No. 23-10326

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

BRAIDWOOD MANAGEMENT, INC., *et al.*

Plaintiffs-Appellees-Cross-Appellants,

JOEL MILLER; GREGORY SCHEIDEMAN,

Plaintiffs-Cross-Appellants,

v.

XAVIER BECERRA, *et al.*,

Defendants-Appellants-Cross-Appellees.

On Appeal from the United States District Court
for the Northern District of Texas,
No. 4:20-CV-283, Hon. Reed C. O'Connor

BRIEF OF GILEAD SCIENCES, INC. AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANTS-APPELLANTS

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CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that the following listed entity as described in Rule 28.2.1, in addition to those disclosed in the parties' statements of interested parties, has an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

Gilead Sciences, Inc. has no parent corporation. No publicly traded corporation owns 10% or more of Gilead Sciences, Inc.'s stock.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

TABLE OF AUTHORITIES

Page(s)

INTEREST OF *AMICUS CURIAE*

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines in areas of unmet medical need. Gilead endeavors to transform and simplify care for people with life-threatening illnesses around the world. Its portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer, inflammation, emerging viruses, and respiratory diseases. And its portfolio of marketed products includes a number of category firsts, including the first hepatitis C virus treatment to provide a complete regimen in a single tablet and the first approved antiviral treatment for COVID-19.[1]

For over 35 years, Gilead has been a pioneer in HIV care. It has driven advances in treatment, prevention, and research towards a cure. Thus far, Gilead's researchers have developed 12 HIV medications approved by the Food and Drug Administration ("FDA"), including the first

[1] Pursuant to Federal Rule of Appellate Procedure 29, *amicus* states that no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus* or its counsel made a monetary contribution to its preparation or submission. The parties consented to the filing of this brief.

single-tablet regimen to treat HIV and the first antiretroviral medicine for the protection of individuals who may be exposed to HIV but have not yet acquired the virus—a drug regimen known as HIV pre-exposure prophylaxis ("PrEP"). Gilead's groundbreaking FDA-approved PrEP medications are called TRUVADA for PrEP® and DESCOVY for PrEP®. These medications, and Gilead's other advances, have helped to transform HIV into a preventable and treatable chronic condition for millions of people.

INTRODUCTION

Over four decades after the HIV epidemic began, HIV remains an urgent public health crisis in the United States. Each year, more than 1,500 individuals in the United States die from HIV-related causes, and over 30,000 Americans acquire the virus. Fortunately, major scientific and medical advances mean that HIV is now a manageable chronic condition for those able to access treatment. But the benefits of new biomedical preventive tools and treatments are not felt equitably. Some groups are still disproportionately impacted by HIV, including young men of all races and ethnicities, Black women, and residents of the U.S. South—including States encompassed in this Circuit.

Ending the HIV epidemic in the United States requires addressing longstanding barriers to HIV prevention, testing, and treatment. Increasing access to PrEP, which is remarkably effective at preventing the transmission of HIV, is therefore an essential part of federal efforts to end the epidemic. According to the Centers for Disease Control and Prevention ("CDC"), when taken as prescribed, PrEP reduces by 99% the risk of acquiring HIV through sex, and is 74% effective at preventing HIV transmission through intravenous drug use. Recognizing this, the

federal government has made increasing PrEP uptake a key pillar of its Ending the HIV Epidemic in the United States ("EHE") initiative, which aims to reduce new HIV cases by at least 90% before 2030.

In light of PrEP's substantial medical benefits, the U.S. Preventive Services Task Force ("USPSTF") issued a Grade A recommendation for PrEP medication. The USPSTF is a panel of experts that evaluates scientific and medical evidence and makes recommendations about clinical preventive services. These are services that help to identify and prevent health conditions earlier and make treatment of health conditions easier, saving lives and improving health. The Affordable Care Act ("ACA") prohibited most commercial insurers from imposing patient cost sharing on preventive services with a Grade A or B recommendation from USPSTF. Through its recommendations, the USPSTF has made invaluable contributions to public health.

One such contribution is the Grade A recommendation for PrEP, which USPSTF issued in 2019. That recommendation covers medically appropriate PrEP medications, as well as essential monitoring and support services—including HIV testing, associated doctor's visits, and counseling services—that should be received by PrEP users to ensure that

PrEP is taken safely and effectively.[2] Thus, given the USPSTF's recommendation (in combination with the ACA's coverage requirements), medically appropriate PrEP and certain associated services must be available with no out-of-pocket costs to most commercially insured patients.

