No. 24-316

IN THE

Supreme Court of the United States

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.,

Petitioners,

v.

BRAIDWOOD MANAGEMENT, INC., ET AL.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF GILEAD SCIENCES, INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

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 medicines include 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.

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 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"). Indeed, Gilead is currently seeking FDA approval for a new investigational product that could become the first-ever PrEP

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[1] Pursuant to Supreme Court Rule 37, *amici* state that no counsel for any party authored this brief in whole or in part, and that no entity or person other than *amici* and their counsel made any monetary contribution toward the preparation and submission of this brief. Petitioner filed a blanket consent with this Court, and the United States provided its consent.

medication to be administered just twice per year. Gilead's groundbreaking FDA-approved PrEP medications are TRUVADA for PrEP® and DESCOVY for PrEP®. These medications, Gilead's other advances, and its potential future products are helping to transform HIV into a preventable and treatable chronic condition for millions of people.

INTRODUCTION AND SUMMARY OF ARGUMENT

Over four decades after the HIV epidemic began, HIV remains an urgent public health crisis in the United States. More than 1.2 million people are living with HIV in the United States, and each year, 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 and adhere to treatment. But the benefits of new biomedical preventive tools and treatments are not reaching groups who are still disproportionately impacted by HIV, including young men of all races, Black women, and residents of the South.

Ending the HIV epidemic in the United States requires addressing longstanding barriers to HIV testing, prevention, and treatment. Increasing access to PrEP, which is remarkably effective at preventing the transmission of HIV, is an essential part of efforts to end the epidemic. According to the Centers for Disease Control and Prevention ("CDC"), when taken as prescribed, PrEP reduces the risk of acquiring HIV through sex by about 99% and from intravenous drug use by at least 74%.[2] Recognizing this, the Federal

[2] NIH, *Pre-Exposure Prophylaxis*, HIVinfo.NIH.gov (Dec. 11, 2023), https://permanent.link/to/amicus/hivinfo-nih-gov-understanding-hiv-fact-sheets-pre-exposure-prophylaxis-prep-tex-

Government has made increasing PrEP uptake a key pillar of its Ending the HIV Epidemic in the United States initiative, which was launched by President Trump during his 2019 State of the Union Address with the explicit goal of reducing new HIV cases by at least 90% before 2030.[3]

In light of PrEP's substantial medical benefits, the U.S. Preventive Services Task Force ("Task Force") issued a Grade A recommendation for PrEP medication. The Task Force 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 requires most commercial insurers to provide preventive services with a Grade A or B recommendation from the Task Force with no patient cost-sharing obligations. Through its recommendations, the Task Force has made invaluable contributions to public health.

One such contribution is the Grade A recommendation for PrEP, which the Task Force issued in 2019 and updated in 2023. 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

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toralpercent20preppercent20ispercent20mostpercent20effectiveusepercent20bypercent20atpercent20leastpercent2074percent25. No PrEP medicines are currently FDA-approved for reducing the risk of acquiring HIV through IV drug use.

[3] President Donald J. Trump's State of the Union Address (Feb. 5, 2019), https://trumpwhitehouse.archives.gov/briefings-statements/president-donald-j-trumps-state-union-address-2/.

that PrEP is taken safely and effectively.[4] Thus, given the Task Force's recommendation (in combination with the preventive services coverage requirement), 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 preventive services coverage requirement extends coverage without cost sharing to many of the over one million people in the United States whom the CDC has historically estimated could benefit from comprehensive HIV prevention strategies, including PrEP. Eliminating patient cost-sharing for PrEP increases the likelihood that people who can benefit from PrEP are able to start and stay on PrEP, significantly reducing their risk of acquiring HIV. Research shows that higher out-of-pocket costs are associated with increased rates of patient abandonment of insurer-approved PrEP prescriptions. A 2024 study found that even a small increase in patient out-of-pocket costs for PrEP from $0 to $10 doubled the

