No. 24-316

IN THE

Supreme Court of the United States

ROBERT F. KENNEDY, JR., 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 *AMICI CURIAE* NATIONAL ALLIANCE OF STATE AND TERRITORIAL AIDS DIRECTORS AND OTHER HIV, LGBTQ, AND HEALTHCARE ORGANIZATIONS IN SUPPORT OF PETITIONERS

CHRISTOPHER R. RIANO
JACOB A. BARRERA
DANIELLE A. GIACCIO
HOLLAND & KNIGHT LLP
787 Seventh Avenue, 31st Floor
New York, NY 10019

AMY O'BRIEN
CURRAN BUTCHER
KAATJE S. GREENBERG
HOLLAND & KNIGHT LLP
800 17th Street NW, Suite 1100
Washington, DC 20006

JOSE I. ABRIGO JR.
Counsel of Record
OMAR GONZALEZ-PAGAN
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585
jabrigo@lambdalegal.org

KAREN L. LOEWY
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
815 16th Street NW, Suite 4140
Washington, DC 20006

[Additional Signatures On Inside Cover]

377825

COUNSEL PRESS

(800) 274-3321 • (800) 359-6859

Bennett Klein
Chris Erchull
GLBTQ Legal Advocates
& Defenders
18 Tremont Street, Suite 950
Boston, MA 02108

Suman Chakraborty
Mintz, Levin, Cohn, Ferris,
Glovsky, and Popeo, P.C
919 Third Avenue
New York, NY 10022

Katie Stewart
Courtney Herndon
Mintz, Levin, Cohn, Ferris,
Glovsky, and Popeo, P.C.
One Financial Center
Boston, MA 02111

TABLE OF CONTENTS

Table of Contents

TABLE OF APPENDICES

TABLE OF CITED AUTHORITIES

Page

Cases

Statutes, Regulations and Other Authorities

Cited Authorities

Page

Page

Page

Cited Authorities

Page

Page

Page

Page

Page

Page

Page

Page

Page

Page

Page

Page

Page

INTEREST OF *AMICI CURIAE*[1]

Amici curiae are organizations committed to promoting and advancing the health of people living with and impacted by HIV/AIDS across the United States. *Amici* organizations include healthcare professionals, public health experts, and attorneys, all of whom share a strong, unified interest in public health measures that advance those collective goals, including policies that promote widespread access to HIV-related preventive care. A full list of *amici* is attached as an Appendix.

SUMMARY OF ARGUMENT

> [T]he AIDS virus is not a political creature. It does not care whether you are Democrat or Republican. It does not ask whether you are black or white, male or female, gay or straight, young or old. . . . Because HIV asks only one thing of those it attacks: Are you human?[2]

Mary Fisher stunned attendees of the 1992 Republican National Convention when she disclosed that she, a married mother of two, was living with HIV. Her disclosure broke stereotypes about HIV, underscored

---

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

2. Mary Fisher, 1992 Republican Convention: A Whisper of AIDS (Aug. 19, 1992) (transcript available at https://awpc.cattcenter.iastate.edu/2017/03/09/a-whisper-of-aids/).

that anyone could contract what was then the most feared and misunderstood disease in America, and urged sound, bipartisan policymaking to combat the epidemic. Fisher's speech is a testament to the sustained, bipartisan support necessary to combat the spread of HIV.

Over the last four decades, Republican and Democratic administrations alike have funded preventive care measures to dramatically slow and, where possible, stop the spread of HIV, which once plagued the nation as a deadly public health crisis. With bipartisan support for sustained strategies with the ultimate goal of eradication, pre-exposure prophylaxis ("PrEP") emerged as a revolutionary means to prevent viral transmission of HIV by a remarkable ninety-nine percent.[3]

In addition to the success of antiretroviral drugs in transforming HIV/AIDS from a death sentence into a manageable condition, PrEP also significantly decreased the rates of new HIV infections across the United States.[4] This preventive care measure has altered the course of the HIV/AIDS epidemic and stood as an extraordinary medical breakthrough, turning the tides of a once-fatal disease through use of a daily pill that prevents HIV transmission by almost one hundred percent.

Still, the full power of PrEP in managing HIV communicability has yet to be achieved, and widespread access to the medication is necessary to achieve it.

---

3. *See* Marta Rosas Cancio-Suárez et al., *From Innovation to Implementation: The Evolution of HIV Pre-Exposure Prophylaxis and Future Implications*, 12 Pathogens 924, 1 (2023).

4. *See id.* at 2.

Removing no-cost access to PrEP would undermine the bipartisan fight to eliminate HIV/AIDS, spurn years of evidence-backed preventive medicine, and jeopardize the health and safety of Americans.

ARGUMENT

Eradication of deadly diseases that threaten public health requires expansive access to preventive care. It is critical that the Fifth Circuit's decision be reversed because it undermines access to such care and, thereby, risks extensive harm to public health.

I. ELIMINATION OF FATAL EPIDEMICS IN THE UNITED STATES, INCLUDING HIV/AIDS, HINGES ON ACCESS TO PREVENTIVE CARE.

Eliminating no-cost access to preventive care such as PrEP will thwart ongoing efforts to wipe out HIV in the United States. Moreover, doing so will ultimately erase much of the progress that has been made to date. Such a result is directly contrary to decades of strong bipartisan support to combat the HIV/AIDS epidemic.

A. Success in HIV/AIDS Eradication Is Contingent Upon Widespread, Continuous Access to PrEP.

The history of the HIV/AIDS epidemic is one of tragedy and loss—but also one of medical and community tenacity and perseverance. While few diseases in history have had such a profound impact, both in loss of life and in public anxiety and fear, we are now at a crossroads. The development and adoption of PrEP as a vital tool against the spread of HIV presents a clear path toward ending

the epidemic. That path depends, however, on widespread, continuous access to PrEP.

