

February 13, 2023

Braidwood Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community

Meredithe McNamara, MD MSc, Section of General Pediatrics, Department of Pediatrics, Yale School of Medicine

Dini Harsono, MSc, Center for Interdisciplinary Research on AIDS, Yale School of Public Health

E. Jennifer Edelman, MD, MHS, Section of General Internal Medicine, Department of Internal Medicine, Yale School of Medicine, and Center for Interdisciplinary Research on AIDS, Yale School of Public Health

Aliza Norwood, MD, FACP, AAHIVS, Division of General Internal Medicine, Department of Internal Medicine, University of Texas at Austin Dell Medical School

Samantha V. Hill, MD MPH, Division of Adolescent Medicine, Department of Pediatrics, University of Alabama at Birmingham

A. David Paltiel, MBA PhD, Yale School of Public Health, Yale School of Management

Gregg Gonsalves, PhD, Yale School of Public Health

Anne Alstott, JD, Yale Law School¹

Introduction and Executive Summary

In September 2022, a federal district judge in Texas ruled in favor of plaintiffs challenging the federal mandates requiring that private insurance policies cover pre-exposure prophylaxis (PrEP), medications that are highly effective in preventing infection with human immunodeficiency virus (HIV), a highly infectious, chronic disease. This virus, if untreated, leads to the deadly disease widely known as acquired immunodeficiency syndrome (AIDS).²

PrEP is one of the most celebrated biomedical successes in the global fight to end the HIV epidemic. Based on the highest quality scientific evidence, the United States Preventive Services Task Force (USPSTF) gave an “A” rating to PrEP, meaning that the USPSTF recommends PrEP as routine preventive care and has concluded that “[t]here is high certainty that the net benefit is substantial.”³ Federal law requires most private insurers to cover preventive care strongly recommended by the USPSTF.⁴ Accordingly, as of June 2020, insurers were required to cover

¹ We received no funding for this project and have no conflicts of interest to declare. The views expressed here are those of the authors and not those of Yale University, the University of Texas, or the University of Alabama. For helpful comments, we thank Nancy Knauer, Wendy Parmet, and Lindsay Wiley.

² *Braidwood Management Inc. v. Becerra*, Civ. Act. No. 4:20-cv-00283-O, N.D. Tx (Sept. 7, 2022), at https://storage.courtlistener.com/recap/gov.uscourts.txnd.330381/gov.uscourts.txnd.330381.92.0_2.pdf.

³ US. Preventive Services Task Force, *Prevention of HIV Infection: Pre-Exposure Prophylaxis*, June 11, 2019, at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#fullrecommendationstart>. For the PrEP evidence review, see Roger Chou et al., *Pre-Exposure Prophylaxis for the Prevention of HIV Infection: A Systematic Review for the U.S. Preventive Services Task Force*, Report No.: 18-05247-EF-1 (June 2019), at <https://www.ncbi.nlm.nih.gov/books/NBK542888/>.

⁴ See 42 U.S.C. § 300gg-13(a)(1) (requiring health insurance plans to cover, without cost sharing, “evidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force”).

PrEP when medically indicated without cost sharing (inclusive of the medicine, labs, and associated office visits) according to stated eligibility criteria (the “PrEP Mandate”).⁵ Furthermore, the U.S. Department of Health and Human Services launched the Ending the HIV Epidemic (EHE) initiative, which outlines a plan to end HIV by 2030 and calls for wide distribution and use of PrEP in high-risk areas. The Center for Disease Control (CDC), in its 2021 Guidelines, has recommended that medical providers discuss PrEP with all sexually active patients.

Despite the demonstrated benefits of PrEP for individual patients and for public health, a U.S. district court in *Braidwood Management v. Becerra (Braidwood)* granted two separate legal challenges to the PrEP Mandate. First, the court held that the process for appointing the USPSTF violated the U.S. Constitution, specifically the Appointments Clause. The court has not yet ordered a remedy, but the plaintiffs have requested a nationwide injunction. If this injunction is granted and upheld, the result could be to invalidate all preventive care mandates issued by the USPSTF. These mandates include not only PrEP but also cancer screenings and immunizations, as well as medications including statins (to prevent cardiovascular disease) and metformin (to prevent and treat diabetes).⁶

Second, the Texas district judge ruled that the PrEP Mandate violates the *Braidwood* plaintiffs’ rights under the Religious Freedom Restoration Act (RFRA). The plaintiff had alleged that “providing coverage of PrEP drugs ‘facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman,’ and [that] providing coverage of PrEP drugs in Braidwood’s self-insured plan would make him complicit in those behaviors.”⁷

The *Braidwood* ruling held that the government has no “compelling interest” in mandating private insurance coverage of PrEP, but the decision did not discuss the scientific evidence on the benefits of PrEP in any depth. The decision further endorsed harmful stereotypes and empirical assumptions about the relationships between PrEP, human behavior, and sexual orientation that have been and continue to be disproven by scientific evidence. The decision also failed to address the public health consequences of granting a religious exemption to the PrEP Mandate. The *Braidwood* court has not yet ruled on remedies, but the plaintiffs in the case have advocated a nationwide injunction on all USPSTF mandates, including the PrEP Mandate. Whatever the court’s decision on remedies may be, the rulings made in *Braidwood* are likely to be the subject of appeals and ongoing litigation.

Several medical societies, including the American Medical Association and the American Cancer Society, have publicly opposed any nationwide injunction directed at the USPSTF mandates,

⁵ 45 C.F.R. § 147.130(b)(1). Centers for Medicare and Medicaid Services, FAQs About Affordable Care Act Implementation Part 47 (July 19, 2021), at <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf>

⁶ USPSTF, Statin Use for the Primary Prevention of Cardiovascular Disease in Adults (Aug. 23, 2022), at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/statin-use-in-adults-preventive-medication>; USPSTF, Prediabetes and Type 2 Diabetes (Aug. 24, 2021), at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>.

⁷ *Braidwood*, at 37.

emphasizing the importance of these mandates for public health (e.g., promoting guideline consistent cancer screening).⁸ Legal and public health scholars have also questioned the soundness of the *Braidwood* decision.⁹ In this report, we contribute a specific focus on the PrEP Mandate. Our goal is to inform litigation and policy by summarizing the scientific evidence that demonstrates the compelling public interest in unfettered access to PrEP. Because *Braidwood* is a U.S. decision, we focus on the scientific evidence showing that HIV remains a serious and deadly threat to public health and that PrEP is a remarkably valuable preventative that benefits not only men who have sex with men but many groups including minority communities, women, and children. We show that the *Braidwood* decision disregards the compelling state interest in HIV prevention via private insurance and fails to consider the state's compelling interest in LGBTQ (lesbian, gay, bisexual, transgender, and queer) equality. We also demonstrate that *Braidwood* constructs a religious exemption that rests on unfounded empirical assertions and opens a legal loophole so vast that it could permit many businesses to claim a religious exemption and opt out of virtually *any* type of preventative measure or health care.

Our analysis makes two critical points:

- *First, the scientific evidence demonstrates that, contrary to the finding in Braidwood, the state has a compelling public interest in enforcing the PrEP Mandate, which benefits the entire community as a public health measure, much like any vaccine or preventative for any transmissible infection.* PrEP has been well-studied and proven to prevent the transmission of HIV, an infection that requires lifelong treatment.¹⁰ In sections I through IV, this report documents in detail the scientific evidence showing the individual- and community-level risks for acquiring HIV and how PrEP effectively reduces those risks.
 - Put simply, the *Braidwood* decision incorrectly frames PrEP as a medication that benefits only some individuals. The court gives too little weight to the fact that, like other preventative measures against infectious disease, the PrEP Mandate protects not only those individuals who take the medication but all members of their larger community and social networks. If the *Braidwood* court decides to enjoin the PrEP Mandate and to grant a religious exemption to PrEP insurance coverage, the *Braidwood* decision will undermine public health for all.
 - The public health consequences of an injunction against the PrEP Mandate would be serious and adverse. Our colleagues at Harvard and Yale modeled the consequences of ending the PrEP Mandate. They found that if PrEP coverage among men who have sex with men is reduced from its current base value of 28%

⁸ See Brief of Amici Curiae American Medical Association, American College Of Obstetricians And Gynecologists, et al., In Support Of Defendants' Motion For Summary Judgment, *Braidwood v. Becerra*, N.D. Tex., Dec. 1, 2022, at <https://www.courtlistener.com/docket/18366645/108/braidwood-management-inc-v-xavier-becerra/>; Amici Curiae Brief Of The American Cancer Society, American Cancer Society Cancer Action Network, et al., Supporting Defendants' Response, *Braidwood v. Becerra*, N.D. Tex., Dec. 1, 2022, at <https://www.courtlistener.com/docket/18366645/107/braidwood-management-inc-v-xavier-becerra/>

⁹ Mello M, and O'Connell AJ. The Fresh Assault on Insurance Coverage Mandates, *NEJM* 2023;388:1-3.

¹⁰ Donnell D, Baeten JM, Bumpus NN, Brantley J, Bangsberg DR, et al. HIV protective efficacy and correlates of tenofovir blood concentrations in a clinical trial of PrEP for HIV prevention. *J Acquir Immune Defic Syndr*. 2014;66(3):340-8. We provide detailed citations in the body of this report.

to 10%, we expect to observe an additional 2,083 new HIV infections (up from a base of 28,200 infections) in the coming year. This is likely a lower-bound estimate, as we explain in Section IV below.