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[4] The coverage mandate for PrEP applied to insurance plans for policy years beginning on or after June 30, 2020. In July 2021, HHS confirmed that commercial insurers must cover not only the PrEP medications but also the ancillary services just described, because federal law requires coverage of all services given a Grade A by the Task Force, and its "Final Recommendation Statement encompasses FDA-approved PrEP antiretroviral medications, as well as … baseline and monitoring services." Dep't of Health & Hum. Servs., *FAQs about Affordable Care Act Implementation Part 47* (July 19, 2021), https://permanent.link/to/amicus/www-dol-gov-sites-dolgov-files-ebsa-about-ebsa-our-activities-resource-center-faqs-aca-part-47-pdf. In 2023, the Task Force identified two additional FDA-approved formulations for PrEP and continued to recommend baseline and monitoring services. Ctrs. for Medicare & Medicaid Servs., *FAQs about Affordable Care Act And Women's Health and Cancer Rights Act Implementation Part 68* (Oct. 21, 2024), https://www.cms.gov/files/document/faqs-implementation-part-68.pdf.

rate of abandonment.[5] Furthermore, HIV diagnoses were two to three times higher among patients who abandoned PrEP prescriptions than among those who filled them.[6]

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 conditions associated with the virus, and progress toward ending a decades-long epidemic. According to one study, avoiding one new HIV infection can result in an average of $850,557 in lifetime healthcare cost savings.[7] Average annual and cumulative healthcare costs were up to seven times higher for people living with HIV compared to those without HIV.[8]

The Fifth Circuit ruled that the Task Force's structure is unconstitutional and thereby cast doubt on the legal obligation of commercial insurers to cover PrEP and associated services without cost sharing. The potential harms from that ruling are staggering. Access to PrEP and related ancillary tests and services is central to efforts to slow and eventually end the spread of HIV. Barriers to PrEP access, conversely, will make that effort less effective, resulting in a higher rate of HIV transmission and greater costs to the healthcare system. Beyond that, prevention is foundational to the U.S. public health response to the HIV epidemic, and PrEP's efficacy revolutionizes this effort, so long as it

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[5] *See generally* Lorraine T. Dean et al., *Estimating the Impact of Out-Of-Pocket Cost Changes on Abandonment of HIV Pre-Exposure Prophylaxis*, 43 Health Affs. 36 (2024).

[6] *Id.*

[7] *See generally* Joshua P. Cohen et al., *Estimation of the Incremental Cumulative Cost of HIV Compared with a Non-HIV Population*, 4 PharmacoEconomics Open 687 (2020).

[8] *Id.*

remains accessible. Gilead writes to ensure that, as the Court considers the parties' arguments in this case, it does so with the benefit of a full and complete understanding of the benefits preventive 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 innovation and effective treatment and prevention strategies.

The earliest cases of AIDS, the disease caused by HIV, were reported in 1981.[9] Since then, over 700,000 people have died of HIV-related illnesses in the United States.[10] 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 there were more than 31,000 estimated new HIV infections in 2022 in the United States.[11] In 2022 alone, HIV caused nearly 5,000 deaths in the United States.[12]

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[9] KFF, *The HIV/AIDS Epidemic in the United States: The Basics* (August 16, 2024), https://www.kff.org/hivaids/fact-sheet/the-hivaids-epidemic-in-the-united-states-the-basics/.

[10] Maureen M. Goodenow, *Letters from the Director: A New Plan to End the HIV Epidemic in the United States*, National Institutes of Health Office of AIDS Research (Apr. 2019), https://permanent.link/to/amicus/oar-nih-gov-about-directors-corner-letters-director-new-plan-end-hiv-epidemic-united-states.

[11] KFF, *supra* note 9.

[12] *Id.* ("[I]n 2022, nearly 5,000 people died with HIV as the underlying cause of death….").

As discussed further below, permitting insurers to impose cost sharing for preventive services recommended by the Task Force would place yet another barrier between PrEP and the individuals who could benefit from the medication and PrEP-related ancillary tests and services.[13]

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 2022, male-to-male sexual contact accounted for 67% of all new HIV diagnoses and male-to-female sexual contact accounted for 22% of new diagnoses.[14] 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.[15]

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

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[13] Many individuals at risk also experience other challenges, such as poverty, that make it even more difficult for them to access PrEP. *See* https://pubmed.ncbi.nlm.nih.gov/32232664/.