1. Decades of History Exhibit the Devastating and Indiscriminate Impact of HIV/AIDS Absent Preventive Care Measures.

When the first cases of HIV/AIDS were reported in 1981, it became apparent that the disease posed a substantial threat to public health. Within the first six months, hundreds of known cases developed, and over one third of those patients died.[5]

By 1987, HIV/AIDS had become pervasive, leading President Ronald Reagan to form the President's Commission on the HIV Epidemic.[6] That same year, Surgeon General C. Everett Koop predicted that HIV/AIDS would become "the most devastating epidemic since the Black Death."[7] Surgeon General Koop subsequently declared, in a message mailed to every American, that "AIDS is one of the most serious health problems that has ever faced the American public."[8]

---

5. *See A Timeline of HIV and AIDS*, HIV.gov, https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline (last visited Feb. 23, 2025).

6. *See* Exec. Order No. 12,601, 3 C.F.R. § 238 (1988).

7. Eleanor Randolph, *AIDS Reporters' Challenge: To Educate, Not Panic, the Public: Initial Squeamishness Hurt Media Credibility*, Wash. Post, June 5, 1987, at D1.

8. U.S. Pub. Health Serv. et al., *Understanding AIDS* (1988), https://stacks.cdc.gov/view/cdc/6927.

Surgeon General Koop's warning was not hyperbole. At the time of the warning, the fatality rate of HIV/AIDS was over ninety percent.[9] At the epidemic's peak in the mid-1990s, HIV/AIDS was the leading cause of death for all Americans between the ages of twenty-five and forty-four and the eighth leading cause of death overall, accounting for two percent of all deaths in the United States.[10] Black Americans were disproportionately affected during this time period, with four times more deaths for Black men than White men, and nine times more deaths for Black women than White women in 1994.[11] To date, HIV/AIDS

---

9. *See* C. Everett Koop, Surgeon Gen., U.S. Pub. Health Serv., Address at Cardozo High School (Feb. 25, 1988) (transcript available at https://profiles.nlm.nih.gov/spotlight/qq/catalog/nlm:nlmuid-101584930X635-doc).

10. Susan Hariri & Matthew T. McKenna, *Epidemiology of Human Immunodeficiency Virus in the United States*, 20 Clinical Microbiology Revs. 478, 478 (2007).

11. *See* U.S. Ctrs. for Disease Control & Prevention, *Update: Mortality Attributable to HIV Infection Among Persons Aged 25–44 Years—United States, 1994*, 45 Morbidity & Mortality Wkly. Rep. 122, 122 (1993), https://www.cdc.gov/mmwr/PDF/wk/mm4506.pdf; *see also* U.S. Ctrs. for Disease Control & Prevention, *Update: Mortality Attributable to HIV Infection Among Persons Aged 25–44 Years—United States, 1991 and 1992*, 42 Morbidity & Mortality Wkly. Rep. 869, 870 (1993), https://www.cdc.gov/mmwr/PDF/wk/mm4245.pdf (indicating such disparities existed before 1994); Kimberley D. Peters et al., U.S. Ctrs. for Disease Control & Prevention, *Deaths: Final Data for 1996*, Nat'l Vital Stats. Reps., Nov. 10, 1998, at 1, 33 tbl. 8, https://www.cdc.gov/nchs/data/nvsr/nvsr47/nvs47_09.pdf (indicating such disparities continued after 1994).

has killed over seven hundred thousand people in the United States.[12]

The trauma that marked the early days of the HIV/AIDS epidemic was not limited to staggering death rates. Prior to the advent of effective treatment measures, HIV infection resulted in progressive attacks on the body's lymphatic and immune systems resulting in a myriad of complications.[13]

Beyond the extensive suffering and loss of life, the epidemic caused misconceptions regarding communicability of the virus, leading to life-altering stigmatization that persists today. Indeed, HIV/AIDS evokes more fear

12. *See* Off. of Infectious Disease & HIV/AIDS Pol'y, U.S. Dep't of Health & Hum. Servs., *EHE Overview*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview (Feb. 21, 2025).

13. *See* William Chris Woodward, *Can You Explain AIDS and How It Affects the Immune System? How Does HIV Become AIDS?*, Sci. Am. (Nov. 8, 1999), https://www.scientificamerican.com/article/can-you-explain-aids-and/; Maureen Foertsch McKinney, *AIDS at 40: The Epidemic Emerges in Illinois*, NPR Ill. (Dec. 8, 2021, 12:33 PM CST), https://www.nprillinois.org/health-harvest/2021-12-07/aids-at-40-the-epidemic-emerges-in-illinois. These opportunistic infections include, but are not limited to: Kaposi's sarcoma (cancer of the blood and lymph vessels); Pneumocystis pneumonia (a lung infection caused by a fungus); Mycobacterium avium complex (a life-threatening bacterial infection); and cachexia, commonly known as wasting syndrome (involuntary loss of more than ten percent of one's body weight due to diarrhea, weakness, or fever). *See AIDS and Opportunistic Infections*, CDC, https://www.cdc.gov/hiv/basics/livingwithhiv/opportunisticinfections.html (May 20, 2021) [http://archive.today/uu7CS].

and misunderstanding than perhaps any other disease in history. When this stigmatization was at its worst, children with HIV were systematically ostracized from school and community settings; families who pressed for the rights of their children with HIV to attend school were subjected to violent backlash and even arson;[14] doctors, dentists, and other healthcare providers commonly refused, based on misguided fears of contagiousness, to treat patients with HIV;[15] and mistreatment by nursing homes, day care centers, funeral homes, restaurants, gyms, and other public accommodations was rampant.[16]

Because of social determinants of health such as socioeconomic status, access to healthcare, and education, certain communities within the United States have been more severely affected by the HIV/AIDS epidemic than others. For instance, for the past two decades, the epidemic has been geographically concentrated in the South, which faces unique challenges in certain areas such as limited access to healthcare services and infrastructure, relatively few healthcare providers with experience handling HIV/AIDS, lack of HIV/AIDS prevention awareness, and higher levels of poverty and stigmatization.[17]

---

14. *See* Gregory M. Herek & Eric K. Glunt, *An Epidemic of Stigma: Public Reactions to AIDS*, 43 Am. Psych. 886, 887 (1988).