As applied to PrEP, the ACA's coverage requirement extends coverage without cost sharing to many of the 1.2 million people in the United States whom the CDC estimates could benefit from comprehensive HIV prevention strategies, including PrEP. The requirement is especially beneficial to those with the greatest unmet need for the medication, as gender, racial, and regional inequalities in PrEP use persist.

For all groups, a reduction in the HIV transmission rate is an unqualified good—it means better health outcomes, a reduction in the medical expense associated with treating HIV and the other chronic

[2] The coverage mandate for PrEP applied to insurance plan or policy years beginning on or after June 30, 2020. In July 2021, the federal government confirmed that commercial insurers must cover not only the PrEP medications but also the ancillary services just described, because the ACA requires coverage of all services given a Grade A by USPSTF, and the "USPSTF Final Recommendation Statement encompasses FDA-approved PrEP antiretroviral medications, as well as … baseline and monitoring services." Dep't of Health & Human Servs., *FAQs about Affordable Care Act Implementation Part 47* (July 19, 2021), https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf.

conditions associated with the virus, and progress toward ending a decades-long epidemic.

Despite all of this, the district court entered a nationwide injunction (subsequently stayed in part by the motions panel) that categorically precludes the government from maintaining or enforcing the coverage mandate for PrEP and the associated preventive services—not just against the plaintiffs, but against any employer or health insurance plan in the United States. Gilead writes to ensure that as the Court considers the parties' appeals in this case, it does so with the benefit of a full and complete understanding of the benefits preventative medicines like PrEP bring to people, communities, and public health.

ARGUMENT

I. PrEP Medicines Are An Essential HIV Prevention Tool.

A. The HIV epidemic must be met with innovative and effective treatments and prevention strategies.

The earliest cases of AIDS, the disease caused by HIV, were reported in 1981.[3] Since then, over 700,000 people have died of HIV-related

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

illnesses in the United States.[4] Thanks to major medical advances, HIV mortality rates have slowed dramatically, and HIV is now a chronic, treatable condition. But despite these enormous strides in treatment, care, and prevention, HIV remains a serious public health challenge. More than 1.2 million Americans are living with HIV, and about 35,000 new cases are diagnosed every year in the United States.[5] More than 1,500 still die from the disease each year.[6]

Because of economic and social barriers to accessing prevention, diagnostic testing, and treatment for HIV, the impacts of HIV are unequally distributed across geographic regions, by race and ethnicity, and across other lines of difference.[7] Geographically, residents of the U.S. South accounted for 53% of new HIV cases in 2019 but only 38% of the country's population.[8] Within the South, Texas has been particularly

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[4] *Id.*
[5] *Id.*
[6] *Id.* ("[M]ore 1,740 people died with HIV/AIDS as the underlying cause of death in 2020.").
[7] Ctrs. for Disease Control & Prevention, *Social Determinants of Health Among Adults Diagnosed with HIV Infection, 2018*, 25 HIV Surveillance Suppl. Rep. 6 (2020), https://www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-supplemental-report-2020-vol25-no3.pdf.
[8] Ctrs. for Disease Control & Prevention, *The State of the HIV Epidemic in the U.S.* (June 23, 2022), https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/state-of-the-hiv-epidemic-factsheet.html.

affected and "is lagging behind in HIV control efforts," including in uptake of PrEP.[9] Racial inequalities persist as well, with Black and Latino people most severely affected by HIV. In 2019, for example, Black people made up 13% of the U.S. population but 40% of people with HIV.[10] And Black women accounted for 54% of new HIV diagnoses among women in 2021, despite comprising just 14% of women in the United States.[11] As discussed further below, permitting insurers to reimpose cost sharing for preventive services recommended by USPSTF would exacerbate these inequalities by placing another barrier between PrEP and the individuals who could benefit most from the medication and related testing, monitoring, and counseling.

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[9] Ume L. Abbas, et al., *Human Immunodeficiency Virus in the State of Texas of the United States: Past Reflections, Present Shortcomings, and Future Needs of the Public Health Response*, 7 Open Forum Infectious Diseases 1, 5–6 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7545115/pdf/ofaa348.pdf; *see also* AIDSVu, *Local Data: Texas*, https://aidsvu.org/local-data/united-states/south/texas/ (last visited June 27, 2023).

[10] HIV.gov, *Impact on Racial and Ethnic Minorities* (Jan. 20, 2023), https://www.hiv.gov/hiv-basics/overview/data-and-trends/impact-on-racial-and-ethnic-minorities/.