[14] Ctrs. for Disease Control & Prevention, *HIV Diagnoses, Deaths, and Prevalence* (Feb. 7, 2025), https://permanent.link/to/amicus/www-cdc-gov-hiv-data-nhss-hiv-diagnoses-deaths-prevalence-html.

[15] Ga. Dep't of Pub. Health, *Perinatal HIV Surveillance Report Georgia, 2022* (July 15, 2024), at 3.

shows that getting to and staying undetectable prevents transmitting HIV through sex.[16] Highly active ART was a pathbreaking invention that changed the course of the HIV epidemic.[17] 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 HIV-related health care providers.[18] And many—around 13% of those living with HIV—are not even aware that they have the virus.[19] Economic and social barriers to accessing prevention, diagnostic testing, and treatment for HIV persist, with HIV disproportionately impacting communities across geographic regions, by race and ethnicity, and socioeconomic status.[20] The South is disproportionately impacted by HIV; in 2022, the South accounted for 53% of all new HIV diagnoses, despite representing 38% of

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

[17] *See generally* Samuel Broder, *The Development of Antiretroviral Therapy and its Impact on the HIV-1/AIDS pandemic*, 85 Antiviral Res. 1 (2010), https://permanent.link/to/amicus/pubmed-ncbi-nlm-nih-gov-20018391.

[18] *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.

[19] *See* KFF, *supra* note 9 *see also* McNamara, *supra* note 18, at 6–7.

[20] CDC, *HIV Surveillance Supplemental Report: Social Determinants of Health among Adults with HIV Diagnosed in 2022 in the United States and Puerto Rico* (vol. 29, no. 3, Aug. 27, 2024), https://permanent.link/to/amicus/stacks-cdc-gov-view-cdc-160325.

the national population.[21] From a race/ethnicity perspective, Black and Latino people are most severely affected by HIV. In 2022, for example, Black people made up 12% of the U.S. population but 37% of estimated new HIV infections.[22] Black women accounted for 54% of new HIV diagnoses among women in 2021, despite comprising just 14% of women in the United States.[23]

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.[24] These conditions include cardiovascular disease, renal dysfunction, dementia, diabetes, osteoporosis, and some cancers.[25] Researchers have thus estimated that avoiding one new case of HIV saves over $850,000 in lifetime healthcare costs.[26] 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.[27]

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[21] AIDSVu, *Deeper Look: HIV in the South* https://aidsvu.org/resources/deeper-look-south/ (last visited Feb. 21, 2025).

[22] HIV.gov, *U.S. Statistics* (Feb. 5, 2025), https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics.

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

[24] *See generally,* Keir McCutcheon et al., *Cardiac and Renal Comorbidities in Aging People Living With HIV*, 134 Circ. Res. 1636 (2024).

[25] Andrea M. Lerner et al., *Comorbidities in Persons with HIV: The Lingering Challenge*, 323 J. Am. Med. Ass'n 19 (2020).

[26] Cohen et al., *supra* note 7.

[27] *Id.*

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[28] as well as impacts on mental health, travel restrictions, and criminal liability.[29] Prevention of new cases is therefore the cornerstone of the public health response to HIV—and PrEP medicines and the ancillary tests and services needed to ensure PrEP medicines can be taken as prescribed are an essential HIV prevention tool.

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.[30] But as early as the 1990s, Gilead recognized the potential of the medicines in TRUVADA® as a prophylactic for blocking the transmission of HIV to HIV-negative people.[31] Gilead spent

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[28] *See generally*, Catherine H. Maulsby et al., *A Scoping Review of Employment and HIV*, 24 AIDS Behav. 2942 (2020).

[29] CDC, *Living with HIV* (Oct. 28, 2024), https://permanent.link/to/amicus/www-cdc-gov-hiv-living-with-index-html.

[30] 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.