15. *See*, *e.g.*, *Bragdon v. Abbott*, 524 U.S. 624, 652–53 (1998).

16. *See* Ronald A. Brooks et al., *Preventing HIV Among Latino and African American Gay and Bisexual Men in a Context of HIV-Related Stigma, Discrimination, and Homophobia: Perspectives of Providers*, 19 AIDS Patient Care & STDs 737, 738 (2005).

17. *See* S. State AIDS Dirs. Work Group, *Southern States Manifesto* 6–8 (2003), https://southernaidscoalition.org/wp-content/uploads/2024/12/2002-Southern-States-Manifesto.

Furthermore, in data reflecting the racial breakdown of 2022 HIV diagnoses, Black people accounted for the largest number of diagnosed HIV cases, and Hispanic/Latinos accounted for the second largest.[18] These disparities are due to factors such as higher rates of poverty, limited access to healthcare, transportation limitations, housing insecurity, and HIV/AIDS stigma.[19] Moreover, despite the misconception that HIV is a risk faced only by men who have sex with men ("MSM"), "[a]bout one-fifth of new HIV infections in 2021 were among women, and over half of those were among Black women."[20]

Fortunately, the outlook of the epidemic is no longer as bleak. Medical interventions for both treatment *and* prevention of HIV/AIDS have advanced substantially since the epidemic began. As a result, HIV/AIDS is no longer a death sentence. Instead, we now have tools at

---

pdf; *Why the South?*, Gilead Compass Initiative, https://www.gileadcompass.com/why-the-south/ (last visited Feb. 23, 2025)

18. *See Fast Facts: HIV in the US by Race and Ethnicity*, CDC (May 21, 2024), https://www.cdc.gov/hiv/data-research/facts-stats/race-ethnicity.html; *HIV Declines Among Young People and Drives Overall Decrease in New HIV Infections*, CDC (May 23, 2023, 1:00 PM ET) [hereinafter *HIV Declines Among Young People*], https://www.cdc.gov/media/releases/2023/p0523-hiv-declines-among-young-people.html [https://perma.cc/U749-BN34].

19. André F. Dailey, et. al., *Association Between Social Vulnerability and Rates of HIV Diagnoses Among Black Adults, by Selected Characteristics and Region of Residence—United States, 2018*, 71 Morbidity & Mortality Wkly. Rep. 167, 169 (2022) https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7105a2-H.pdf.

20. *HIV Declines Among Young People*, *supra* note 18.

our disposal to end the epidemic. Attainment of that goal, however, hinges on sufficient deployment of widespread, continuous access to PrEP.

2. Decreased Risk of HIV Transmission Through Preventive Care Measures Is One of the Most Salient Public-Health Victories in U.S. History.

In recent decades, medical advancements, combined with strong, bipartisan support from governmental leaders, have resulted in unprecedented progress in combating the spread and impact of HIV/AIDS. These developments present a meaningful opportunity to end the epidemic for good; yet, that opportunity relies on expansive access to PrEP.

Beginning in the late 1990s, the advent of highly effective oral antiretroviral medications transformed HIV/AIDS from a disease offering little hope of survival into a manageable chronic condition.[21] More recently, the use of oral antiretroviral medications that treat HIV/AIDS has also revolutionized our ability to prevent HIV transmission.[22]

---

21. *See* Thomas C. Quinn, *HIV Epidemiology and the Effects of Antiviral Therapy on Long-Term Consequences*, 22 AIDS S7, S8–S9 (Supp. 3, 2008).

22. With respect to HIV-positive people on antiretroviral treatment, the CDC concluded that "people who take [antiretroviral therapy] daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner." Eugene McCray & Jonathan Mermin, *National Gay Men's HIV/AIDS Awareness Day Dear Colleague Letter*, CDC (Sept. 27, 2017),

The FDA first approved the antiretroviral medication Truvada in 2004 as a treatment for HIV/AIDS, in combination with other medications, for individuals who had already contracted the virus and hoped to manage the disease.[23] The FDA later approved Truvada taken as a single daily pill for HIV prevention (i.e., PrEP) in 2012.[24] PrEP reduces the risk of HIV infection from sexual contact by over ninety-nine percent when taken as prescribed—a statistic unthinkable at the epidemic's inception.[25] This remarkable efficacy led the United States Preventive Services Taskforce ("USPSTF") in 2019 to give PrEP an "A" rating, recommending it as routine preventive care for individuals at increased risk of HIV.[26] As a result

---

https://www.cdc.gov/hiv/library/dcl/dcl/092717.html [https://web.archive.org/web/20180110074326/https://www.cdc.gov/hiv/library/dcl/dcl/092717.html#expand].

23. *See* Letter from Debra Birnkrant, Dir., Div. of Antiviral Drug Prods., Off. of Drug Evaluation IV, Ctr. for Drug Evaluation & Rsch., to Martine Kraus, Dir., Regul. Affs., Gilead Scis., Inc. (Aug. 2, 2004) (available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21752ltr.pdf).