- *Second, the Braidwood religious exemption ignores the compelling state interest in LGBTQ equality and would invite religious employers (or those who claim to be religious) to deny insurance coverage for nearly any health condition.* We show that, on any of three legal interpretations, the *Braidwood* religious exemption disregards compelling state interests in protecting public health and protecting LGBTQ people from invidious stereotyping and exclusion. Further, the religious exemption sketched in *Braidwood* is so overbroad that its logic could justify a religious exemption to *any* public health protective measure, and indeed any medical treatment of any type, because any such measure could benefit LGBTQ people.
 - In the simplest terms, the *Braidwood* ruling attempts to reduce PrEP, a highly effective, evidence-based measure for preventing HIV, to a niche treatment that “supports” sexual orientations, sexual behavior, and substance use that the plaintiffs oppose on religious grounds. In fact, PrEP is used by hundreds of thousands of people in the U.S. of all sexual orientations, genders, and marital statuses. Due to structural racism, racial and ethnic minoritized groups are most impacted by HIV and have the greatest potential to benefit from PrEP. The *Braidwood* decision glosses over the compelling state interest in HIV prevention. And the decision’s religious exemption appears to be based on factually incorrect stereotypes about PrEP and its benefits.
 - The *Braidwood* decision seems to claim that any religious exemption to the PrEP Mandate should be granted without regard to the actual facts and based solely on spiritual belief. But that logic would permit a religious employer to deny insurance coverage for *any* medical condition for any group whose conduct is disfavored by the religion. Emergency treatment for heart failure, for example, could preserve the lives of LGBTQ people or unmarried people, thus “facilitating” their sexual relationships. Further, the *Braidwood* religious exemption would open the door to such an objection from nearly any employer, because the courts cannot reliably distinguish between sincere and insincere religious beliefs.

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Analysis

I. THE PREP MANDATE SERVES THE COMPELLING STATE INTEREST OF PROTECTING INDIVIDUAL AND PUBLIC HEALTH BY REDUCING THE SPREAD OF HIV, AN INFECTIOUS, CHRONIC DISEASE THAT REQUIRES LIFELONG TREATMENT, WHICH REMAINS A MAJOR BURDEN ON U.S. PUBLIC HEALTH.

We begin with a brief review of the HIV epidemic in the United States, including current patterns of virus transmission and healthcare practices. These facts are largely ignored by the court's ruling in *Braidwood*, which did not consider the massive cost to public health if the USPSTF mandates, including the PrEP Mandate, were ruled to be invalid.

About 1.2 million Americans have been infected with HIV, with approximately 35,000 new diagnoses in 2019.¹¹ There is no cure for HIV, which progresses to acquired immunodeficiency syndrome (AIDS) if untreated. AIDS compromises the immune system so thoroughly that, without treatment, the average time from immunologic failure to death is 3 years.¹² Anyone can be at risk for acquiring HIV, with some groups are more likely to be infected than others including sexually active people, men who have sex with men, and people who inject drugs.

Due to significant scientific advances in HIV treatment, HIV is a manageable chronic disease for those able to access necessary health care. HIV can be treated with antiretroviral therapy (ART), a combination of medications that can reduce an individual's viral load and prevent transmission to sexual or drug injecting partners.

Viral suppression is the hallmark of successful HIV treatment and occurs with consistent use of ART. To maintain virologic suppression, people with HIV must take about 85% of their prescribed ART. Those who have undetectable viral loads for six months or more cannot transmit HIV through sexual contact, a landmark public health discovery known as “U equals U” or “undetectable equals untransmittable.”¹³ Thus, retaining individuals in care and supporting consistent use of ART to achieve an undetectable viral load are crucial goals of comprehensive care and prevention. Viral suppression requires several events in sequential order: (1) testing and identification of positive cases, (2) linkage to care, (3) retention in care, and (4) consistent use of ART. Several factors can impede this process, including HIV-related stigma, poor access to HIV services, and lack of social support.¹⁴

¹¹ HIV.gov, U.S. Statistics, Fast Facts, at <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics#:~:text=Fast%20Facts,who%20have%20sex%20with%20men>. In 2019, 34,800 new HIV diagnoses were reported in the U.S. In 2020, the last year for which reported data are available, diagnoses fell to 30,635, but the decrease was likely due to COVID-19 pandemic barriers to testing. *Id.*

¹² HIV.gov, What are HIV and AIDS?, at <https://www.hiv.gov/hiv-basics/overview/about-hiv-and-aids/what-are-hiv-and-aids>.

¹³ Rodger AJ, Cambiano V, Bruun T, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodifferent Couples When the HIV-Positive Partner Is Using Suppressive Antiretroviral Therapy. *JAMA*.2016;316(2):171–181.

¹⁴ Geter A, Sutton MY, Hubbard McCree D. Social and structural determinants of HIV treatment and care among black women living with HIV infection: a systematic review: 2005-2016. *AIDS Care*. 2018 Apr;30(4):409-416; Gari S, Doig-Acuña C, Smail T, Malungo JR, Martin-Hilber A, Merten S. Access to HIV/AIDS care: a systematic review of socio-cultural determinants in low and high income countries. *BMC Health Serv Res*. 2013 May 28;13:198.

Although ART is a life-saving advancement, it is not 100% effective and does not nullify the public health risk of HIV. Many people with HIV do not take ART – out of the 1.2 million people in the United States living with HIV, 13% do not know they are infected (4 in 10 young adults), and only 65.9% have received any form of HIV care.¹⁵ In Texas, for instance, nearly 15% of people with HIV do not know their status.¹⁶ Without detection and treatment, HIV can be transmitted to sexual partners and can progress to AIDS.

While the annual rate of rise in new HIV infections is slowing, 34,800 people were diagnosed with HIV in 2019, with disproportionate effects felt among women, minority populations and youth. In a sobering call to action in 2016, the CDC released risk estimates projecting that 1 in 2 Black men who have sex with men and 1 in 5 Latino men who have sex with men will be diagnosed with HIV during their lifetimes without systematic prevention efforts that improve upon the status quo.¹⁷ HIV creates particularly harsh health risks for adolescents and young adults, who face unique challenges in achieving viral suppression. In 2020, adolescents (13–19 years old) and young adults (20–24 years old) constituted 3% of the total number of people with HIV in the United States but accounted for 20% of newly diagnosed infections.¹⁸ Only 12% of those aged 12–24 years living with HIV have undetectable viral loads and 25% of adolescents and young adults with HIV have not received care of any kind.¹⁹

Thanks to scientific innovation, effective treatments are now available, and HIV diagnosis is no longer necessarily a death sentence. However, once an individual has the infection, they face a host of potential health issues including HIV comorbidities (e.g., diabetes, hypertension) and co-infections (e.g., Hepatitis C), barriers to accessing care, and HIV treatment non-adherence that carries the potential for developing drug resistance.²⁰ Thus, given the unavoidability of certain harms once infection occurs, prevention is the bedrock of a multifaceted public health response to HIV.

Even individuals with optimally treated HIV face the sequelae of chronic disease. Some people experience impaired kidney function and bone density loss, a known adverse effect of first-line choices for ART. Over time, HIV causes chronic immune activation and premature aging, with many associated negative health effects. Between 25 and 50% of people with HIV develop HIV-

¹⁵ HIV.gov, U.S. Statistics, Fast Facts, at <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>.

¹⁶ <https://www.dshs.texas.gov/hiv-std-program/hiv-dashboard/texas-dshs-hiv-std/epi-profile-section-1>

¹⁷ HIV.gov, U.S. Statistics, Fast Facts, at <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>.

¹⁸ Lamb MR, Fayorsey R, Nuwagaba-Biribonwoha H, et al. High attrition before and after ART initiation among youth (15–24 years of age) enrolled in HIV care. *AIDS*. 2014;28:559–68; Miller RL, Chiaramonte D, Strzyzkowski T, Sharma D, Anderson-Carpenter K, Fortenberry JD. Improving Timely Linkage to Care among Newly Diagnosed HIV-Infected Youth: Results of SMILE. *J Urban Health*. 2019;96:845–55.

¹⁹ Centers for Disease Control and Prevention. Monitoring selected national HIV prevention and care objectives by using HIV surveillance data—United States and 6 dependent areas, 2019. *HIV Surveillance Supplemental Report* 2021;26(No.2).

²⁰ Joel Gallant, Priscilla Y Hsue, Sanatan Shreay, Nicole Meyer. Comorbidities among US patients with prevalent HIV infection—a trend analysis, *J Infect Dis*, 2017 Dec.; 216(12); 1525–1533; Higa DH, Marks G, Crepaz N, Liao A, Lyles CM. Interventions to improve retention in HIV primary care: a systematic review of U.S. studies. *Curr HIV/AIDS Rep*. 2012 Dec;9(4):313–25; Benson C, Wang X, Dunn KJ, Li N, Mesana L, Lai J, Wong EY, Chow W, Hardy H, Song J, Brown K. Antiretroviral adherence, drug resistance, and the impact of social determinants of health in HIV-1 patients in the US. *AIDS Behav*. 2020 Dec;24(12):3562–3573.

Associated Neurocognitive Disorder (HAND), a spectrum of cognitive, motor and/or mood disorders, the most severe manifestation of which is dementia. Cardiovascular disease, including heart attack and heart failure, are also known consequences of chronic infection. Compared to age-matched controls without HIV, those with HIV have higher rates of non-AIDS related cancers such as Hodgkin's lymphoma and breast, lung, cervical, colorectal, anal, and prostate cancer.²¹ People with HIV are diagnosed with these comorbidities at much earlier ages and live fewer years than people without HIV.²²

Resistance of HIV to various types of ART is a reality for many people who are perinatally-infected, meaning those who acquired HIV at birth, and long-term survivors, meaning those whose infection predates the advent of ART or who have been infected for ten years or more. These individuals often need to use complex ART regimens with multiple pills that are harder to comply with and have a greater risk of toxicity.²³ Resistance is also more likely to occur in individuals who do not take ART consistently. Factors associated with non-adherence to treatment include co-morbid mental illnesses such as depression and post-traumatic stress disorder (of which there are a disproportionately high incidences in people with HIV), residing in a nonmetropolitan location, stigma, lack of health insurance, housing instability and young age. Those who miss even a single visit in the first year of care have nearly twice the mortality rate of those who do not.²⁴ Approximately 43% of community transmission is attributable to those who are diagnosed with HIV but not receiving medical care.²⁵

The public and private costs related to HIV are astronomical. The United States federal government alone dedicates \$28 billion per year to HIV programs and research spending.²⁶ The estimated lifetime treatment cost of a single case of HIV is \$420,000, a figure that does not consider reduction in quality of life due to impact on employment, as well as physical and mental functioning.²⁷ HIV can constrain an individual's ability to work and earn income, in part due to its effects on physical and mental functioning. Work responsibilities may conflict with health care needs, which are high in the first few years following diagnosis. Those with less advanced educational backgrounds are at a particularly high risk for employment loss. Not only does HIV impact many people who are economically disadvantaged, but its economic burden tends to

²¹ Mitsuyasu RT. Non-AIDS-defining cancers. *Top Antivir Med.* 2014;22(3):660-665.