[11] AIDSVu, *Black Women and PrEP: An AIDSVu Infographic* (June 21, 2023), https://aidsvu.org/black-women-and-prep-an-aidsvu-infographic/.

For all populations, HIV is transmissible through direct contact with blood or other bodily fluids from a person with HIV who has a detectable viral load. The transmission category most associated with new HIV diagnoses is sex. The CDC estimates that in 2021, male-to-male sexual contact accounted for 67% of all new HIV cases and male-to-female sexual contact accounted for 22% of new diagnoses.[12] HIV can also be transmitted from person to person through needle sharing, or during pregnancy, childbirth, or breastfeeding. Indeed, the chance of transmission from mother to child during pregnancy, delivery, or breastfeeding is as high as 45%, if adequate preventive measures are not taken.[13]

Once diagnosed, HIV is treated with antiretroviral therapy ("ART"), a combination of medications that, when taken consistently, can suppress the virus to an undetectable level. An undetectable viral load means that the amount of virus in the blood is so low that it cannot be measured by a laboratory test. Research shows that getting to and staying

[12] Ctrs. for Disease Control & Prevention, *Basic Statistics*, https://www.cdc.gov/hiv/basics/statistics.html.
[13] Ga. Dep't of Pub. Health, *Perinatal HIV Surveillance Report Georgia, 2020-2021* (Mar. 31, 2023), at 3.

undetectable prevents transmitting HIV through sex.[14] Highly active ART was a pathbreaking invention that changed the course of the HIV epidemic.[15] However, people living with HIV continue to face significant barriers to maintaining viral suppression. Many are not able to access the treatment or are not retained in care, due to obstacles that range from HIV-related social stigma to a dearth of available providers.[16] And many—around 13% of those living with HIV—are not even aware that they have the virus, leading to preventable transmission of HIV.[17]

All individuals who acquire HIV face negative effects from the virus. People living with HIV are more likely to develop aging-related conditions at a younger age than the general population, even when their disease is well controlled. These conditions include cardiovascular disease, renal disfunction, dementia, diabetes, osteoporosis, and some

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[14] Nat'l Inst. of Allergy & Infectious Diseases *HIV Undetectable=Untransmittable (U=U), or Treatment as Prevention* (May 21, 2019), https://www.niaid.nih.gov/diseases-conditions/treatment-prevention.

[15] *See generally* Samuel Broder, *The Development of Antiretroviral Therapy and its Impact on the HIV-1/AIDS pandemic*, 85 Antiviral Res. 1 (2010).

[16] *See* Meredithe McNamara, et al., Braidwood *Misreads the Science: The PrEP Mandate Promotes Public Health for the Entire Community*, at 6–9 (Feb. 13, 2023), https://law.yale.edu/sites/default/files/documents/pdf/prep_report_final_feb_13_2023_rev.pdf.

[17] *See* KFF, *supra* note 3; *see also* McNamara, *supra* note 16, at 6–7.

cancers.[18] Researchers have thus estimated that avoiding one new case of HIV saves over $850,000 in lifetime healthcare costs.[19] And the average annual and cumulative healthcare costs for people living with HIV are up to seven times higher than the costs for those without HIV.[20]

Of course, the individual and social costs of HIV extend far beyond medical costs. The disease takes an emotional toll on those affected, including families and communities. And living with HIV is associated with higher rates of unemployment, and much more.[21] Prevention of new cases is therefore the cornerstone of the public health response to HIV—and PrEP medicines and the ancillary services needed to ensure PrEP medicines can be taken as prescribed are an essential HIV prevention tool.

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[18] Andrea M. Lerner, et al., *Comorbidities in Persons with HIV: The Lingering Challenge*, 323 J. of the Am. Med. Ass'n 19 (2020).
[19] Joshua P. Cohen, et al., *Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population*, 4 PharmacoEconomics Open 687 (2020), https://link.springer.com/article/10.1007/s41669-020-00209-8.
[20] *Id.*
[21] Bruce R. Schackman et al., *The Lifetime Medical Cost Savings from Preventing HIV in the United States*, 53 Med. Care 293 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4359630/.