[31] 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),

over two decades studying its potential as a preventive therapy, and invested at least $1.1 billion in researching and developing the drug.[32] When the FDA approved TRUVADA for PrEP® in 2012, it was the first drug approved to prevent sexually-acquired HIV-1.[33] Gilead's DESCOVY for PrEP® was approved for sexually-acquired HIV-1 prevention in 2019, excluding individuals at risk of acquiring HIV-1 from receptive vaginal sex.[34] Gilead continues to innovate in the HIV prevention field and has submitted a new drug application to the FDA for an investigational twice-yearly injectable PrEP called lenacapavir.[35] In one large clinical trial, 100% of women taking lenacapavir did not contract HIV,[36] and in a second, more than 99% of individuals on lenacapavir did not contract HIV.[37]

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https://docs.house.gov/meetings/GO/GO00/20190516/109486/hhrg-116-go00-wstate-odayd-20190516.pdf/.

[32] *Id.* at 2.

[33] *Id.* at 2–3.

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

[35] Gilead, Company Statement, *Gilead Submits New Drug Application to U.S. Food and Drug Administration for Twice-Yearly Lenacapavir for HIV Prevention* (Dec. 19, 2024), https://www.gilead.com/company/company-statements/2024/gilead-submits-new-drug-application-to-us-food-and-drug-administration-for-twice-yearly-lenacapavir-for-hiv-prevention.

[36] Linda-Gail Bekker et al., *Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women*, 391 N. Eng. J. Med., 1179, 1186 (2024).

[37] Colleen F. Kelley et al., *Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons*, N. Eng. J. Med. (Online) 1, 13 (Nov. 27, 2024) https://www.nejm.org/doi/pdf/10.1056/NEJMoa2411858.

Currently available PrEP medicines are remarkably effective at preventing HIV and have a well-established safety profile, as the Task Force found in providing and then, in 2023, reissuing a Grade A recommendation for PrEP and related testing and counseling services.[38] 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.[39] Additionally, research has also shown that PrEP is also highly effective at reducing new HIV diagnoses at the population-level. An analysis using real-world data across all 50 states demonstrated that states with higher levels of PrEP coverage experienced larger declines in new HIV diagnoses from 2012-2021, whereas states with the lowest levels of PrEP coverage saw an annual increase in new HIV diagnoses during the same timeframe.[40] We believe that new PrEP medicines, such as the investigational twice-yearly option, have the potential to further help combat the HIV epidemic, if approved.

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[38] U.S. Preventive Servs. Task Force, Final Recommendation Statement, *Prevention of Acquisition of HIV: Preexposure Prophylaxis* (Aug. 22, 2023), https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[39] HIV.gov, *Pre-Exposure Prophylaxis* (Feb. 5, 2025), https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis. No PrEP medicines are currently FDA approved for reducing the risk of acquiring HIV through IV drug use.

[40] Patrick Sullivan et al., "Association of State-Level PrEP Coverage and State-Level HIV Diagnoses, US, 2012-2021," (Conference on Retroviruses and Opportunistic Infections, 2024, Denver, Colo., Oral Session-09, Abstract 95), https://www.croiconference.org/abstract/association-of-state-level-prep-coverage-and-state-level-hiv-diagnoses-us-2012-2021/.

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 discussions that include counseling about sexual health and HIV prevention; and to be tested for HIV as well as sexually transmitted infections ("STIs").[41] 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 while infected with HIV could lead to antiretroviral resistance and limit future treatment options, making the HIV harder to treat.[42] Similarly, medication adherence counseling is critical for patients 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 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.[43] *See infra*, at 21. Because

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[41] U.S. Pub. Health Serv., *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update*, at 43–44, https://permanent.link/to/amicus/stacks-cdc-gov-view-cdc-112360 ("CDC PrEP Guidelines").

[42] *Id.* at 29.

[43] McNamara, *supra* note 18, at 12.

these aspects of the PrEP intervention are essential, they too are covered without cost sharing.[44]

Current CDC Guidelines recommend that *all* sexually active adults and adolescents be informed about PrEP for the prevention of HIV acquisition.[45] And the CDC estimates PrEP is recommended for a total of about 1.2 million people in the United States.[46] Yet, in 2022, only 36% of those for whom PrEP is recommended were prescribed it.[47] 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.