²² Marcus JL, Leyden WA, Alexeeff SE, et al. Comparison of overall and comorbidity-free life expectancy between insured adults with and without HIV infection, 2000-2016. *JAMA Netw Open.* 2020;3(6):e207954.

²³ McClung RP, Oster AM, Ocfemia MCB, Saduvala N, Heneine W, Johnson JA et al. Transmitted drug resistance among HIV-1 diagnoses in the United States, 2014–2018. *Clin Infect Dis.* 2022 Mar 23; 74(6):1055-1062.

²⁴ Mugavero MJ, Lin HY, Willig JH, Westfall AO, Ulett KB, Routman JS, Abroms S, Raper JL, Saag MS, Allison JJ. Missed visits and mortality among patients establishing initial outpatient HIV treatment. *Clin Infect Dis.* 2009 Jan 15;48(2):248-56.

²⁵ Li Z, Purcell DW, Sansom SL, Hayes D, Hall HI. Vital Signs: HIV transmission along the continuum of care - United States, 2016. *MMWR Morb Mortal Wkly Rep.* 2019 Mar 22;68(11):267-272.

²⁶ HIV.gov, Federal HIV Budget (April 19, 2022), at <https://www.hiv.gov/federal-response/funding/budget#:~:text=The%20U.S.%20government%20investment%20in,benefits%2C%20and%20other%20mandatory%20spending.>

²⁷ Centers for Disease Control and Prevention, HIV Cost-effectiveness, at <https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html>; see also Bingham A, Shrestha RK, Khurana N, Jacobson EU, Farnham PG. Estimated Lifetime HIV-Related Medical Costs in the United States. *Sex Transm Dis.* 2021 Apr 1;48(4):299-304 (estimating lifetime cost of HIV treatment at \$460,000).

further entrench people in poverty.²⁸ Unemployment rates among people with HIV range from 45-65%.²⁹

In addition to these health and economic harms, HIV carries social stigma and legal penalties. The United States has a shameful history of blaming the gay community for HIV while criminalizing same-sex intimacy and targeting the gay community for prosecution.³⁰ The Supreme Court repudiated this discriminatory tradition in part in *Lawrence v. Texas*, striking down a Texas law that criminalized consensual intimacy between persons of the same sex.³¹

Even after *Lawrence*, however, the law has continued to target individuals with HIV.³² The United States banned immigration by people with HIV through 2010. Today, people with HIV cannot serve in some branches of the military. Men who have recently had sex with men, even if they do not have HIV, cannot donate blood, a policy which is estimated to deprive the United States blood supply of 345,000-615,300 pints of blood per year.³³ Today, more than thirty states criminalize the sexual and non-sexual conduct of people with HIV – prosecuting even when interactions are consensual and/or involve activities that pose little to no risk of HIV transmission.³⁴ Some of these discriminatory laws apply only to men who have sex with men (e.g., the blood donation ban), and other measures apply only to HIV – and do not apply to individuals with other transmissible diseases. These laws remain even though the criminalization of conduct by individuals with HIV appears to have no positive impact on public health and may exacerbate HIV stigma.³⁵ Indeed, an analysis of 25 empirical studies found that

²⁸ Denning P and DiNenno E. Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States? U.S. Centers for Disease Control and Prevention, no date given, at <https://www.cdc.gov/hiv/group/poverty.html>; Schechter, M. T., Hogg, R. S., Aylward, B., Craib, K. J., Le, T. N., and Montaner, J. S. Higher socio-economic status is associated with slower progression of HIV infection independent of access to health care; Pellowski, J. A., Kalichman, S.C., Matthews, K. A., and Adler, N. A pandemic of the poor: Social disadvantage and the U.S. HIV epidemic. *Am Psych.* 2013;68: 197-209; Harrison, K. M., Ling, Q., Song, R., & Hall, H. I. County-level socioeconomic status and survival after HIV diagnosis. *Ann Epidem.* 2008;18: 919-927.

²⁹ Dray-Spira, R., Gueguen, A., and Lert, F. Disease severity, self-reported experience of workplace discrimination and employment loss during the course of chronic HIV disease: Differences according to gender and education. *Occ and Env Med.* 2018;65: 112-119; Liu, Y., Canada, K., Shi, K., & Corrigan, P. HIV-related stigma acting as predictors of unemployment of people living with HIV/AIDS. *AIDS Care.* 2012; 24(1): 129-135.

³⁰ Jordan Blair Woods, LGBT Identity and Crime, 105 Cal. L. Rev. 668-734 (2017).

³¹ 539 U.S. 558 (2003).

³² Burris S, Cameron E. The Case Against Criminalization of HIV Transmission. *JAMA.* 2008;300(5):578–581; Kaplan, Margo, Rethinking HIV-Exposure Crimes, 87 Ind. L. J. 1517 (2012).

³³ Joshua Blecher-Cohen, Disability Law and HIV Criminalization, 130 Yale L.J. 1560, 1566-67 (2021); Ayako Miyashita and Gary Gates, Effects of Lifting Blood Donation Bans on Men Who Have Sex with Men, Williams Institute (2014), at <https://williamsinstitute.law.ucla.edu/publications/blood-donation-ban-msm/>. The FDA has proposed new guidelines that would be based on an individual risk assessment rather than a blanket denial to MSM and their female partners. Food and Drug Administration, FDA Proposes Individual Risk Assessment for Blood Donations, While Continuing to Safeguard U.S. Blood Supply, Jan. 27, 2023.

³⁴ Blecher-Cohen, supra, at 1563-64 (2021); Centers for Disease Control, HIV and STD Criminalization Laws (2022), at <https://www.cdc.gov/hiv/policies/law/states/exposure.html>; Harsono D, Galletly CL, O'Keefe E, Lazzarini Z. Criminalization of HIV Exposure: A Review of Empirical Studies in the United States. *AIDS Behav.* 2017; 21(1):27-50.

³⁵ Lazzarini Z, Galletly CL, Mykhalovskiy E, Harsono D, O'Keefe E, Singer M, Levine RJ. Criminalization of HIV transmission and exposure: research and policy agenda. *Am J Public Health.* 2013;103(8):1350-3; Csete J, Elliott R, Bernard EJ. So many harms, so little benefit: a global review of the history and harms of HIV criminalisation.

people had a low awareness of HIV disclosure laws, and that HIV exposure laws had very little protective impact on HIV-related sexual behaviors.³⁶

II. THE STATE HAS A COMPELLING INTEREST IN ENSURING ACCESS TO PREP, WHICH IS A HIGHLY EFFECTIVE EVIDENCE-BASED PREVENTATIVE MEASURE AGAINST HIV THAT CAN PRODUCE MAJOR PUBLIC HEALTH BENEFITS AS PREP USE EXPANDS.

PrEP comprises a collection of medications that prevent HIV infection. Currently, three medications are FDA approved for PrEP: emtricitabine and tenofovir disoproxil fumarate or Truvada (oral), emtricitabine and tenofovir alafenamide Descovy (oral), and cabotegravir or Apretude (an injectable form). PrEP is approved for individuals weighing over 35 kg (77 pounds), regardless of age. Importantly, physicians who prescribe PrEP also provide comprehensive medical care, including testing for bacterial and viral sexually transmitted infections (STIs), sexual health counseling, substance use counseling and other key aspects of preventive healthcare.

Several randomized-control trials have demonstrated the efficacy of PrEP in reducing HIV in a wide range of populations.³⁷ When taken daily, PrEP reduces the risk of HIV infection from sex by over 99%. By preventing HIV infection in individuals, PrEP also prevents the spread of HIV to sexual partners. There is no lower age limit on the appropriateness of PrEP and as such, HIV prevention in adolescents with PrEP has been resoundingly recommended by leading authorities in pediatrics.³⁸

In addition to the “A” rating awarded by the USPSTF, additional branches of the federal government have recognized and endorsed the central importance of PrEP to HIV prevention. In 2019, the U.S. Department of Health and Human Services launched the Ending the HIV Epidemic (EHE) initiative which outlines a plan to end HIV by 2030 and calls for wide distribution and use of PrEP in high-risk areas.³⁹ HHS officials emphasized that the HIV

Lancet HIV. 2023;10(1):e52-e6; Scott Burris, Leo Beletsky, et al., Do Criminal Laws Influence HIV Risk Behavior? An Empirical Trial, 39 *Az. St. L.J.* 467 (2007).

³⁶ Harsono D, Galletly CL, O’Keefe E, Lazzarini Z. Criminalization of HIV Exposure: A Review of Empirical Studies in the United States. *AIDS Behav.* 2017;21(1):27-50.