B. Widespread access to PrEP is key to ending the HIV epidemic.

In 2012, the FDA approved the first PrEP medication, TRUVADA for PrEP®. TRUVADA® was initially developed and marketed by Gilead as an HIV treatment medication to be used in combination with other antiretroviral medicines.[22] But as early as the 1990s, Gilead recognized the promise of TRUVADA as a prophylactic for blocking the transmission of HIV to HIV-negative people.[23] Gilead spent over two decades studying its potential as a preventive therapy, and invested at least $1.1 billion in researching and developing the drug.[24] When the FDA approved TRUVADA for PrEP® in 2012, it was the first drug approved to prevent

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[22] Gilead, Press Release, *U.S. Food and Drug Administration Approves Gilead's Truvada® for Reducing the Risk of Acquiring HIV* (July 16, 2012), https://www.gilead.com/news-and-press/press-room/press-releases/2012/7/us-food-and-drug-administration-approves-gileads-truvada-for-reducing-the-risk-of-acquiring-hiv. PrEP medications used for HIV prevention contain fewer ingredients than a complete HIV treatment regimen, and are not effective in treating HIV.

[23] Statement of Daniel O'Day Chairman & CEO, Gilead Sciences, Inc. before the Comm. on Oversight & Reform, U.S. House of Representatives, at 5 (May 16, 2019), https://docs.house.gov/meetings/GO/GO00/20190516/109486/hhrg-116-go00-wstate-odayd-20190516.pdf/.

[24] *Id.* at 2.

HIV.[25] Gilead's DESCOVY for PrEP® was approved for HIV prevention in 2019.[26]

PrEP is remarkably effective at preventing HIV and has a well-established safety profile, as the USPSTF found in providing a Grade A recommendation for PrEP and related monitoring and counseling services.[27] Research shows that, when taken as prescribed, PrEP reduces the risk of acquiring HIV from sex by about 99%, and it is at least 74% effective at preventing HIV transmission through intravenous drug use.[28]

The CDC recommends that patients on a daily oral PrEP medication follow up with their healthcare providers every three months to receive refills and support for medication adherence; to engage in

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[25] *Id.* at 2–3.

[26] Food & Drug Admin., News Release, *FDA Approves Second Drug to Prevent HIV Infection as Part of Ongoing Efforts to End the HIV Epidemic* (Oct. 3, 2019), https://www.fda.gov/news-events/press-announcements/fda-approves-second-drug-prevent-hiv-infection-part-ongoing-efforts-end-hiv-epidemic.

[27] U.S. Preventive Servs. Task Force, Final Recommendation Statement, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#bootstrap-panel--8.

[28] Ctrs. for Disease Control & Prevention, *PrEP Effectiveness* (June 6, 2022), https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html.

discussions that include counseling about sexual health and HIV prevention; and to be tested for HIV as well as sexually transmitted infections ("STIs").[29] These testing, monitoring, and counseling services are necessary to ensure that PrEP is used safely and effectively. Testing for HIV, for example, ensures that PrEP is only used by individuals who are HIV-negative, both at initiation of PrEP medicines and while taking it. This HIV testing is critical (and required by the products' FDA-approved labeling) because while PrEP medicines are antiretrovirals, they do not constitute complete regimens to treat HIV. Taking an incomplete HIV treatment regimen could lead to antiretroviral resistance and limit future treatment options, making the HIV harder to treat.[30] Similarly, adherence counseling is critical for patient and public health because the efficacy of PrEP medication is highly correlated with taking the medication consistently (a concept known as adherence). Providing patients with counseling on adherence increases the likelihood that patients will take their PrEP medication consistently, thus decreasing their chances

[29] U.S. Pub. Health Serv., *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update*, at 43–44, https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf ("CDC PrEP Guidelines").
[30] *Id.* at 29.

of acquiring HIV. As discussed below, studies have demonstrated that access to these ancillary preventive services has a "potent multiplier effect on public health," including by identifying and treating other conditions such as STIs.[31] *See infra*, at 26–27. Because these aspects of the PrEP intervention are essential, they too are covered without cost sharing.[32]

Current CDC Guidelines recommend that *all* sexually active adults and adolescents be informed about PrEP for the prevention of HIV acquisition.[33] And the CDC estimates PrEP is recommended for a total of about 1.2 million people in the United States.[34] Yet, in 2021, only a third of those for whom medication is recommended were prescribed it.[35] That figure is a reflection of the barriers, including stigma and other social or economic factors, that continue to be obstacles to fully realizing PrEP's preventive benefits.

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[31] McNamara, *supra* note 16, at 12.
[32] *FAQs about Affordable Care Act Implementation Part 47*, *supra* note 2.
[33] CDC PrEP Guidelines, *supra* note 29, at 13.
[34] Ctrs. for Disease Control & Prevention, *PrEP for HIV Prevention in the U.S.*, https://www.cdc.gov/nchhstp/newsroom/fact-sheets/hiv/PrEP-for-hiv-prevention-in-the-US-factsheet.html ("PrEP for HIV Prevention").
[35] Ctrs. for Disease Control & Prevention, *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections*, https://www.cdc.gov/nchhstp/newsroom/2023/2021-hiv-incidence.html.