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 higher economic and social barriers to accessing preventive medication such as PrEP—including a lack of accessible providers, discrimination within the health system, and HIV-related stigma.[48] These barriers to access are starkly reflected in the latest data on PrEP uptake: For example, although Black people represented 39% of new HIV diagnoses in 2022,

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[44] *FAQs about Affordable Care Act And Women's Health and Cancer Rights Act Implementation Part 68*, *supra* note 4.

[45] CDC PrEP Guidelines, *supra* note 41, at 13.

[46] HIV.gov, *Expanding PrEP Coverage in the United States to Achieve EHE* Goals (Oct. 18, 2023), https://www.hiv.gov/blog/expanding-prep-coverage-in-the-united-states-to-achieve-ehe-goals. ("Expanding PrEP Coverage").

[47] *Id.*

[48] *See e.g.*, AIDSVu, *Dr. Whitney S. Rice on Social Determinants of Health Among Women* (Mar. 8, 2023), https://aidsvu.org/news-updates/qa/news-updates-qa-dr-whitney-s-rice-on-social-determinants-of-health-among-women/.

only 14% of PrEP users are Black.[49] And although women represent 19% of new HIV diagnoses, only 8% of those who take PrEP are women.[50] 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 critical. Because "[g]ender-based relationship inequalities . . . complicate condom negotiation and other forms of self-protective sexual behaviors," heterosexual women benefit from methods of HIV prevention that they can independently control.[51] Further, effective prevention among women helps to ensure that HIV is not later transmitted from mother to child during pregnancy, childbirth, or breastfeeding. "The highest rates of perinatal transmission [are] found among infants born to Black women," a reality that "highlight[s] the need to improve HIV prevention for Black women," including through "more widespread provision of" PrEP.[52]

For these reasons, increasing PrEP uptake—especially among groups and in regions with the greatest unmet need for PrEP—is a centerpiece of federal gov-

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[49] AIDSVu, *AIDSVu Releases New PrEP Data and Launches PrEPVu.org, A New PrEP Equity Platform* (June 25, 2024), https://aidsvu.org/news-updates/aidsvu-releases-new-prep-data-and-launches-prepvu-org-a-new-prep-equity-platform/

[50] *Id.*

[51] McNamara, *supra* note 18, at 15.

[52] 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* NIH, *HIV Medicines During Pregnancy and Childbirth* (Jul. 26, 2024), https://permanent.link/to/amicus/hivinfo-nih-gov-understanding-hiv-fact-sheets-hiv-medicines-during-pregnancy-and-childbirth.

ernment 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 Ending the HIV Epidemic in the United States initiative, which was launched by the Trump Administration in 2019 with bipartisan support.[53] To achieve that reduction, the initiative aims to have 50% of people who could benefit from PrEP taking it by 2030.[54] The preventive services coverage requirement directly supports the federal government's strategy to expand access to PrEP to help end the HIV epidemic in the United States by obligating most commercial insurers to offer PrEP and ancillary services to insured patients without cost sharing.

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

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

In the past, cost-sharing obligations may have prevented patients from using PrEP. As one study reported, before PrEP medications and ancillary services became available without cost sharing to most privately insured patients, "[h]igh deductibles and copays

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[53] HIV.gov, *What is Ending the HIV Epidemic in the U.S.?* (Feb. 1, 2025), https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/ ("*What is* Ending the HIV Epidemic").

[54] HIV.gov, *AHEAD Dashboard – EHE Indicators: PrEP Coverage* (Aug. 28, 2020), https://www.hiv.gov/blog/ahead-dashboard-ehe-indicators-prep-coverage.

were" widely cited by patients as "key barriers" to accessing PrEP.[55] 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.[56]

The cost of PrEP medicines and associated patient cost-sharing for those medicines are not the only barrier to PrEP access. Manufacturer patient support programs, like Gilead's Advancing Access® Program, provide copay assistance to commercially insured eligible individuals to help them access their prescribed Gilead PrEP medications; however, there is generally no comparable financial assistance for PrEP-related ancillary services (e.g., clinical visits, laboratory tests). Patients who cannot afford these visits will not be able to receive prescriptions for PrEP. The public health

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[55] 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://permanent.link/to/amicus/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://permanent.link/to/amicus/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.