³⁷ David H. Spach and Aley G. Kalapila, Pre-Exposure Prophylaxis, National HIV Curriculum (2022), at <https://www.hiv.uw.edu/go/prevention/preexposure-prophylaxis-prep/core-concept/all#major-prep-studies>; Grant RM, Lama JR, Anderson PL, et al; iPrEx Study Team. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *NEJM*. 2010;363(27):2587-99 (iPrEx); TDF2: Thigpen MC, Kebaabetswe PM, Paxton LA, et al; TDF2 Study Group. Antiretroviral preexposure prophylaxis for heterosexual HIV transmission in Botswana. *NEJM*2012;367(5):423-34 (TDF2); Partners PrEP: Baeten JM, Donnell D, Ndase P, et al; Partners PrEP Study Team. Antiretroviral prophylaxis for HIV prevention in heterosexual men and women. *NEJM*2012;367(5):399-410 (Partners PrEP); Choopanya K, Martin M, Suntharasamai P, et al; Bangkok Tenofovir Study Group. Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* 2013;381(9883):2083-90.

³⁸ Hsu, KK, Rakhmanina, NY, and Committee on Pediatric AIDS. Adolescents and young adults: the pediatrician’s role in HIV testing and pre-and postexposure hiv prophylaxis. *Pediatrics*. 2022; 149(1):e2021055207.

³⁹ Fauci AS, Redfield RR, Sigounas G, Weahkee MD, Giroir BP. Ending the HIV Epidemic: A Plan for the United States. *JAMA*. 2019;321(9):844–845.

pandemic remains a public health crisis in the United States and globally.⁴⁰ The initiative is built on four pillars, one of which is to prevent at-risk individuals from acquiring HIV infection, including the use of pre-exposure prophylaxis (PrEP).

In 2021, the Centers for Disease Control updated its research-based clinical practice guidelines to recommend that medical providers inform all sexually-active adults and adolescents about PrEP. Specifically, the guidelines recommend that “[c]linicians should evaluate all adult and adolescent patients who are sexually active or who are injecting illicit drugs and offer to prescribe PrEP to persons whose sexual or injection behaviors and epidemiologic context place them at substantial risk of acquiring HIV infection.”⁴¹

The key point is that PrEP not only benefits individuals but the entire community. Like vaccinations against infectious diseases such as measles and chicken pox, PrEP safeguards individuals at risk of getting HIV and protects their sexual partners, as well as the future partners of those partners and any pregnancies that may arise. Modeling has predicted that widespread uptake of PrEP would drastically reduce the public health burden of HIV and also other sexually transmitted infections.⁴² For example, studies have demonstrated that free, widespread PrEP access would lead to quality-adjusted life-year gains between 1,993 and 23,442, depending on the US city. In regions with high PrEP uptake, HIV incidence has declined not only among those who take PrEP but at a population level.⁴³

By discouraging PrEP use, the *Braidwood* decision would increase HIV transmission in the community. Our colleagues at Harvard and Yale sought to estimate the number of new HIV infections that would result from ending the PrEP Mandate for men who have sex with men (MSM) in the United States. They developed a simple model of HIV transmission and prevention and used data obtained from the Centers for Disease Control and the HIV Prevention Trials Network (HPTN) to estimate HIV incidence over a single year in a population of ~1 million PrEP-eligible MSM. Under current PrEP Mandate provisions and 28% PrEP coverage of eligible MSM, they predict 28,200 new HIV infections among MSM in the coming year; suspension of the PrEP Mandate reducing PrEP coverage to 10% will result in an additional 2,083 HIV infections. More generally, for every 1% decrease in the number of eligible MSM receiving PrEP treatment, the model predicts 116 new HIV infections in the coming year. We discuss the assumptions in the model and explain why these are conservative, lower-bound estimates in Section IV.

⁴⁰ U.S. Public Health Service, Centers for Disease Control, Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline (2021), at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

⁴¹ *Id.*

⁴² Jenness SM, Weiss KM, Goodreau SM, Gift T, Chesson H, Hoover KW, et al. Incidence of gonorrhea and chlamydia following human immunodeficiency virus preexposure prophylaxis among men who have sex with men: a modeling study. *Clin Infect Dis.* 2017;65(5):712–8.

⁴³ Grulich AE, Guy R, Amin J, Jin F, Selvey C, Holden J, Schmidt HA, Zablotska I, Price K, Whittaker B, Chant K, Cooper C, McGill S, Telfer B, Yeung B, Levitt G, Ogilvie EE, Dharan NJ, Hammoud MA, Vaccher S, Watchirs-Smith L, McNulty A, Smith DJ, Allen DM, Baker D, Bloch M, Bopage RI, Brown K, Carr A, Carmody CJ, Collins KL, Finlayson R, Foster R, Jackson EY, Lewis DA, Lusk J, O'Connor CC, Ryder N, Vlahakis E, Read P, Cooper DA; Expanded PrEP Implementation in Communities New South Wales (EPIC-NSW) research group. Population-level effectiveness of rapid, targeted, high-coverage roll-out of HIV pre-exposure prophylaxis in men who have sex with men: the EPIC-NSW prospective cohort study. *Lancet HIV.* 2018;5(11):e629-e637.

Thus, it is a mistake to frame PrEP, as the *Braidwood* decision does, as an individual treatment and a “niche” drug for men who have sex with men, the unmarried, and individuals who inject drugs. To be sure, individuals take the medication and gain a significantly lower risk of HIV infection, but the benefits of HIV prevention expand into the individual’s social network and the larger community.

A. PREP IS A GATEWAY TO PRIMARY CARE AND IMPROVES THE OVERALL WELL-BEING OF THOSE WHO TAKE THIS MEDICATION.

Due to a longstanding history of bias and distrust, those at risk for HIV may avoid traditional healthcare settings. PrEP, however, is associated with increased contact with the healthcare system and access to comprehensive medical services. PrEP services facilitate access to influenza vaccination, depression and substance use screening and diabetes screening.⁴⁴ Further, accessing PrEP is a strong motivator for continued engagement in primary care.⁴⁵ By building ties to medical homes and preventive services, this trend may divert people from over-burdening emergency care and other safety net resources.

The psychosocial benefits of PrEP are also profound.⁴⁶ Fear of HIV contributes to heightened anxiety, shame, and lower quality of life. Individuals who take PrEP report reduced feelings of anxiety and stress that stem from a sense of control over one’s health in an environment where HIV has inflicted systematic disempowerment.⁴⁷ Clinical settings that offer PrEP may also offer coordinated social services that help individuals obtain health insurance, housing and food assistance, safety planning, and employment.

B. PREP SERVICES LEAD TO DIAGNOSIS AND TREATMENT OF OTHER SEXUALLY TRANSMITTED INFECTIONS, WHICH BENEFITS INDIVIDUALS AND PUBLIC HEALTH AT LARGE.

Rising rates of bacterial and viral sexually transmitted infections (STIs) cause health and psychosocial harms including worse maternal-fetal outcomes, higher risk of HIV infection, and increased healthcare costs. Based on CDC guidelines, PrEP services should include comprehensive STI testing and treatment, counseling about safe sex practices and access to condoms. PrEP has been used to scale up and leverage enhanced STI surveillance, leading to a particularly potent multiplier effect on public health.

⁴⁴ Marcus, JL, et al. HIV Preexposure Prophylaxis as a Gateway to Primary Care. *Am J Pub Health*. 2018;108(10): 1418-1420.; Oldfield, B.J., Edelman, E.J. Addressing Unhealthy Alcohol Use and the HIV Pre-exposure Prophylaxis Care Continuum in Primary Care: A Scoping Review. *AIDS Behav* 25, 1777–1789 (2021). <https://doi.org/10.1007/s10461-020-03107-6>

⁴⁵ Sewell WC, Powell VE, Ball-Burack M, et al. Brief Report: "I Didn't Really Have a Primary Care Provider Until I Got PrEP": Patients' Perspectives on HIV Preexposure Prophylaxis as a Gateway to Health Care. *J Acquir Immune Defic Syndr*. 2021;88(1):31-35. 9

⁴⁶ Yang C, Krishnan N, Kelley E, et al. Beyond HIV prevention: a qualitative study of patient-reported outcomes of PrEP among MSM patients in two public STD clinics in Baltimore. *AIDS Care*. 2020;32(2):238-241.

⁴⁷ Miller SJ, Harrison SE, Sanasi-Bhola K. A scoping review investigating relationships between depression, anxiety, and the PrEP care continuum in the United States. *Int J Environ Res Public Health*. 2021;18(21):11431.

Many studies have demonstrated the positive impact of PrEP services on reducing STIs. A 2010 multinational clinical trial of Truvada called the Preexposure Prophylaxis Initiative (iPrEx) lends insight into mechanisms for this effect. Participants in the study, who included men who have sex with men in the US and 5 other countries, received comprehensive PrEP services whether they received the study drug or placebo. Strikingly, 25% of participants in this trial had never received an HIV test beforehand, indicating that PrEP access can increase HIV screening. During the study period, investigators tested for various STIs including syphilis, gonorrhea, chlamydia, genital warts, and genital ulcers, as well as self-reported sexual behaviors, including number of sexual partners and condom use.⁴⁸

STIs, which were treated when identified, decreased significantly and similarly during the study period for the PrEP and placebo groups. Regarding sexual practices, (1) the number of sexual partners decreased significantly and similarly for both study groups and (2) condom use significantly increased for all participants shortly after study enrollment (about 50% of participants reported regular condoms use at baseline, compared to about 75-85% at study conclusion). In addition to more frequent contact with preventive medical services, the iPrEx investigators posited that consulting a clinician, as well as taking a medication daily, may have helped individuals restructure their thinking and behavior sexual health.

In a second stage, the iPrEX study unblinded the patients and offered PrEP to the placebo group, which permitted a “real-world” trial, with patients choosing to accept or forgo it.⁴⁹ Drug concentrations were tested in blood samples to assess degree of compliance with PrEP. Notably, syphilis rates were noted to be lower in patients whose blood samples had higher PrEP concentrations, suggesting PrEP care services may positively impact overall sexual health behaviors.