The unmet need for PrEP is particularly acute in the South, among Black and Hispanic people, and among women. These groups face higher, disproportionate rates of HIV transmission and lower PrEP utilization. They also face economic and social barriers to accessing preventive treatments such as PrEP—including a lack of accessible providers, discrimination within the health system, and HIV-related stigma.[36] These barriers to access are starkly reflected in the latest data on PrEP uptake: For example, although Black people represented 42% of new HIV diagnoses in 2021, only 14% of PrEP users are Black.[37] And although women represent 18% of new HIV diagnoses, only 8% of those who take PrEP are women.[38] This indicates a high unmet need for PrEP among both Black people and women, and likely among Black women as well.

For women, HIV prevention methods like PrEP are absolutely essential. Because "[g]ender-based relationship inequalities … complicate

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[36] *See e.g.*, AIDSVu, *Dr. Whitney S. Rice on Social Determinants of Health Among Women* (Mar. 8, 2023), https://aidsvu.org/dr-whitney-s-rice-on-social-determinants-of-health-among-women/.
[37] AIDSVu, *AIDSVu Releases New Data Highlighting Ongoing Inequities in PrEP Use among Black and Hispanic People and across Regions of the Country* (June 21, 2023), https://aidsvu.org/aidsvu-releases-new-data-highlighting-ongoing-inequities-in-prep-use-among-black-and-hispanic-people-and-across-regions-of-the-county/.
[38] *Id.*

condom negotiation and other forms of self-protective sexual behaviors," heterosexual women benefit from methods of HIV prevention that they can independently control.[39] Further, effective prevention among women helps to assure that HIV is not later transmitted from mother to child during pregnancy, childbirth, or breastfeeding. "The highest rates of perinatal transmission [ar]e found among infants born to Black women," a reality that "highlight[s] the need to improve HIV prevention for Black women," including through the more widespread provision of" PrEP.[40]

For these reasons, increasing PrEP uptake—especially among groups and in regions with the greatest unmet need for PrEP—is therefore a centerpiece of federal government initiatives to end the HIV epidemic. The government has committed to reducing the number of new HIV cases in the United States by 90% by 2030 through its EHE

[39] McNamara, *supra* note 16, at 15.

[40] Margaret A. Lampe et al., *Achieving Elimination of Perinatal HIV in the United States*, 151 Pediatrics (Apr. 18, 2023), https://doi.org/10.1542/peds.2022-059604. Other effective preventive measures include optimal use of ART during pregnancy. *See* Tex. Consortium for Perinatal HIV Prevention, *Guidelines for Care for HIV-Infected Pregnant Women in Texas*, https://tinyurl.com/2p9zsxxp.

initiative.[41] To achieve that reduction, EHE aims to have 50% of people who could benefit from PrEP taking it by 2030.[42] Toward that goal, the Department of Health and Human Service's ("HHS") Ready, Set, PrEP program provides PrEP at no cost to thousands of individuals without health insurance, and Gilead has partnered with the government to donate PrEP to up to 200,000 individuals annually through 2030.[43]

These programs reduce HIV transmission rates and ultimately will help to end the HIV epidemic in the United States. The ACA's requirement that most commercial insurers offer PrEP and ancillary services to insured patients without cost sharing serves the same ends.

II. Coverage Without Patient Cost Sharing For Preventive Services Is Significant For People Who Can Benefit From PrEP, Their Communities, And The Public As A Whole.

A. Coverage without cost-sharing requirements has expanded access to PrEP and other related preventive services.

In the past, cost-sharing obligations may have prevented patients from using PrEP. As one study reported, before PrEP medications and

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[41] HIV.gov, *What is* Ending the HIV Epidemic in the U.S.*?* (July 1, 2022), https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/ ("What is *Ending the HIV Epidemic*").
[42] PrEP for HIV Prevention, *supra* note 34.
[43] What is *Ending the HIV Epidemic*, *supra* note 41.

ancillary services became available without cost sharing to most privately insured patients, "[h]igh deductibles and copays were" widely cited by patients as "key barriers" to accessing PrEP.[44] Some found these financial burdens "cost prohibitive," while others viewed preventive services as discretionary and chose not to invest their resources in paying for PrEP.[45]

Studies have found that the cost of PrEP medicines and associated patient cost-sharing for those medicines are not the barrier to PrEP access. Manufacturer patient assistance programs, like Gilead's Advancing