24. *See* U.S. Food & Drug Admin., U.S. Dep't of Health & Hum. Servs., *Truvada for PrEP Fact Sheet: Ensuring Safe and Proper Use* 1 (2012), https://www.fda.gov/files/drugs/published/Truvada-for-PrEP-Fact-Sheet—Ensuring-Safe-and-Proper-Use.pdf.

25. *See Pre-Exposure Prophylaxis (PrEP)*, CDC (July 5, 2022), https://www.cdc.gov/hiv/risk/prep/index.html [https://perma.cc/CT2Q-VNWM].

26. *See Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis*, U.S. Preventive Servs. TASK FORCE (Aug. 22, 2023), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#bootstrap-panel—8.

of this rating, most insurers are required to cover PrEP *without cost sharing* (*i.e.*, with zero out-of-pocket cost to the insured) when prescription is medically indicated.[27]

While use of PrEP remains below desired levels,[28] its increasing availability has had an appreciable impact on the rate of new HIV infections in the United States. Notably, after many years of plateau, there has recently been a marked *decrease* in the annual number of new HIV infections: from 36,500 new infections in 2017 to about 32,100 new infections in 2021.[29]

The decline in incidence has been particularly pronounced among young people.[30] This recent decrease, after a lengthy stagnation of progress, coincides with—and, evidence indicates, was caused in part by—the requirement to cover PrEP without cost sharing.[31] As such, continued coverage by insurers without cost sharing

27. Beginning January 1, 2021, Medicaid expansion programs and most private insurance plans were required, based on the USPSTF's "A" rating, to cover PrEP without cost sharing. Robert A. Bonacci et al., *Estimated Uncovered Costs for HIV Preexposure Prophylaxis in the US, 2018*, 42 Health Affs. 546, 546–47 (2023).

28. *See* Kathryn Macapagal, *This HIV Prevention Medicine Is for Everyone. Why Do So Few People Take It?*, STAT (Jan. 20, 2022), https://www.statnews.com/2022/01/20/this-hiv-prevention-medicine-is-for-everyone-why-do-so-few-people-take-it/.

29. *HIV Declines Among Young People*, *supra* note 18.

30. *See id.*

31. *Cf.* A. David Paltiel et al., *Increased HIV Transmissions with Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of* Braidwood Management v. Becerra, 10 Open F. Infectious Diseases ofad139, 2 (2023).

is critical to the realization of PrEP's full potential to end the HIV/AIDS epidemic.

Notwithstanding these notable improvements, significant challenges remain. Far too few susceptible people are currently taking PrEP. In 2021, fewer than one third of the 1.2 million people who could benefit from PrEP were prescribed it, an increase from thirteen percent in 2017.[32]

Moreover, the disparities discussed in Section I.A.1, *supra*, regarding the impact of the epidemic are also seen in access to PrEP. The majority of people who could benefit from PrEP are Black and/or Hispanic/Latino.[33] In 2021, however, the CDC estimated that only 11% of Black and 20% of Hispanic/Latino people who could benefit from PrEP were prescribed it; by contrast, 78% of White people who could benefit from PrEP were prescribed it.[34] These racial disparities, discussed in greater detail above, indicate that improved measures to facilitate widespread access to PrEP are critical to ending the HIV/AIDS epidemic. Continued zero-cost-sharing coverage is one integral component of that effort.

B. Public Health Progress Will Be Undermined Without Widespread Access to PrEP and Other Preventive Care Measures.

The remarkable progress that the United States has made toward halting the spread of HIV will be

32. *See HIV Declines Among Young People*, *supra* note 18.

33. *Id.*

34. *Id.*

undermined if the Fifth Circuit's decision is not reversed.[35] Absent a national, bipartisan recommitment to providing widespread, no-cost access to PrEP, the United States will experience an increase of thousands of new cases of HIV annually, leading to exorbitant—and avoidable—costs for both individual patients and the U.S. healthcare system.

The critical role that PrEP has played in the United States' progress toward HIV prevention by "decreasing the risk of HIV infection in persons at high risk of HIV acquisition" cannot be overstated.[36] The USPSTF's recommendation of PrEP is based on rigorous scientific research, including twelve randomized controlled trials that evaluated the effect of PrEP (against a placebo or absence of intervention) on the risk of HIV acquisition.[37] In a meta-analysis of these trials, PrEP was associated with a marked decrease in the incidence of HIV infections across population subgroups.[38]

---

35. *See*, *e.g.*, Eamon O. Murchu et al., *Oral Pre-Exposure Prophylaxis (PrEP) to Prevent HIV: A Systematic Review and Meta-Analysis of Clinical Effectiveness, Safety, Adherence and Risk Compensation in All Populations*, 12 BMJ Open e048478, 1 (2022).

36. U.S. Preventive Servs. Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendation Statement*, 321 JAMA 2203, 2208–10 (2019).

37. *See id.* at 2208. Because recommendations about preventive care should be guided by scientific and medical expertise, and not politics, USPSTF should be independent and shielded from political vicissitudes. In this regard, *amici* agree with the *amici* State of Illinois, et al. that the structure of the USPSTF is constitutional.

38. *See id.* at 2209.