Some studies of PrEP have shown increases in STI diagnoses during the investigative period, which should be viewed as a net positive as frequent screening and identification leads to treatment and prevention of onward transmission, thereby reducing the public health burden of these potentially harmful infections.⁵⁰

III. LIKE OTHER PREVENTATIVE MEASURES AGAINST INFECTIOUS DISEASES, PREP PROTECTS NOT ONLY THOSE INDIVIDUALS WHO TAKE THE

⁴⁸ Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, Goicochea P, Casapía M, Guanira-Carranza JV, Ramirez-Cardich ME, Montoya-Herrera O, Fernández T, Veloso VG, Buchbinder SP, Chariyalertsak S, Schechter M, Bekker LG, Mayer KH, Kallás EG, Amico KR, Mulligan K, Bushman LR, Hance RJ, Ganoza C, Defechereux P, Postle B, Wang F, McConnell JJ, Zheng JH, Lee J, Rooney JF, Jaffe HS, Martinez AI, Burns DN, Glidden DV. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *NEJM*. 2010; 363(27):2587-99; Grant RM, Anderson PL, McMahan V, Liu A, Amico KR, Mehrotra M, Hosek S, Mosquera C, Casapía M, Montoya O, Buchbinder S, Veloso VG, Mayer K, Chariyalertsak S, Bekker LG, Kallas EG, Schechter M, Guanira J, Bushman L, Burns DN, Rooney JF, Glidden DV; iPrEx study team. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis*. 2014;14(9):820-9. Syphilis rates can be used as a more accurate surrogate marker of sexual behavior than other bacterial STIs because syphilis can be transmitted even with condom use.

⁴⁹ Id.

⁵⁰ Traeger MW, Cornelisse VJ, Asselin J, et al. Association of HIV preexposure prophylaxis with incidence of sexually transmitted infections among individuals at high risk of hiv infection. *JAMA*. 2019;321(14):1380–1390.

MEDICATION BUT MEMBERS OF THEIR LARGER COMMUNITY AND SOCIAL NETWORKS.

HIV is a population-level threat, not just an individual infection. Anyone with HIV who has a detectable viral load can transmit the virus to their sexual partners, who in turn can infect others. People who inject drugs may also infect others if they share needles. Thus, the personal decisions of HIV-negative individuals to protect themselves with PrEP also protect entire social networks and communities. The World Health Organization, the Centers for Disease Control, the National Institute for Allergy and Infectious Diseases, and many leading bodies in public health have, accordingly, advocated for unfettered access to PrEP.

A. PRÉP REDUCES THE RISK OF HIV IN ALL PEOPLE AT RISK OF CONTRACTING HIV, NOT ONLY MEN WHO HAVE SEX WITH MEN, UNMARRIED PEOPLE, AND PEOPLE WHO INJECT DRUGS, AS *BRAIDWOOD* IMPLIES.

HIV has been inaccurately framed a pathogen that solely affects men who have sex with men, but in fact, anyone who is sexually active is at risk of HIV infection and can benefit from PrEP.⁵¹ Indeed, HIV infections have been declining for men who have sex with men in the United States.⁵² In accordance with the ways in which HIV is transmitted and where community transmission is most concentrated, the CDC offers guidelines on those who are most likely to benefit from PrEP. The CDC recommends PrEP for sexually active individuals who have had intercourse within the past 6 months with an HIV-positive sexual partner, those who have had a bacterial sexually transmitted infection within the past 6 months and those with a history of inconsistent or no condom use. The CDC also recommends PrEP for people who inject drugs including those who have an HIV-positive injecting partner, those who share injection supplies or those who have a sexual risk of acquiring HIV.⁵³ Furthermore, the CDC recommends that all sexually active people receive counseling about PrEP.

Thus, the populations eligible for PrEP are identified based on health risk, not strictly by sexual orientation or marital status as the *Braidwood* decision supposes. In fact, the CDC was intentional in their most recent guidelines to remove PrEP recommendations based on sexual orientation.⁵⁴ PrEP is valuable for some men who have sex with men, but this is only one at-risk group among many, and not all men who have sex with men have indications for PrEP use. As we document in the following sections, other at-risk groups include women, Black and Latinx people, couples who wish to bear children, and residents of the South and Southwest, including Texas.

⁵¹ Fonner VA, Dalglish SL, Kennedy CE, Baggaley R, O'Reilly KR, Koechlin FM, Rodolph M, Hodges-Mameletzis I, Grant RM. Effectiveness and safety of oral HIV preexposure prophylaxis for all populations. *AIDS*. 2016;30(12):1973-83.

⁵² Centers for Disease Control, HIV and Gay and Bisexual Men: HIV Incidence, at <https://www.cdc.gov/hiv/group/msm/msm-content/incidence.html>.

⁵³ U.S. Public Health Service, Centers for Disease Control, Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline (2021), at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>.

⁵⁴ *Id.*

B. PREP IS ESPECIALLY VALUABLE TO GROUPS WHERE RATES OF INFECTION ARE RISING, INCLUDING YOUTH, WOMEN AND BLACK AND LATINX PEOPLE.

Minority communities bear a disproportionate risk of HIV. In 2019, the most recent year for which reliable data are available, Black people accounted for the largest number of diagnosed infections (14,300) and Latinx people reporting the second highest number (10,200).⁵⁵ Young people account for a significant share of HIV diagnoses: in 2019, 60% of new cases of HIV occurred in people under age 34 (21,000 cases of the 34,800 new cases in total).⁵⁶

A recommended use of PrEP is to prevent HIV transmission when one partner in a couple is HIV-positive, while the other is not (“serodiscordant” couples). Male-to-female transmission of HIV is a leading cause of new infections, with greater rates occurring in the South. Most women in the U.S. who acquire HIV were infected by a male partner.⁵⁷ Women now comprise 21% of all new cases of AIDS, up from 8% in 1985. AIDS is among the top five leading causes of death for Black women 25-54 and is the tenth leading cause of death for Latinx women aged 35-44.⁵⁸ Thus, women in heterosexual relationships have a major interest in the availability of PrEP, particularly in vulnerable minority groups.⁵⁹ Gender-based relationship inequalities, which complicate condom negotiation and other forms of self-protective sexual behaviors, highlight an urgent need for HIV prevention methods, like PrEP, that empower women. PrEP is highly effective in preventing HIV transmission in heterosexual couples.⁶⁰

C. PREP ALSO PROVIDES INDIRECT BENEFITS TO CHILDREN BY PREVENTING INFECTION IN PARENTS.

One-third of serodiscordant heterosexual couples want to have children. Without PrEP, there is a risk of transmission of HIV to the fetus if the pregnant individual becomes infected.⁶¹ PrEP thus allows serodiscordant couples to safely conceive without transmitting the virus. In studies where an HIV-negative woman takes PrEP consistently and has sex with an HIV-positive partner, no cases of transmission to the uninfected partner or perinatal transmission have been documented.

⁵⁵ Centers for Disease Control, HIV in the United States by Race/Ethnicity, at <https://www.cdc.gov/hiv/group/raciaethnic/other-races/incidence.html>.

⁵⁶ Centers for Disease Control, HIV by Age: HIV Incidence, at <https://www.cdc.gov/hiv/group/age/incidence.html>.

⁵⁷ Adimora AA, Ramirez C, Poteat T, Archin NM, Averitt D, Auerbach JD, Agwu AL, Currier J, Gandhi M. HIV and women in the USA: what we know and where to go from here. *Lancet*. 2021;397(10279):1107-1115.

⁵⁸ Heron M. Deaths: Leading causes for 2009. National vital statistics reports: From the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System. 2012;61:1–94.

⁵⁹ McMahon JM, Myers JE, Kurth AE, et al. Oral pre-exposure prophylaxis (PrEP) for prevention of HIV in serodiscordant heterosexual couples in the United States: opportunities and challenges. *AIDS Patient Care STDS*. 2014;28(9):462-474; Baldwin A, Light B, Allison WE. Pre-Exposure Prophylaxis (PrEP) for HIV Infection in Cisgender and Transgender Women in the U.S.: A Narrative Review of the Literature. *Arch Sex Behav*. 2021;50(4):1713-1728; Buot ML, Docena JP, Ratemo BK, Bittner MJ, Burlew JT, Nuritdinov AR, Robbins JR. Beyond race and place: distal sociological determinants of HIV disparities. *PLoS One*. 2014;9(4):e91711.

⁶⁰ Id.

⁶¹ Hanscom B, Janes HE, Guarino PD, et al. Brief report: preventing HIV-1 infection in women using oral preexposure prophylaxis: a meta-analysis of current evidence. *J Acquir Immune Defic Syndr*. 2016;73(5):606-608; Heffron R, Ngunjiri K, Vellozo J, et al. Implementation of a comprehensive safer conception intervention for HIV-serodiscordant couples in Kenya: uptake, use and effectiveness. *J Int AIDS Soc*. 2019;22(4):e25261..

PrEP is safe to use during pregnancy. Thanks to PrEP and other HIV prevention efforts, perinatal transmission is now incredibly rare.⁶²

Further, PrEP may play a role in protecting children by preventing HIV in parents and improving parent-child interactions.⁶³ Up to 50% of parents with HIV lose custody of their children while coping with the disease. More than a quarter of parents with HIV report limiting contact with their child because they fear catching an opportunistic infection or, due to misconceptions, transmitting the virus. Parents also report that they may not disclose their status to a child because they fear discrimination and judgement from extended family and community members. HIV may inflict distinct harm on vulnerable families by destabilizing parent-child relationships. By ensuring the well-being of parents, PrEP profoundly benefits children.