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[44] Emma Sophia Kay et al., *Is Insurance a Barrier to HIV Preexposure Prophylaxis? Clarifying the Issue*, 110 Am. J. Pub. Health 61, 63 (2020), https://doi.org/10.2105/AJPH.2019.305389; Thomas H.F. Whitfield et al., *Why I Quit Pre-Exposure Prophylaxis (PrEP)? A Mixed-Method Study Exploring Reasons for PrEP Discontinuation and Potential Re-initiation Among Gay and Bisexual Men*, 22 AIDS & Behav. 3566 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6077114/ (reporting results of a survey from before the coverage mandate finding that insurance and other costs were a "major barrier" to PrEP adherence); Andrew Silapaswan, et al., *Pre-Exposure Prophylaxis: A Narrative Review of Provider Behavior and Interventions to Increase PrEP Implementation in Primary Care*, 32 J. Gen. Internal Med. 192, 193 (2017), https://pubmed.ncbi.nlm.nih.gov/27761767/ (reporting prior to the PSTF mandate that "[i]nsurance coverage and out-of-pocket costs of PrEP have also been cited as barriers to implementation"); Adedotun Ogunbajo et al., *Multilevel Barriers to HIV PrEP Uptake and Adherence Among Black and Hispanic/Latinx Transgender Women in Southern California*, 25 AIDS & Behav. 2301 (2021), https://doi.org/10.1007/s10461-021-03159-2.

[45] Kay, *supra* note 44, at 62–63.

Access® Program, provide copay assistance to eligible individuals to help them access Gilead-branded PrEP medications; however, there is no comparable financial assistance for PrEP-related ancillary services (e.g., clinical visits, laboratory tests, etc.). Thus, the public health literature indicates that the medical visits and laboratory tests that are required for those who use PrEP "may make PrEP too expensive for the populations for whom PrEP is most recommended."[46]

Congress enacted the ACA's preventive services coverage requirements to remove these and other obstacles to care. The law had its intended effect, as other *amici* have detailed.[47] In part because of the ACA, over 150 million people can now receive a wide range of preventive services at no cost, including the ancillary services needed to ensure that PrEP can be taken as prescribed. And "[s]tudies demonstrate" associated

[46] *Id.* at 61.

[47] *See generally* Br. for Am. Pub. Health Ass'n. & Pub. Health Deans & Scholars as *Amici Curiae* in Support of Partial Stay Pending Appeal, *Braidwood Mgmt., Inc. v. Becerra*, No. 23-10326, ECF No. 40-2 (April 28, 2023).

"increases in access to preventive services, including colon cancer screening, HPV vaccination, … and contraceptive use."[48]

Since the enactment of the ACA, the United States has made rapid progress in expanding access to PrEP, which has contributed to the decline in new HIV cases. In 2021, the year the government clarified that PrEP and ancillary services were required to be covered by most insurance plans, the number of individuals prescribed PrEP increased by almost 22% compared to the year before.[49] And between 2017 and 2022, the number of individuals taking PrEP more than doubled.[50]

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[48] Dep't of Health & Human Servs., Off. of Health Policy, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, at 10 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf.

[49] Calculations based on data on PrEP coverage and number of persons prescribed PrEP from Ctrs. for Disease Control & Prevention, *Atlas Plus*, https://www.cdc.gov/nchhstp/atlas/index.htm.

[50] Calculations based on data on PrEP coverage and number of persons prescribed PrEP from Ctrs. for Disease Control & Prevention, *Atlas Plus*, https://www.cdc.gov/nchhstp/atlas/index.htm; *see also* Ctrs. for Disease Control & Prevention, *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections* (May 23, 2023), https://www.cdc.gov/media/releases/2023/p0523-hiv-declines-among-young-people.html ("Among key HIV prevention indicators, the greatest improvement [between 2017 and 2021] was in the number of people taking PrEP to prevent HIV.")

If the district court's broad injunctive remedy were upheld, this progress that has been made toward ending the HIV epidemic could be lost. One study estimates that up to 20% of large employers may reimpose cost sharing on preventive services if permitted to do so,[51] leading many patients to forgo preventive care. Another survey prompted by the district court's ruling found that at least 2 in 5 individuals would be unwilling to pay cost-sharing obligations for 11 (of 12 surveyed) common preventive services recommended by the USPSTF—including STI and HIV testing that is required for PrEP users.[52]

Access to PrEP and the related monitoring and counseling services without patient cost sharing is therefore critical to maintaining and building on progress in preventing HIV. If this access is eliminated, the

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[51] *See* Emp. Benefit Res. Inst., *Will Employers Introduce Cost Sharing for Preventive Services? Findings from EBRI's First Employer Pulse Survey* (Oct. 27, 2022), https://www.ebri.org/docs/default-source/fast-facts/ff-445-pssurvey-27oct22.pdf?sfvrsn=52f4382f_4 (finding that 8% of employers plan to impose cost sharing and 12% may do so).