[56] Kay, *supra* note 55, at 62–63.

literature confirms that commonsense point by indicating that the medical visits and laboratory tests that are required for those who use PrEP are themselves unaffordable for many, and "may make PrEP too expensive for the populations for whom PrEP is most recommended."[57]

Coverage of preventive services removed these and other obstacles to care. The law had its intended effect, as other *amici* detailed in briefs filed in support of the petition for certiorari.[58] Over 150 million people can now receive a wide range of preventive services at no cost because of the preventive-services mandate, including the ancillary services needed to ensure that PrEP can be taken as prescribed. And "[s]tudies demonstrate" associated "increases in access to preventive services, including colon cancer screening, HPV vaccination, . . . and contraceptive use."[59]

Since the requirement to cover certain highly effective preventive services with no patient cost-sharing went into effect, 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

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[57] *Id.* at 61.

[58] *See generally* Br. for Am. Pub. Health Ass'n., Pub. Health Deans & Scholars, Robert Wood Johnson Found., & Pub. Health Advoc. as *Amici Curiae* in Support of Petitioners, *Becerra v. Braidwood Mgmt., Inc.*, No. 24-316 (U.S. Oct. 21, 2024).

[59] HHS, Off. of Health Policy, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, at 10 (Jan. 11, 2022), https://permanent.link/to/amicus/aspe-hhs-gov-sites-default-files-documents-786fa55a84e7e3833961933124d70dd2-preventive-services-ib-2022-pdf.

plans, the number of individuals prescribed PrEP increased by almost 22% compared to the year before.[60] And between 2017 and 2022, the number of individuals taking PrEP more than doubled.[61]

If the Fifth Circuit's decision were upheld, this progress that has been made toward ending the HIV epidemic could be lost. Indeed, one study estimates that up to 20% of large employers may reimpose cost sharing on preventive services if permitted to do so,[62] leading many patients to forgo preventive care. Another survey prompted by the district court's ruling below 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

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[60] Calculations based on data on PrEP coverage and number of persons prescribed PrEP from Ctrs. for Disease Control & Prevention, *Atlas Plus*, https://permanent.link/to/amicus/www-cdc-gov-nchhstp-about-atlasplus-html-cdc_aaref_valwww-cdc-gov-nchhstp-atlas-index-htm.

[61] Calculations based on data on PrEP coverage and number of persons prescribed PrEP from Ctrs. for Disease Control & Prevention, *Atlas Plus*, https://permanent.link/to/amicus/www-cdc-gov-nchhstp-about-atlasplus-html-cdc_aaref_valwww-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://permanent.link/to/amicus/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.")

[62] *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).

the Task Force—including STI and HIV testing that is required for PrEP users.[63]

Access to PrEP and the ancillary tests and services without patient cost sharing is therefore critical to maintaining and building on progress in preventing HIV. If this access is disrupted, the 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.[64] And the presence of cost-sharing obligations would deter individuals who would benefit from PrEP from starting and staying on the medication.[65]

B. Broad access to PrEP and related preventative 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. This is not only a matter of concern for those who either have or know someone who has HIV, but for all citizens. "The cost of managing HIV is substantial and

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[63] 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_crosstabs_MC_HEALTH_ACA_COURT_CASE_Adults.pdf.

[64] 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.

[65] *See generally* Dean et al., *supra* note 5.

burdensome to patients and the healthcare system"—every new case results an estimated net increase of over $850,000 in lifetime healthcare costs.[66] Given that "Medicaid is the largest source of insurance coverage for people with HIV in the United States, covering an estimated 40% of the nonelderly adults with HIV, compared to just 15% of the nonelderly adult population overall,"[67] "diminished uptake of high-value preventive services for low-income individuals would have significant implications for federal and state budgets as both levels of government share responsibility for Medicaid expenditures."[68]

Due to the high rate of abandonment for even marginal increases in cost-sharing, the preventive services coverage requirement 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 ("MSM") could substantially reduce the incidence of HIV, achieving up to a 43% reduction in new cases among the MSM population as a whole.[69] And this figure likely understates the potential impact, as the MSM population is

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[66] Cohen, et al., *supra* note 7, at 692–93.