Adherence to PrEP is highly correlated with a drastic reduction in new HIV cases,[39] and removing no-cost access will have "dramatic and injurious consequences for both individuals and public health, undermining years of effort and investment to end the HIV epidemic in the US."[40]

The out-of-pocket cost of PrEP can also be daunting on an individual level. A monthly supply of the medication is priced between $60 per month for a generic drug and $2,000 per month for a brand-name drug; quarterly laboratory tests and physician visits can add an additional $15,000 per year.[41] As discussed in Section II.A, *infra*, if faced with out-of-pocket costs, some of the twenty-eight percent of Americans at increased risk for HIV who currently take PrEP[42] will be deterred from continued use and may interrupt or ration their medication or cease treatment entirely.[43]

---

39. *See id* at 2204–05, 2207 (observing that adherence support is a key component of providing PrEP, and lack of health insurance is a barrier to achieving the full benefit of PrEP).

40. Paltiel et al., *supra* note 31, at 3.

41. Sarah Varney, *HIV Preventive Care Is Supposed to Be Free in the US. So, Why Are Some Patients Still Paying?*, KFF Health News, https://kffhealthnews.org/news/article/prep-hiv-prevention-costs-covered-problems-insurance/ (March 4, 2022).

42. *See* Paltiel et al., *supra* note 31, at 2.

43. *See* 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, 43 (2024) (finding a marked increase in abandonment of PrEP when a $10 out-of-pocket charge was imposed); *cf.* Sarah K. Calabrese et al., *Putting PrEP into Practice: Lessons Learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure*

A recent analysis conducted simulations comparing six different co-pays levels for PrEP (ranging from $0 to $500) and their impact on rates of prescription abandonment (i.e., receiving a prescription, but not filling it at a pharmacy).[44] When out-of-pocket costs for PrEP increased from $0 to $500, abandonment rates increased from 5.5% to 42.6%.[45] In this study, PrEP abandonment was associated with a two- to three-fold increase in HIV diagnoses during a one-year follow-up.[46] The positive impact of no-cost access to PrEP in lowering HIV transmission and healthcare spending will be quashed if the Fifth Circuit's decision is affirmed.

One study estimates that the United States will see an additional 2,057 primary HIV infections *in the first year alone* if ten percent of PrEP-indicated MSM—just one of the demographic groups at increased risk of contracting HIV[47]—

Prophylaxis and Associated Care, 11 PLoS One e0157324, 6 (2016) (observing, in a study of PrEP prescribing behavior, that difficulties surrounding financial coverage were "the most commonly cited challenge to PrEP implementation").

44. *See* Lorraine T. Dean et al., *supra* note 43, at 39.

45. *See id.* at 39–40

46. *See id.* at 42.

47. For instance, Mary Fisher, the HIV-positive mother and advocate who spoke at the 1992 Republican Convention, contracted HIV from her husband, a former intravenous drug user. *See*, *e.g.*, Maureen Dowd, *Proud Mary*, POZ, Oct.–Nov. 1994, at 32, 35, https://issuu.com/smartandstrong/docs/poz_hiv_aids_0004/40. People who use intravenous drugs are another demographic group especially vulnerable to HIV. *See*, *e.g.*, *Fast Facts: HIV in the US by Race and Ethnicity*, *supra* note 18.

loses access to no-cost PrEP.[48] These 2,057 new infections alone would lead to at least $863 million in additional healthcare costs.[49]

The predicted 2,057 preventable primary HIV infections from one year without no-cost access to PrEP will not stand in isolation. 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 another person, who in turn can infect others.[50] On average, each person with HIV in the United States will transmit the infection to 0.92 people during their lifetime.[51] Thus, the

48. *See* Paltiel et al., *supra* note 31, at 2.

49. This dollar amount multiplies the estimated average discounted lifetime HIV-related medical cost of over $420,000 by the number of preventable new HIV infections caused by curtailed access to no-cost coverage for PrEP. *See* Adrienna Bingham et al., *Estimated Lifetime HIV-Related Medical Costs in the United States*, 48 Sexually Transmitted Diseases 299, 302 (2021) (estimating an average lifetime HIV-related medical cost of $420,285 discounted and $1,079,999 undiscounted, in 2019 dollars); *cf.* Bruce R. Schackman et al., *The Lifetime Medical Cost Savings from Preventing HIV in the United States*, 53 Med. Care 293, 298 (2015) (estimating, in 2015, that the estimated discounted medical cost saved by *avoiding* HIV was $229,000 for each person at high risk of HIV infection).

50. *See* Meredithe McNamara et al., Braidwood *Misreads the Science: The PrEP Mandate Promotes Public Health for the Entire Community* 27 (2023), https://law.yale.edu/sites/default/files/documents/pdf/prep_report_final_feb_13_2023_rev.pdf.

51. *See* Yao-Hsuan Chen et al., *Estimating the HIV Effective Reproduction Number in the United States and Evaluating HIV Elimination Strategies*, 28 J. Pub. Health Mgmt. Prac. 152, 156 (2022).

2,057 individuals who have preventable new infections during the first year will infect 1,892 individuals during the course of their lifetimes (a total of 3,949 preventable HIV infections). Over their lifetimes, these 3,949 individuals will cost the healthcare system an additional estimated $1.66 billion.[52]

Extending the static one-year model from this study five years into the future paints a bleak picture—20,000 additional preventable HIV infections and $8 billion in costs incurred by the U.S. healthcare system—should this Court uphold the Fifth Circuit's decision.

C. Reliance on Preventive Care Measures to Combat the HIV/AIDS Epidemic Is Deeply Rooted in Historic, Bipartisan Support.

Recognizing the pivotal role that preventive care has played in responding to the HIV/AIDS epidemic, presidents and lawmakers from both ends of the political spectrum have expended significant resources over the past few decades in developing laws, programs, and funding opportunities to support these services. This support for preventive care has ranged from measures designed to detect the disease at an earlier stage—e.g., routine testing, education, and outreach—to those designed to prevent it from developing entirely—e.g., PrEP.[53]

---

52. *See supra* note 49 (outlining the methodology used to arrive at this dollar amount).