[52] Paige Minemyer, *Patients Are Likely to Avoid Preventive Care Should ACA Coverage Ruling Stand, Survey Finds*, Fierce Healthcare (Mar. 8, 2023), https://www.fiercehealthcare.com/payers/patients-are-likely-avoid-preventive-care-should-aca-coverage-ruling-stand-survey-finds; *see* Morning Consult, *National Tracking Poll #2301147: Crosstabulation Results* (Jan. 28–29, 2023), https://assets.morningconsult.com/wp-uploads/2023/03/06150931/2301147_cross-tabs_MC_HEALTH_ACA_COURT_CASE_Adults.pdf.

number of PrEP users could drop precipitously—just as a group of researchers found in modeling certain potential adverse effects of the district court's ruling.[53] And the presence of cost-sharing obligations would deter individuals who would benefit from PrEP from starting and staying on the medication.

B. Broad access to PrEP and related preventive services without patient cost sharing is essential to patients and the public health.

The widespread access to PrEP and ancillary services enabled by the coverage mandate is vital to slowing, and eventually stopping, the transmission of HIV. Insurers, the entities that ultimately control coverage and cost-sharing decisionmaking in the absence of legal constraint, now must continue to provide coverage without patient cost-sharing for PrEP and ancillary services. The ACA coverage mandate thus helps ensure continued patient access to these critical preventive services. The benefits of this access are substantial. For example, mathematical models predict that mass uptake of PrEP among men who have sex with men

[53] A. David Paltiel, et al., *Increased HIV Transmissions With Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of* Braidwood Management v. Becerra, Open Forum Infections Diseases, at 3 (Mar. 16, 2023), https://doi.org/10.1093/ofid/ofad139.

("MSM") could substantially reduce the incidence of HIV, achieving up to a 43% reduction in new cases among the MSM population as a whole.[54] And this figure understates the potential impact, as the MSM population is only one population among many that would benefit from PrEP.[55]

By the same token, eliminating the mandate to cover PrEP and ancillary services without cost sharing for most commercially insured individuals could have the devastating effect of increasing HIV transmission. Researchers estimate that ending the coverage mandate could result in an additional 2,083 HIV cases per year among MSM alone.[56] For every 1% decrease in the number of MSM taking PrEP, there would be 114 additional—and entirely preventable—HIV cases in that population.[57] These numbers, which concern just one set of potential PrEP users, provide only a glimpse of the risk to the public health from ending cost-free coverage for PrEP and related monitoring and counseling services.

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[54] Parastu Kasaie, et al., *The Impact of Preexposure Prophylaxis Among Men Who Have Sex with Men: An Individual-Based Model*, 75 J. Acquired Immune Deficiency Syndrome 175 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5488295/ (finding PrEP effective at reducing HIV cases at the population level using modeling).
[55] *See* PrEP for HIV Prevention, *supra* note 34.
[56] *See* McNamara, *supra* note 16, at 11; Paltiel, *supra* note 53.
[57] Paltiel, *supra* note 53, at 3.

Expanded access to PrEP and ancillary services without cost sharing benefits not only the individuals who take the medication but also their communities. Researchers have estimated that increasing the number of PrEP users by just 25% would eliminate more than half of new cases of HIV in some U.S. cities.[58] Studies confirm that in areas where PrEP use is widespread, the rate of HIV transmission declines not only among PrEP users but also across the population.[59] For example, a CDC-led study found that PrEP uptake was significantly associated with decreases in HIV diagnoses at the State level in the United States.[60] Easy access to PrEP without cost sharing thus "protects the[] sexual partners" of those who may acquire HIV, "as well as the future partners of those

[58] Ruchita Balasubramanian et al., *Projected Impact of Expanded Long-Acting Injectable PrEP Use Among Men Who Have Sex with Men on Local HIV Epidemics*, 91 J. Acquired Immune Deficiency Syndrome 144 (2022), https://pubmed.ncbi.nlm.nih.gov/35636746/.

[59] Andrew E. Gulich et al., *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*, 5 Lancet HIV e629, e634–35 (2018).