[67] Lindsey Dawson et al., *Medicaid and People with HIV*, KFF (Mar. 27, 2023), https://www.kff.org/hivaids/issue-brief/medicaid-and-people-with-hiv/.

[68] Br. of 49 Bipartisan Econ. & Other Soc. Sci. Scholars in Support of Defs.-Appellants at 16–17, *Braidwood Mgmt., Inc.* v. *Becerra*, No. 23-10326, (5th Cir. June 27, 2023).

[69] 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://permanent.link/to/amicus/www-ncbi-nlm-nih-gov-pmc-articles-pmc5488295 (finding PrEP effective at reducing HIV cases at the population level using modeling).

only one population among many that can benefit from PrEP.[70]

By the same token, disrupting 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.[71] For every 1% decrease in the number of MSM taking PrEP, there would be 114 additional—and entirely preventable—HIV cases in that population.[72] These numbers, which concern just one set of potential PrEP users, underscore the potential risk to the public health from ending cost-free coverage for PrEP and related monitoring and counseling services.

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.[73] 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.[74]

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[70] *See* Expanding PrEP Coverage, *supra* note 46.

[71] *See* McNamara, *supra* note 18, at 11; Paltiel, *supra* note 64.

[72] Paltiel, *supra* note 64, at 3.

[73] 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://permanent.link/to/amicus/pubmed-ncbi-nlm-nih-gov-35636746.

[74] Andrew E. Gulich et al., *Population-level Effectiveness of Rapid, Targeted, High-Coverage Roll-Out of HIV Pre-Exposure*

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.[75] 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 partners," any children born to those individuals, and many more individuals.[76]

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.[77] HIV prevention, including through PrEP, is therefore essential for the most affected communities.[78]

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

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Prophylaxis in Men Who Have Sex with Men: The EPIC-NSW Prospective Cohort Study, 5 Lancet HIV e629, e634–35 (2018).

[75] 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://permanent.link/to/amicus/pubmed-ncbi-nlm-nih-gov-32097453.

[76] McNamara, *supra* note 18, at 11.

[77] *Id.* at 20.

[78] 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://permanent.link/to/amicus/www-ncbi-nlm-nih-gov-pmc-articles-pmc4937112.

range of STIs.[79] Moreover, PrEP acts as a crucial gateway to primary care and other preventive services.[80] PrEP use is associated with increased receipt of depression screening, diabetes testing and monitoring, and hypertension treatment, among other services.[81] Thus, studies have found that PrEP use may have a positive association with users' mental health, and help with efforts to prevent and treat STIs and chronic diseases other than HIV.[82]

CONCLUSION

The requirement that commercial insurers cover PrEP and related ancillary services with no cost sharing benefits people who can benefit from PrEP, their communities, and the healthcare system. The requirement further benefits the public health by facilitating

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[79] See Samuel M. Jenness et al., *Incidence of Gonorrhea and Chlamydia Following Human Immunodeficiency Virus Preexposure Prophylaxis Among Men Who Have Sex With Men: A Modeling Study*, 65 Clinical Infectious Diseases 712 (2017), https://permanent.link/to/amicus/www-ncbi-nlm-nih-gov-pmc-articles-pmc5848234; *see also* McNamara *supra* note 18, at 12–13 (discussing studies).

[80] 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 Syndromes 31 (2021), https://permanent.link/to/amicus/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://permanent.link/to/amicus/www-ncbi-nlm-nih-gov-pmc-articles-pmc8679108.

[81] Ikeda, *supra* note 80; Jennifer Manne-Goehler et al, *The ART Advantage: Healthcare Utilization for Diabetes and Hypertension in Rural South Africa*, 75 J. Acquired Immune Deficiency Syndromes 561 (2017), https://permanent.link/to/amicus/pmc-ncbi-nlm-nih-gov-articles-pmc5516957-pdf-nihms868921-pdf.

[82] *Id.*; *see also* Sewell, *supra* note 80.

broad access to PrEP and related ancillary services without cost sharing—access which is essential to controlling, and ultimately ending, the HIV epidemic in the United States.

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