D. PrEP IS ESPECIALLY VALUABLE IN GEOGRAPHIC AREAS AND SOCIAL NETWORKS WHERE THE RISK OF INFECTION IS HIGHEST.

A CDC analysis of HIV infection data in 2016-2017 identified several jurisdictions in the US where more than 50% of new HIV diagnoses occurred, including seven states with a substantial rural burden.⁶⁴ In response to these findings, the federal government announced a plan in 2019 that aims to end the HIV epidemic by 2030 (Ending the HIV Epidemic in the U.S. (EHE)) to coordinate programs, resources, and infrastructure and develop and implement locally tailored EHE strategies to reduce HIV infections by 75 percent by 2025, and by at least 90 percent by 2030.⁶⁵

Structural challenges in these regions include sparse services and fewer providers with competence in HIV care, limited availability of mental health and addiction services, and social stigma.⁶⁶ Black people in rural settings are more likely to receive a late-stage HIV diagnosis than Black people in urban and metropolitan settings. Persons in rural areas are less likely to achieve viral suppression in six months after linkage to care.⁶⁷ Thus, it is far more feasible and desirable

⁶² HIV.gov, Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States (2021), at <https://clinicalinfo.hiv.gov/en/guidelines/perinatal/prep?view=full>. In a study of pregnant and non-pregnant women in a high HIV prevalence community, nearly 11% of the pregnant women planned to initiate PrEP during pregnancy. This is a striking figure given the overall low awareness of PrEP even in communities with high rates of HIV. Scott RK, Hull SJ, Richards RC, Klemmer K, Salmoran F, Huang JC. Awareness, acceptability, and intention to initiate HIV pre-exposure prophylaxis among pregnant women. *AIDS Care*. 2022 Feb;34(2):201-213.

⁶³ Bogart, LM., Cowgill B, Kennedy DP, Ryan GW, Elijah J, Murphy DA, Schuster MA, Corona R, Beckett MK, Elliott MN, Zhou AJ, Parra MT, Park SK, Patch J, Kanouse DE, Morton SC, Bozette SA, Miu A, Scott GB, and Shapiro MF. How parental HIV affects children (2009), at https://www.rand.org/pubs/research_briefs/RB9372.html.

⁶⁴ Centers for Disease Control, Ending the HIV Epidemic in the United States (EHE), Combined HIV Diagnoses for 2016-2017, United States, at <https://www.cdc.gov/endhiv/diagnoses-2016-2017.html>.

⁶⁵ Centers for Disease Control, Ending the HIV Epidemic in the United States (EHE), Overview (2022), at <https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview>.

⁶⁶ Sullivan PS, Mena L, Elopre L, Siegler AJ. Implementation strategies to increase PrEP uptake in the south. *Curr HIV/AIDS Rep*. 2019;16(4):259-269.

⁶⁷ Lyons SJ, Dailey AF, Yu C, Johnson AS. Care outcomes among Black or African American persons with diagnosed HIV in rural, urban, and metropolitan statistical areas — 42 US jurisdictions, 2018. *MMWR Morb Mortal Wkly Rep* 2021;70:229–235.

to prevent HIV than meet the care needs of those infected. PrEP delivery is less onerous and easier to implement than comprehensive HIV services.

Texas, the site of the *Braidwood* decision, is a geographic area with high HIV risk and therefore high potential benefit from PrEP. Texas is home to five of the fifty highest-priority counties identified by the EHE plan as having high numbers of new HIV diagnoses, and the state ranks second in the nation for new infections.

Increasing PrEP availability is one of the four pillars of EHE, and the South and rural areas are an important target. Inhabitants of the American South accounted for more than 50% of new HIV diagnoses in 2017, but only 27% of all PrEP prescriptions were provided in that region.⁶⁸ Among the constraints are the long travel distances typical of rural areas. For instance, 38% of Black people eligible for PrEP live an hour or more away from a PrEP provider.⁶⁹ Additional barriers include physicians' lack of knowledge about PrEP, lack of comfort in prescribing it, and other provider factors.⁷⁰ If upheld, the *Braidwood* decision will undermine public health by reinforcing socioeconomic barriers to PrEP access and condemn vulnerable people to a higher risk of HIV in geographic settings rife with structural barriers.

IV. PREP CAN PROTECT PUBLIC HEALTH ONLY IF THE MEDICATION IS COVERED BY INSURANCE SO THAT IT IS WIDELY AVAILABLE AT NO OUT-OF-POCKET COST TO PATIENTS.

Both elements of the *Braidwood* decision threaten access to PrEP. First, the nationwide PrEP Mandate now requires private insurers to cover PrEP without out-of-pocket expense to the patient. If the court issues an injunction blocking the mandate nationwide, insurers could require those who take PrEP to pay for all or part of the medication (e.g., by requiring deductibles to be met and/or imposing co-insurance and co-pays).

Unfortunately, insurers have a strong financial incentive to do so, because PrEP is expensive.⁷¹ In the absence of the PrEP Mandate, insurance companies and self-insured employers could exclude PrEP from coverage or impose high co-pays that discourage PrEP use. Even under current law, some insurers have failed to comply with the PrEP Mandate.⁷²

Second, even if the PrEP Mandate remains in effect, the religious exemption granted by the *Braidwood* decision would threaten PrEP access. As construed by the court, the law would

⁶⁸ Ojikutu BO, Bogart LM, Mayer KH, Stopka TJ, Sullivan PS, Ransome Y. Spatial access and willingness to use pre-exposure prophylaxis among black/African American individuals in the United States: cross-sectional survey. *JMIR Public Health Surveill.* 2019;5:e12405.

⁶⁹ *Id.*

⁷⁰ Benedikt Pleuhs, Katherine G. Quinn, Jennifer L. Walsh, Andrew E. Petroll, and Steven A. John. Health Care Provider barriers to HIV pre-exposure prophylaxis in the United States: a systematic review. *AIDS Patient Care and STDs.* 2020; 111-123.

⁷¹ Srikanth K, Killelea A, Strumpf A, Corbin-Gutierrez E, Horn T, McManus KA. Associated costs are a barrier to hiv preexposure prophylaxis access in the United States. *Am J Public Health.* 2022;112(6):834-838; Kay ES, Pinto RM. Is insurance a barrier to HIV preexposure prophylaxis? Clarifying the issue. *Am J Public Health.* 2020;110(1):61-64.

⁷² Sarah Varney, HIV Preventive Care is Supposed to be Free in the U.S. So, Why are Some Patients Still Paying?, KHN, March 3, 2022, at <https://khn.org/news/article/prep-hiv-prevention-costs-covered-problems-insurance/>.

exempt from PrEP coverage any individual or business whose owners profess a religious objection. (The court's analysis requires that the religious belief be sincere, but it is virtually impossible for courts and health plans to distinguish between sincere religious beliefs and opportunistic objections made to capture a financial savings.)

The *Braidwood* religious exemption would arbitrarily deny PrEP to patients depending on the religious identity of their employers. Two similar workers could find that one is fully eligible for PrEP while the other is denied coverage, based only on the religious beliefs of their bosses. The result could be a serious limitation on PrEP access with ripple effects through the entire community. As Section III documents, PrEP operates at the population level as well as the individual level. By creating arbitrary gaps in PrEP access, the religious exemption would needlessly exacerbate the risk of HIV transmission in the community as a whole.

These economic concerns are more than theoretical. Even today, with the PrEP Mandate fully in force, public health authorities are working to expand PrEP access. While 1.2 million people in the US have an indication for PrEP according to USPSTF guidelines, only 25% of those eligible have received a prescription.⁷³ Particularly vulnerable populations who have an indication for PrEP but are not currently accessing it include Black and Latinx individuals and women.⁷⁴ These populations are also those who are disproportionately affected by HIV. Black people represented 14% of those who take PrEP in 2021, but 42% of new HIV diagnoses in 2020, while Latinx people represented 17% of those who take PrEP in 2021 and 27% of new HIV diagnoses in 2020.⁷⁵ Only 10% of women for whom PrEP was indicated have received a prescription for it.⁷⁶ Youth ages 13-24 represent 16% of those who take PrEP, but 25% of new HIV diagnoses, of which approximately 80% are in Black and Latinx youth.⁷⁷

Our colleagues at Harvard and Yale sought to estimate the impact of a nationwide injunction against the PrEP Mandate. They estimated additional HIV transmissions attributable to reduced private health insurance coverage for PrEP in a population of PrEP-eligible men who have sex with men (MSM) in the United States.

They developed a simple model of HIV transmission and prevention under alternative insurance and PrEP coverage assumptions. Using input parameter values obtained from the Centers for Disease Control and the HIV Prevention Trials Network (HPTN) 083 trial, they estimated HIV incidence over a single year in a population of 989,200 PrEP-eligible MSM facing an untreated HIV transmission rate of 1.56 cases per 100 person-years. They assumed that PrEP reduced this rate by 75%. Recognizing that some PrEP-eligible men who have sex with men might identify alternative sources of insurance, they explored the impact of varying levels of PrEP coverage

⁷³ Centers for Disease Control, NCHSSTP Newsroom, PrEP for HIV Prevention in the United States, at <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html>.

⁷⁴ Kim H and Martin E. Barriers to accessing pre-exposure prophylaxis among women experiencing intimate partner violence in the United States: a systematic literature review. *AIDS Care*. 2022 Sept 14;1-15.

⁷⁵ AIDSVu, AIDSVu Releases New Data Showing Significant Inequities in PrEP Use among Black and Hispanic Americans, July 29, 2022, at <https://aidsvu.org/prep-use-race-ethnicity-launch-22/>.

⁷⁶ Centers for Disease Control, NCHSSTP Newsroom, PrEP for HIV Prevention in the United States, at <https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html>.

⁷⁷ Centers for Disease Control, HIV by Age: PrEP Coverage, at <https://www.cdc.gov/hiv/group/age/prep-coverage.html>.

from an initial base value of 28% (range: 20-30%) with ACA-mandated private insurance and no cost sharing to 10% (range: 0-20%) if the PrEP Mandate was eliminated. They explored the sensitivity of the findings to uncertainty in HIV incidence and the ease of obtaining alternative insurance for preventive services.