[60] Dawn K. Smith, et al., *Evidence of an Association of Increases in Pre-exposure Prophylaxis Coverage With Decreases in Human Immunodeficiency Virus Diagnosis Rates in the United States*, 71 Clinical Infectious Diseases 3144 (2020), https://pubmed.ncbi.nlm.nih.gov/32097453/.

partners," any children born to those individuals, and many more individuals.[61]

Broad access to PrEP and ancillary services without cost sharing is especially important in communities that are disproportionately impacted by HIV. These communities often face structural challenges—including fewer hospitals and healthcare personnel—that complicate efforts to treat HIV once it is acquired.[62] HIV prevention, including through PrEP, is therefore essential for the most affected communities.[63]

For these groups and others, the benefits of expanded access to PrEP and related services without cost sharing go far beyond HIV prevention. Because of the comprehensive STI monitoring and counseling on risk-reduction behaviors required for PrEP users, PrEP use is associated with earlier identification of and treatment for, and in some cases lower rates of, a range of STIs.[64] Moreover, PrEP acts as a crucial

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[61] McNamara, *supra* note 16, at 11.
[62] *Id.* at 20.
[63] *See* Donna Hubbard McCree, et al., *An Approach to Achieving the Health Equity Goals of the National HIV/AIDS Strategy for the United States Among Racial/Ethnic Minority Communities*, 131 Pub. Health R. 526 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4937112/.
[64] *See* Samuel M. Jenness et al., *Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis*

gateway to primary care and other preventive services.[65] PrEP use is associated with increased receipt of depression screening, diabetes testing and monitoring, and the flu vaccine, among other services.[66] Thus, studies have found that PrEP use may benefit users' mental health, and help to prevent and treat STIs and chronic diseases other than HIV.[67]

In addition to these public health benefits, broad access to PrEP without cost sharing could produce enormous cost savings for the U.S. healthcare system. Every HIV case averted by PrEP saves hundreds of thousands of dollars in lifetime medical costs, *see supra* 11 & n. 19, and

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Among Men Who Have Sex With Men: A Modeling Study. 65 Clinical Infectious Diseases 712 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5848234/; *see also* McNamara *supra* note 16, at 12–13 (discussing studies).

[65] Whitney C. Sewell 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*, 88 J. Acquired Immune Deficiency Syndrome 31 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8369038/; *see also* Daniel Ikeda et al., *Roll-out of HIV pre-exposure prophylaxis: a gateway to mental health promotion*, 6 BMJ Global Health 12 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8679108/.

[66] Ikeda, *supra* note 65.

[67] *Id.*; *see also* Sewell, *supra* note 65.

widespread uptake would save billions of dollars by preventing thousands of new HIV cases every year.[68]

CONCLUSION

The requirement that commercial insurers cover PrEP and related ancillary services with no cost sharing is significant for both people who can benefit from PrEP and their communities. The requirement further benefits the public health by facilitating broad access to PrEP and related ancillary services without cost sharing that is essential to controlling, and ultimately ending, the HIV epidemic in the United States.

June 27, 2023

Respectfully submitted,

/s/ Kwaku A. Akowuah

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[68] Ctrs. for Disease Control & Prevention, *HIV Cost-Effectiveness*, https://www.cdc.gov/hiv/programresources/guidance/costeffectiveness/index.html.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of June, 2023, an electronic copy of the foregoing was filed with the Clerk of Court for the United States Court of Appeals for the Fifth Circuit using the appellate CM/ECF system, and that service will be accomplished by the appellate CM/ECF system.

/s/ Kwaku A. Akowuah
Kwaku A. Akowuah

CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limitation of Federal Rules of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Fifth Circuit Rule 32.2, this document contains 5,358 words.

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Dated: June 27, 2023

/s/ Kwaku A. Akowuah
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June 28, 2023

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No. 23-10326 Braidwood Mgmt v. Becerra
USDC No. 4:20-CV-283

Dear Mr. Akowuah,

The amicus brief attached to the motion seeking leave to file has been filed as of June 27, 2023. Since the amicus brief was consented, the motion seeking leave to file is unnecessary. No action has been taken on same.

Also, you must electronically file a "Form for Appearance of Counsel" within 14 days from this date. You must name each party you represent, see **FED. R. APP. P.** 12(b) and **5TH CIR. R.** 12 & 46.3. The form is available from the Fifth Circuit's website, www.ca5.uscourts.gov. If you fail to electronically file the form, the brief will be stricken and returned unfiled.

Sincerely,

LYLE W. CAYCE, Clerk

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Mary Frances Yeager, Deputy Clerk
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