burden to the employee and potentially deprive them of PrEP. Ultimately, the lower court's proposed remedy would only exacerbate stigma, reduce PrEP use, and result in an increase in HIV transmission, contravening the compelling governmental interest.

Ironically, employers who obtain religious exemptions to PrEP coverage would still be required to cover medically necessary HIV anti-retroviral therapies for their employees who contract HIV, increasing the cost of insurance for the entire risk pool. Increased premiums harm both the employer and the employees as well as contribute to the ever-rising cost of health care.

4. Permitting Appellees'/Cross-Appellants' RFRA Exception Will Impermissibly Broaden RFRA

In our society, "your right to swing your arms ends just where the other man's nose begins."[94] The lower court's ruling could initiate a torrent of coverage objections under RFRA that could further fragment health insurance coverage. To that end, courts have recognized that a religious claimant's proposed less restrictive means of achieving the compelling interest would not be valid if such alternative means would impose harm on society.[95]

RFRA is untenable if it operates as a blunt tool, invalidating entire laws or regulatory schemes at the behest of individual objectors, contorting the ability to fulfill statutory and regulatory aims and obligations. To permit Appellees/Cross-Appellants to prevail would be "the regulatory equivalent of taxing non-adherents to support the faithful."[96] In other words, a religious accommodation should aim not to come at the expense of others or of society. Instead, courts should

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[94] Zechariah Chafee, Jr., *Freedom of Speech in War Time*, 32 Harv. L. Rev. 932, 957 (1919).

[95] *See Cutter v. Wilkinson*, 544 U. S. 709, 722-23 (2005) (interpreting the Religious Land Use and Institutionalized Persons Act of 2000, which uses a similar least restrictive means test).

[96] Brief of Church-State Scholars as *Amici Curiae* in Support of Respondents at 3, *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367 (2020) (Nos. 19-431 and 19-454).

narrowly tailor relief to the particular facts of the plaintiffs to ensure that the requested relief addresses the stated burden. Here, Appellees/Cross-Appellants have not asked for a remedy that will provide the relief they request. Instead, their overbroad relief will pave the way for absurd results and significant negative externalities:

- The Appellees/Cross-Appellants could object to paying Family and Medical Leave Act compensation where an employee is caring for a child born out of wedlock.
- Jehovah's Witness employers could deny coverage of surgeries requiring blood transfusions.
- Christian Scientist employers could refuse to cover common medical services for non-religious employees on the basis that healing should occur though prayer rather than modern medicine.

Courts could be drawn into a dizzying spiral of RFRA exemptions. In this case, fewer people will be able to access preventive services, including PrEP, as well as other recommended preventive services. The consequences — a worsened public health crisis, increased HIV transmission and health care costs, and undermined insurance markets

— would be devastating. Accepting the lower court's holdings would reverberate in the form of perverse and unlimited exemptions, costing society as a whole at the hands of a few.

CONCLUSION

For the foregoing reasons, *amici* respectfully submit that the Court preserve the ability of the Secretary of the Department of Health and Human Services to adopt the USPSTF's recommendations so that they may continue to facilitate access to life-saving HIV and hepatitis preventive interventions.

Furthermore, we urge the Court to find that denying access to PrEP is inconsistent with and impermissibly broadens RFRA's religious liberty protections, causing great harm to our society by inevitably causing increased HIV transmission.

Dated: June 23, 2023

Respectfully submitted,

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**U.S. Court of Appeals Fifth Circuit Admission Pending*
***Admitted to the Bar Under D.C. App. R. 46-A*

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CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2023, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system.

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 4,763 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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No. 23-10326 Braidwood Mgmt v. Becerra
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Dear Mr. Hughes,

The unopposed motion for leave to file amici brief is unnecessary. The brief has been filed.

However, please include in the sufficient brief that you have consent for filing same. Also, the brief is lacking a statement per FRAP 29(a)(4)(E). Please make both of these corrections within 14 days from this date, and please refile using the proposed sufficient brief event.

Sincerely,

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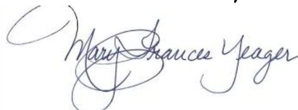

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