Under current PrEP Mandate provisions and 28% PrEP coverage of eligible MSM, the model forecasts 28,200 new HIV infections among MSM in the coming year. If suspension of the PrEP Mandate provisions lowers PrEP coverage to 10%, *the model predicts an additional 2,083 HIV infections in this population*. Sensitivity analysis reveals a linear relationship between changes in PrEP coverage and total new transmissions: for every 1% decrease in the number of eligible MSM receiving PrEP treatment, the model predicts 116 new HIV infections in the coming year. The adverse effects of reduced coverage rise linearly with changes in incidence.

Notably, these predictions restrict attention to MSM and to primary infections, ignoring additional groups at risk of HIV and the additional downstream (secondary) transmissions averted. They therefore represent a conservative, lower bound on the likely number of new HIV transmissions arising from suspension of the PrEP Mandate.

V. THE *BRAIDWOOD* RULING DISREGARDS THE STATE'S COMPELLING PUBLIC INTERESTS IN PUBLIC HEALTH AND IN THE FULL SOCIAL INCLUSION OF LGBTQ PEOPLE. AS FRAMED BY THE COURT, THE RELIGIOUS EXEMPTION INCORPORATES UNFOUNDED EMPIRICAL ASSERTIONS AND OPENS A LOOPHOLE SO WIDE THAT IT COULD PERMIT MANY BUSINESSES TO OPT OUT OF VIRTUALLY ANY TYPE OF PREVENTATIVE MEASURE OR HEALTH CARE.

The *Braidwood* decision granted a religious exception to PrEP insurance coverage based on a statute, the Religious Freedom Restoration Act (RFRA). The business owner in *Braidwood* argued that paying for PrEP violated his religious beliefs because “he believes that (1) the Bible is ‘the authoritative and inerrant word of God,’ (2) the ‘Bible condemns sexual activity outside marriage between one man and one woman, including homosexual conduct,’ (3) providing coverage of PrEP drugs ‘facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman,’ and (4) providing coverage of PrEP drugs in Braidwood’s self-insured plan would make him complicit in those behaviors.”⁷⁸ The court found that there was no compelling state interest in promulgating the PrEP Mandate for religious employers and rejected any empirical inquiry into the claimed connection between PrEP and sexual behavior among LGBTQ+ and unmarried individuals or PrEP and the use of injectable drugs.

A. *BRAIDWOOD* FAILS TO RECOGNIZE THE STATE'S COMPELLING INTERESTS IN PREVENTING HIV AND PROTECTING LGBTQ EQUALITY.

As we document above, the state has a compelling interest in preventing HIV, and PrEP has been shown by convincing evidence to be effective. The *Braidwood* opinion dismisses this interest in a few short pages on the ground that the government has not specifically shown that insurance coverage *by objecting religious employers* is necessary to further this interest. As we have

⁷⁸ Braidwood, at 37.

pointed out, this logic is fundamentally flawed because PrEP provides community-level protection, which protects not just the individual workers of the objecting employer but their sexual partners and, by extension, the community.

In setting aside the state's interest in HIV protection, the *Braidwood* opinion claims that the government provided "no evidence of the scope of religious exemptions, the effect such exemptions would have on the insurance market or PrEP coverage, the prevalence of HIV in those communities, or any other evidence relevant 'to the marginal interest' in enforcing the PrEP Mandate in these cases."⁷⁹ However, as we have shown, rates of HIV are extremely high in Texas and elsewhere in the South, and the denial of insurance coverage for PrEP has been shown to reduce PrEP use. Ignoring these facts, the *Braidwood* analysis implies that granting a religious exemption to the PrEP Mandate would merely affect a few people at the margin. This is precisely the mistaken individualism we have contested throughout this report; insurance coverage for PrEP has a multiplier effect on public health beyond the HIV status of individuals directly denied medication.

In addition to the compelling interest in preventing HIV in the entire population, the state has a compelling interest in protecting the full social inclusion of LGBTQ people and in combatting discrimination. In recent years, the Supreme Court has repeatedly struck down, as unconstitutional, statutes that target LGBTQ people. In *Obergefell v. Hodges*, the Supreme Court held that the Constitution requires states to recognize marriages between persons of the same sex, writing that, "[i]t demeans gays and lesbians for the State to lock them out of a central institution of the Nation's society."⁸⁰ In *Lawrence v. Texas*, the Court struck down laws criminalizing same-sex intimacy, with Justice O'Connor (concurring), noting that "Texas' sodomy law brands all homosexuals as criminals, thereby making it more difficult for homosexuals to be treated in the same manner as everyone else."⁸¹

And in *Romer v. Evans*, the Court invalidated a Colorado constitutional provision that denied discrimination protections to LGBTQ people, with the Court noting that

[discriminatory] laws ... raise the inevitable inference that the disadvantage imposed is born of animosity toward the class of persons affected. "[I]f the constitutional conception of 'equal protection of the laws' means anything, it must at the very least mean that a bare ... desire to harm a politically unpopular group cannot constitute a legitimate governmental interest."⁸²

The religious exemption in *Braidwood* is not a federal or state statute like those challenged in these cases. Nevertheless, the animus accommodated by the *Braidwood* analysis stands at odds with these constitutional commitments to equality. The language of the opinion, endorsing the view that the PrEP Mandate renders insurance payors "complicit" in same-sex intimacy, harks

⁷⁹ *Braidwood*, at 40.

⁸⁰ 76 U.S. 644 (2015).

⁸¹ 539 U.S. 558 (2003).

⁸² 517 U.S. 620 (1996) (internal citation omitted).

back to harmful and discredited stereotypes of LGBTQ+ people as outcasts who engage in promiscuous and anti-social behavior.

Further, the *Braidwood* ruling did not recognize that the availability of health insurance is itself an important governmental objective and not solely a private matter. The United States has, via regulation and extensive subsidies, expressly delegated to private employers the critical state function of ensuring wide access to health care. These subsidies include tax credits under the Affordable Care Act, the tax deduction for employers who provide health insurance, and the tax exclusion for employees who receive health coverage. The Supreme Court has recognized, in the context of racial equality, that state-subsidized institutions have an obligation not to contravene important national and constitutional commitments.⁸³ The *Braidwood* court did not acknowledge the state's compelling commitment to LGBTQ equality. Nor did the decision situate employer health insurance in the proper context of a state-subsidized regime that carries out an important state function.

B. THE *BRAIDWOOD* RELIGIOUS EXEMPTION IS AMBIGUOUS AND, ON ANY OF THREE POSSIBLE INTERPRETATIONS, IS UNTENABLE. AS FRAMED BY THE COURT, THE EXEMPTION RESTS ON UNFOUNDED EMPIRICAL ASSERTIONS AND OPENS A LOOPHOLE SO VAST THAT IT COULD PERMIT MANY BUSINESSES TO OPT OUT OF VIRTUALLY ANY TYPE OF PREVENTATIVE MEASURE OR HEALTH CARE.

A close examination shows that the legal meaning of the religious exemption granted in *Braidwood* is unclear. According to the court's opinion, the plaintiffs believe that "providing coverage of PrEP drugs 'facilitates and encourages homosexual behavior, intravenous drug use, and sexual activity outside of marriage between one man and one woman,' and [that] providing coverage of PrEP drugs in Braidwood's self-insured plan would make him complicit in those behaviors."⁸⁴

The meaning of "facilitates and encourages" is open to at least three interpretations, all of which either rely on mistaken facts or clear the way for sweeping religious objections to nearly any form of insurance coverage, including by employers who do not sincerely hold relevant religious beliefs. We address them in turn.

1. PrEP does not increase the behavior to which the Braidwood religious plaintiffs object.

First, the *Braidwood* religious exemption might be grounded in the factual claim that the availability of PrEP increases the number of people who identify as gay, engage in same-sex or extramarital intimacy, or use injectable drugs (collectively, "plaintiffs' religiously disfavored groups"). These are causal and empirical claims, and they are incorrect.

In theory, any preventive treatment might alter behavior, leading individuals to take greater risks because they feel safer doing so. However, the actual effect of any given preventive treatment on behavior and risk calculation is far more nuanced and highly individualized. The *Braidwood*

⁸³ *Bob Jones University v. United States*, 461 U.S. 574 (1983).

⁸⁴ *Braidwood*, at 37.

plaintiffs and ruling employ pathologizing terms (“homosexual behavior, prostitution, sexual promiscuity and intravenous drug use”), which we reject, and the causal claims are refuted by empirical evidence.

The hypothesis that prevention increases sexual behavior has been historically posited – and refuted – across a range of public health measures, including the use of penicillin for the treatment of syphilis and the use of vaccines to prevent the human papilloma virus (HPV). For example, individuals who receive the HPV vaccine do not engage in sexual activity sooner in life than those who do not. A systematic review found the opposite: those who do not receive the HPV vaccine are *more* likely to have earlier sexual debut.⁸⁵

The same finding applies to PrEP: a large body of research finds that these medications do not systematically increase whole numbers of sex acts.⁸⁶ As discussed in section II, the 2010 iPrEx clinical trial evaluated the sexual behavior of study participants, including number of sexual partners which decreased for both PrEP and control groups.⁸⁷ This finding suggests that, in certain settings, PrEP use is actually accompanied by less sexual activity after beginning use, contrary to the Braidwood plaintiffs’ assertions.

In a second stage in 2014, the iPrEx study tested PrEP drug concentrations to evaluate the relationship between adherence (i.e., that patients reliably take their medication) and sexual behaviors, with syphilis infection being used as a proxy for sexual behavior because it can be transmitted even with barrier protection. Syphilis infections decreased dramatically, suggesting no evidence of increased sexual behavior in those using PrEP.⁸⁸ Additional studies have shown that PrEP use correlates with reduced sexual activity while in use.⁸⁹

⁸⁵ Kasting ML, Shapiro GK, Rosberger Z, Kahn JA, and Zimet GD. Tempest in a teapot: A systematic review of HPV vaccination and risk compensation research. *Hum Vacc & Immunotherapeutics*. 2016;12(6):1435-1450.