53. Bipartisan support for preventive care has also extended to addressing other public health issues. *See, e.g.*, Opioid Settlement Accountability Act, H.R. 6956, 118th Cong. (2024) (proposing

A significant marker of bipartisan support for HIV/AIDS preventive care was the enactment of the Ryan White CARE Act (the "Act") in 1990, which established the largest federally funded program for people with HIV/AIDS in the United States.[54] The Act was signed into law in 1990 by then-President George H. W. Bush in an effort to address what was understood to be a catastrophic health crisis. The Act has been updated four times, by both Democratic and Republican presidents, to meet the evolving needs of people with HIV/AIDS.[55]

The Act directed the creation of the Ryan White HIV/AIDS Program in an effort to expand access to life-saving services for people with HIV/AIDS, fund preventive services to improve viral suppression, and slow HIV transmission rates by providing access to antiretroviral

---

preventive activities to combat the opioid crisis); Emergency Access to Insulin Act of 2023, S. 1497, 118th Cong. (proposing to provide insulin to uninsured or underinsured individuals); Healthy, Hunger-Free Kids Act of 2010, Pub. L. No. 111-296, 124 Stat. 3183 (codified as amended in scattered sections of 7 & 42 U.S.C.) (enhancing nutrition in school lunches and combating obesity epidemic).

54. Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Pub. L. No. 101-381, 104 Stat. 576 (codified as amended at 42. U.S.C. §§ 300ee–ff-140).

55. *See* Ryan White CARE Act Amendments of 1996, Pub. L. No. 104-146, 110 Stat. 1346 (reauthorizing the Act under President Clinton); Ryan White CARE Act Amendments of 2000, Pub. L. No. 106-345, 114 Stat. 1319 (reauthorizing the Act under President Clinton); Ryan White HIV/AIDS Treatment Modernization Act of 2006, Pub. L. No. 109-415, 120 Stat. 2767 (reauthorizing the Act under President Bush); and Ryan White HIV/AIDS Treatment Extension Act of 2009, Pub. L. No. 111-87, 123 Stat. 2885 (reauthorizing the Act under President Obama).

medication, testing, and counseling. Following over two decades of implementation, in 2023, the Ryan White HIV/AIDS Program achieved a record-breaking 90.6% viral suppression rate among its more than 576,000 clients, who represent over 50% of the people diagnosed with HIV/AIDS in the United States.[56]

Bipartisan support for HIV/AIDS prevention did not end there. In 2003, under then-President George W. Bush, the United States Leadership Against Global HIV/AIDS, Tuberculosis, and Malaria Act of 2003 was signed into law.[57] This law created the President's Emergency Plan for AIDS Relief ("PEPFAR"), which became "the largest health program worldwide for a single disease."[58] The law recognized the need for "clinical medical interventions" and "prevention", including by "making available pharmaceuticals and diagnostics" to stem the global spread of HIV/AIDS.[59]

---

56. *Ryan White HIV/AIDS Program Achieves Record-Breaking 90.6% Viral Suppression Rate Among Its More than 576,000 Clients*, Health Res. & Servs. Admin. (Dec. 2, 2024), https://www.hrsa.gov/about/news/press-releases/ryan-white-record-breaking-viral-suppression-rate.

57. *See* United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Pub. L. No. 108-25, 117 Stat. 711 (codified as amended at 22 U.S.C. §§ 7601–7682).

58. *About the President's Emergency Plan for AIDS Relief (PEPFAR)*, U.S. Health Res. & Serv. Admin., https://www.hrsa.gov/office-global-health/global-hivaids-program/about-pepfar (last visited Feb. 23, 2025).

59. 22 U.S.C. §§ 7601(15), (21)(A), (22)(C); *see also* George W. Bush, U.S. Pres., Remarks on the Signing of H.R. 1298, the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of

PEPFAR received overwhelming bipartisan support at the time of its enactment, and this support has continued through four presidential administrations and reauthorizations of PEPFAR.[60] Since PEPFAR's inception, the resources provided through it have saved an estimated 26 million lives and allowed approximately 7.8 million babies to be born HIV-free.[61]

PEPFAR's success can be largely attributed to prevention measures such as increased access to and use of viral-load-suppression treatments, HIV testing services, and antiretroviral medications, such as PrEP.[62] This strong support for PEPFAR providing access to PrEP is exemplified by the current Administration's waiver allowing PrEP to be offered to pregnant and breastfeeding women during the pause on U.S. foreign assistance.[63]

2003 (May 27, 2003) (transcript available at https://georgewbush-whitehouse.archives.gov/news/releases/2003/05/20030527-7.html) ("We will purchase low-cost anti-retroviral medications and other drugs that are needed to save lives.").

60. Most recently, in March 2024, PEPFAR was reauthorized for another year. *See* Further Consolidations Appropriations Act, 2024, Pub. L. No. 118-47, 138 Stat. 460, 740.

61. *See PEPFAR Latest Global Results & Projections Factsheet, (Dec. 2024)*, U.S. Dep't of State (Dec. 1, 2024), https://www.state.gov/pepfar-latest-global-results-factsheet-dec-2024/.