⁸⁶ Traeger MW, Schroeder SE, Wright EJ, Hellard ME, Cornelisse VJ, Doyle JS, Stoové MA. Effects of pre-exposure prophylaxis for the prevention of human immunodeficiency virus infection on sexual risk behavior in men who have sex with men: a systematic review and meta-analysis. *Clin Infect Dis*. 2018;67(5):676-686.

⁸⁷ See Grant et al (2010), supra; Grant et al. (2014), supra.

⁸⁸ Grant et al. (2014), supra.

⁸⁹ Blumenthal J, Moore DJ, Jain S, Sun X, Ellorin E, Corado K, Hoenigl M, Dube M, Haubrich R, Morris SR, and the California Collaborative Treatment Group (CCTG) TAPIR Study Team. Recent hiv risk behavior and partnership type predict hiv pre-exposure prophylaxis adherence in men who have sex with men. *AIDS Patient Care and STDs*. 2019: 220-226. This study showed that those reporting no or single partnerships at study conclusion increased from 0.5% to 9% in PrEP users; Whitfield THF, Jones SS, Wachman M, Grov C, Parsons JT, Rendina HJ. The impact of pre-exposure prophylaxis (PrEP) use on sexual anxiety, satisfaction, and esteem among gay and bisexual men. *J Sex Res*. 2019;56(9):1128-1135; Beymer MR, DeVost MA, Weiss RE, Dierst-Davies R, Shover CL, Landovitz RJ, Beniasians C, Talan AJ, Flynn RP, Krysiak R, McLaughlin K, Bolan RK. Does HIV pre-exposure prophylaxis use lead to a higher incidence of sexually transmitted infections? A case-crossover study of men who have sex with men in Los Angeles, California. *Sex Transm Infect*. 2018;94(6):457-462; Streeck H, Jansen K, Crowell TA, Esber A, Jessen HK, Cordes C, Scholten S, Schneeweiss S, Brockmeyer N, Spinner CD, Bickel M, Esser S, Hartikainen J, Stoeckl A, Lehmann C, Marcus U, Vehreschild JJ, Knorr A, Brillen AL, Tiemann C, Robb ML, Michael NL. HIV pre-exposure prophylaxis was associated with no impact on sexually transmitted infection prevalence in a high-prevalence population of predominantly men who have sex with men, Germany, 2018 to 2019. *Euro Surveill*. 2022;27(14):2100591; McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet*. 2016;387(10013):53-60; Marcus JL, Glidden DV, Mayer KH, et al. No evidence of sexual risk compensation in the iPrEx trial of daily oral HIV preexposure prophylaxis. *PLoS One*. 2013;8(12):e81997.

A 2019 systematic review evaluated 17 studies and demonstrated equivocal findings, including no major increase in sexual activity in those who take PrEP.⁹⁰ Some of the studies examined showed no association between PrEP use and sexual practices, whereas others showed a slight association in either direction (meaning that PrEP is either associated with safer or less safe sexual practices). Qualitative research offers additional insights into the nuances of sexual decision making among those who take PrEP and again, does not demonstrate any pervasive trend suggesting that use of the medication encourages sex. Individuals taking PrEP, like all sexually active people, calculate the risk and reward of a wide range of sexual behaviors with individualized goals.⁹¹

Further, no data establish that PrEP increases the use of injectable drugs. This is likely because people who use such drugs have very low uptake of PrEP and there are significant barriers to conducting clinical research in this marginalized population. Thus, there is no existing evidence to support the plaintiffs' claim that PrEP "facilitates and encourages" drug use.

2. *Alternatively, if the Braidwood religious objection, as the court suggests, exists independent of the facts, it is so overbroad that it could permit religious objectors to opt out of insurance coverage for any preventative or procedure.*

The *Braidwood* court dismisses the government's argument that the Braidwood plaintiffs' objection is "an empirical [claim] that requires factual support"⁹² and cites dicta in a concurring opinion in a case involving contraception for the proposition that the plaintiffs' "sincere religious belief" is all that is required to establish that any rule "substantially burdens" the plaintiffs' religion.⁹³ Notably, the contraceptive cases have a distinct legal and factual setting: the plaintiffs in those cases objected expressly to the use of contraception, and not to behaviors supposedly "facilitated" by it.⁹⁴ By contrast, the *Braidwood* objectors do not object to anyone taking PrEP – they object based on their view that PrEP "facilitates" disfavored sexual behavior and use of drugs.

The *Braidwood* court's rejection of empirical reality as irrelevant suggests a second interpretation of the *Braidwood* religious exemption, which is that employers can opt out of the PrEP Mandate because they sincerely believe, even without any factual foundation, that members of disfavored groups will reap health benefits from PrEP.

But this interpretation of the *Braidwood* religious exemption would be wildly overbroad, opening the way for employers to opt out of any treatment that may benefit members of groups whose identity or conduct contravenes employers' beliefs.⁹⁵ Following this line of reasoning, a

⁹⁰ Traeger, et al. (2018), *supra*.

⁹¹ Klasko-Foster L, Wilson K, Bleasdale J, Gabriel SJ, & Przybyla 2. "Shades of risk": Understanding current PrEP users' sexually transmitted infection perceptions, *AIDS Care*. 2022;34(3): 353-358.

⁹² *Braidwood* at 38.

⁹³ *Id.*

⁹⁴ See *Burwell v. Hobby Lobby Stores*, 573 U.S. 682 (2014) (plaintiffs believed that the use of contraceptives is immoral).

⁹⁵ See Mello M, and O'Connell AJ, The Fresh Assault on Insurance Coverage Mandates, *NEJM* 2023;388:1-3.

court would be bound to approve a religious objection to any medical procedure or, indeed, healthcare in general, without any showing that the belief is grounded in reality.⁹⁶

The measles vaccine, to take a concrete example, benefits the whole community, and the community includes LGBTQ people, whose identity and sexuality the plaintiffs reject. Under the *Braidwood* logic, the plaintiffs could seek an exemption for covering measles vaccines. The same flawed logic would apply with equal force to any medical treatment. Hospital care for heart failure, for example, benefits anyone with need, including LGBTQ people. Preserving their lives would enable them to continue to live an identity or engage in sexual behavior that violates the religious employer's beliefs. Interpreted this way, the *Braidwood* religious exception is not an exception but an entry point for religious employers to opt out of health coverage entirely.

This breathtakingly broad version of the *Braidwood* religious exemption should not stand in light of the compelling public interests that support the PrEP Mandate and other health insurance requirements. Suppose, for example, that a large Christian business objected to pollution restrictions on the ground that the Bible teaches that man has unfettered dominion over the Earth. The logic of *Braidwood* would seemingly permit such businesses to opt out of environmental protections and pollute the environment without restriction.

Further, the *Braidwood* court rests on the finding that the plaintiffs' religious beliefs about the consequences of PrEP were "sincere" without taking into account the massive difficulties in proving sincerity of belief. The religious exemption as articulated by the court invites individuals and businesses to put forward insincere beliefs in order to act on animus toward LGBTQ people and other marginalized groups. Neither courts nor any other governmental authority can reliably distinguish sincere from insincere beliefs, and thus the religious exemption, if permitted without any empirical foundation, is an open invitation to misuse.

3. *As a third possibility, the Braidwood religious exemption might rest on the claim that PrEP "primarily" benefits members of the LGBTQ community, people who have extramarital sex, and those who use injectable drugs, but this version of the religious exemption is disastrously overbroad.*

A third interpretation of the *Braidwood* religious exemption might rest on the (unstated) empirical proposition that PrEP primarily benefits members of religiously disfavored groups (the "primary benefit" rationale). That is, the *Braidwood* court might assume that the PrEP Mandate uniquely violates the plaintiffs' religious beliefs – in ways that other kinds of health care would not – because PrEP is perceived to be primarily a medication that benefits LGBTQ people and individuals who inject drugs.

The *Braidwood* court does not articulate this view, but it may be implicit, given the plaintiffs' framing of PrEP. While men who have sex with men do benefit from the availability of PrEP, so

⁹⁶ See Noah Feldman, A Texas Judge Just Took Religious "Freedom" Too Far, Bloomberg, Sept. 14, 2022, at <https://www.bloomberg.com/opinion/articles/2022-09-14/texas-prep-drug-ruling-in-braidwood-case-should-be-overturned>.

do many others, including all sexually active adults and their current and future children, as Part III of this report documents.

The *Braidwood* court offers no standard for determining when a public health measure produces “primary” benefits to a group whose identity and relationships are rejected by religious plaintiffs. Nor could any workable standard be created. It is true that men who have sex with men and people who inject drugs do face a higher-than-average risk of contracting HIV. But within those groups, some individuals have higher or lower risks. For example, HIV risk is lower for men who have sex with men and also use condoms; it is also lower for people who inject drugs who have access to unused needles.

The “primary benefit rationale for the religious exemption is ultimately incoherent because HIV risk (and, thus, the projected benefit of PrEP) depends on many factors. HIV disproportionately affects Black and other minority communities. Adolescents and young adults are at greater-than-average risk for HIV, as are people who drink alcohol and people who live in urban areas.⁹⁷

It is difficult to avoid the conclusion that the *Braidwood* plaintiffs and the court chose to endorse, without question, damaging and inaccurate stereotypes of LGBTQ people and people who inject drugs. If the *Braidwood* court blocks the national PrEP Mandate, the result will be new HIV transmissions, with attendant harm to the health and quality of life of people who are at risk for HIV throughout the United States, as well as individuals in their social networks. These harms would be disproportionately (or primarily) inflicted on minority communities and the economically disadvantaged, facts that are noticeably absent from the *Braidwood* analysis.

⁹⁷ HIV.gov, Alcohol and HIV Risk (2022), at <https://www.hiv.gov/hiv-basics/hiv-prevention/reducing-risk-from-alcohol-and-drug-use/alcohol-and-hiv-risk>.