62. *See id.* In 2024 alone, PEPFAR provided 83.8 million people with HIV testing services, and assisted 2.5 million people with becoming enrolled on PrEP. *See id.*

63. *See* Glob. Health Sec. & Dipl., U.S. Dep't of State, *HIV Care & Treatment and Prevention of Mother to Child Transmission Activities Approved Under PEPFAR Limited*

Focused government attention on the use of preventive care measures to reduce HIV infection rates has continued in recent years. In 2010, then-President Barack Obama announced the first National HIV/AIDS Strategy ("2010 National Strategy") setting forth a goal of lowering the number of new HIV infections by twenty-five percent by 2015.[64]

The 2010 National Strategy identified several preventive measures as integral to achieving this goal, including the allocation of resources to communities with greater risk of infection and annual HIV testing for high-risk individuals.[65] While the revolutionary treatments developed in the 1990s and 2000s had not yet attained their current recognition as effective prophylactic care, the 2010 National Strategy still highlighted the critical role that preventive measures can play in reducing the spread of HIV.

Following the FDA's 2012 approval of PrEP,[66] both Republican and Democratic presidents incorporated expanded use and access to PrEP into their plans for

---

Waiver 1 (2025), https://www.unaids.org/sites/default/files/media_asset/GHSD_PEPFAR-Limited-Waiver-Approved-Activities.pdf.

64. *See* The White House, *National HIV/AIDS Strategy for the United States* 5 (2010), https://obamawhitehouse.archives.gov/sites/default/files/uploads/NHAS.pdf.

65. *Id*. at 16.

66. *See*, *e.g.*, U.S. Food & Drug Admin., U.S. Dep't of Health & Hum. Servs., *Truvada for PrEP Fact Sheet: Ensuring Safe and Proper Use* 1 (2012), https://www.fda.gov/files/drugs/published/Truvada-for-PrEP-Fact-Sheet—Ensuring-Safe-and-Proper-Use.pdf.

combatting the HIV epidemic. In 2019, during his first term in office, President Donald J. Trump launched the Ending the HIV Epidemic in the U.S. ("EHE") initiative, which sought to reduce the rate of new HIV infections by seventy-five percent by 2025 and by ninety percent by 2030.[67]

The EHE initiative cited preventive care medications, like PrEP, as critical instruments for achieving these objectives, noting the effectiveness of PrEP in significantly reducing the risk of contracting HIV.[68] To that end, the EHE initiative included the development of the Ready, Set, PrEP program to respond to the lack of access to and affordability of PrEP by covering one hundred percent of prescription costs for some high-risk, low-income individuals.[69]

PrEP was again acknowledged as a critical tool for combatting HIV infections in the Biden Administration's National HIV/AIDS Strategy ("2022 National Strategy"), which outlined the administration's plan for reaching the infection reduction goals set by the EHE initiative.[70]

---

67. *See* Off. of Infectious Disease & HIV/AIDS Pol'y, *supra* note 12.

68. *See id.* PrEP is a critical instrument for achieving the EHE initiative's objectives, acting as both a preventive measure and a means to empower individuals to take charge of their health outcomes. *Cf.* Deven T. Hamilton et al., *Achieving the "Ending the HIV Epidemic in the U.S." Incidence Reduction Goals Among At-Risk Populations in the South*, 23 BMC Pub. Health 716, 2 (2023).

69. *See* U.S. Dep't of Health & Hum. Servs., *Ready, Set, PrEP* 2 (2020), https://files.hiv.gov/s3fs-public/RSP-HCPFactsheet.pdf.

70. *See* The White House, *National HIV/AIDS Strategy for the United States 2022–2025* 12–13 (2022), https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf.

The foremost goal of the 2022 National Strategy—*Prevent New HIV Infections*—highlighted the importance of expanding access to and continued use of "safe, effective prevention interventions" including PrEP, in achieving infection reduction goals.[71] The 2022 National Strategy also highlighted the need for "low-barrier access to prevention and supportive services" to ensure that these interventions can "be available to people who need them."[72]

---

71. *Id.* at 28–29. Additionally, Congress appropriated hundreds of millions of dollars annually during the Biden administration to support continued EHE implementation, including over one hundred million dollars each year to support HIV/AIDS prevention efforts such as expanding access to HIV testing, low- and no-cost PrEP prescriptions, and linkage to HIV care. *See* Off. of Infectious Disease & HIV/AIDS Policy, U.S. Dep't of Health & Hum. Servs., *Ending the HIV Epidemic Funding*, HIV.gov, https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/funding (Feb. 21, 2025).

72. The White House, *supra* note 70, at 35. The Biden Administration developed a $10 million PrEP pilot program through the CDC to provide PrEP to select states with lower rates of PrEP use. *See* Proclamation No. 10867, 89 Fed. Reg. 96,515, 96,515 (Nov. 29, 2024). Further, under President Biden, HHS repeatedly proposed a budget of $9.8 billion over 10 years to establish a national PrEP-delivery program to provide PrEP at no cost to uninsured and underinsured individuals and expand the number of medical providers prescribing PrEP in underserved communities. *See* U.S. Dep't of Health & Hum. Servs., *Fiscal Year 2023 Budget in Brief* 9 (2023), https://www.hhs.gov/sites/default/files/fy-2023-budget-in-brief.pdf; U.S. Dep't of Health & Hum. Servs., *Fiscal Year 2024 Budget in Brief* 4 (2024), https://www.hhs.gov/sites/default/files/fy-2024-budget-in-brief.pdf; U.S. Dep't of Health & Hum. Servs., *Fiscal Year 2025 Budget in Brief* 6 (2025), https://www.hhs.gov/sites/default/files/fy-2025-budget-in-brief.pdf.

Regardless of political affiliation, presidents and lawmakers have consistently agreed that one of the factors most critical to eradicating HIV/AIDS is the expanded and continued use of preventive care to reduce the rate of new HIV infections.[73]

In addition to undermining significant progress made in the fight to end the HIV/AIDS epidemic, removing no-cost access to life-saving services and medications like PrEP would undermine decades of public policy and bipartisan efforts to confront this grave public health crisis. The Fifth Circuit's decision blatantly disregards a long history of bipartisan support to expand access to low- and no-cost preventive care to curtail the spread of HIV.

As aptly stated days ago by the current Secretary of State, Marco Rubio, "That was always the goal[—]an AIDS-free generation, so no child was born with HIV."[74]

---

73. *See e.g.*, Bush, *supra* note 59 (noting the importance of HIV testing, low-cost antiretroviral medications, and training for healthcare professionals in preventing HIV infections); The White House, *supra* note 64, at 5 (noting that the "collective [preventive] efforts" including HIV testing, blood screening, and use of antiretroviral medications for expectant mothers "were important for helping to reduce HIV infection rates"); Anthony S. Fauci et al., *Ending the HIV Epidemic: A Plan for the United States*, 321 JAMA 844, 845 (2019) (discussing the Trump Administration's EHE initiative and noting that, "theoretically, the HIV epidemic in this country could be ended quickly by expanding access to treatment to all persons with HIV and PrEP to all those at high risk").

74. Interview by Scott Jennings with Marco Rubio, Sec'y., U.S. Dep't of State, in Washington, D.C. (Feb. 10, 2025), https://www.state.gov/secretary-of-state-marco-rubio-with-scott-jennings-on-siriusxm-patriot/ (discussing the need to continue

II. PROMOTING PUBLIC HEALTH REQUIRES NO-COST ACCESS TO EVIDENCE-BASED PREVENTIVE CARE MEASURES, INCLUDING WITH REGARD TO HIV.

Ample empirical evidence shows that widespread, no-cost access to preventive measures, such as PrEP, significantly improve both individual health outcomes and the broader public health. The USPSTF's designation of such measures for no-cost coverage is therefore integral to the United States' broader public health objectives.

A. No-Cost Access to Preventive Health Measures like PrEP Dramatically Improves Individual Outcomes and National Public Health.

Chronic diseases impose massive healthcare costs beyond their devastating impact on human life. Traditional diagnostic care commences at the onset of symptoms, often resulting in delayed diagnoses, rapid disease progression, avoidable medical interventions and hospitalizations, inferior health outcomes, and exorbitant costs. Given that chronic disease is "one of the greatest threats to public health as well as economic well-being worldwide," clearly "there is urgent need for innovative solutions to bend the curve on chronic disease burden through preventative, personalized care."[75]

---

funding PEPFAR notwithstanding other cuts to foreign aid funding).

75. Kavita Singhania & Arjun Reddy, *Improving Preventative Care and Health Outcomes for Patients with Chronic Diseases Using Big Data-Driven Insights and Predictive Modeling*, Int'l J. Applied Health Care Analytics, Feb. 2, 2024, at 1, 3. Such solutions

Preventive care is a proactive approach that can, for people not yet symptomatic, delay or eliminate onset of disease, reduce complications and costs, and significantly improve overall health and quality of life.[76] Disease prevention encompasses four levels—general, primary, secondary, and tertiary—each serving critical public health functions.[77] Primary prevention measures, such as PrEP, vaccinations, and colorectal cancer screenings, combine social, medical, and educational interventions to eliminate risk of disease occurrence and development, while promoting individual and national public health.[78]

Over five hundred studies have established that preventive care decreases mortality rates and improves health outcomes for chronic conditions.[79] Not only does

---

cover a wide swath of services, including screenings, immunizations, routine check-ups, patient counseling, and medications designed to detect disease at an earlier stage or prevent it from developing entirely. *See*, *e.g.*, *Preventive Services*, HealthCare.gov, https://www.healthcare.gov/glossary/preventive-services/ [https://perma.cc/4NZ2-UCWC]; *Browse Information for Consumers*, USPSTF, https://www.uspreventiveservicestaskforce.org/uspstf/index.php/recommendation-topics/information-for-consumers [https://perma.cc/7JZE-FBBD].

76. *See*, *e.g.*, Singhania & Reddy, *supra* note 75, at 3; *Preventive vs. Diagnostic Care: What to Know and Why It Matters*, UCLA Health (Dec. 7, 2022), https://www.uclahealth.org/news/article/preventive-vs-diagnostic-care-what-to-know-and-why-it-matters [https://perma.cc/R68K-6F4E].

77. *See* H.H. Khakimova & R.S. Barotova, *The Importance of Prevention in Medical Practice*, Web of Med.: J. Med, Prac. & Nursing, Feb. 2024, at 96, 96–97 (2024).

78. *See id.* at 97.

79. *See* Singhania & Reddy, *supra* note 75, at 4.

investment in preventive care measures alleviate disease, close healthcare gaps, and enhance public health, it does so while considerably reducing healthcare expenditures, decreasing governmental costs, and reviving labor productivity and societal contributions.[80]

The absence of preventive care, particularly among certain groups such as racial and ethnic minorities and people of lower socioeconomic status, will have "dramatic and injurious consequences for both individuals and public health, undermining years of effort and investment to end the HIV epidemic in the U.S.,"[81] and will similarly negatively affect health outcomes in other disease areas. Americans tend to deprioritize preventive care, especially when associated with out-of-pocket costs. The 2022 National Health Interview Survey found that twenty-eight percent of patients reported delaying care or completely foregoing healthcare due to cost.[82] Furthermore, cost sharing, even if the out-of-pocket amount is modest, deters patients from seeking preventive care.[83] The negative

---

80. *See id.* at 3–4.

81. Paltiel et al., *supra* note 31, at 3. *See generally* Jennifer A. Pellowski et al., *A Pandemic of the Poor: Social Disadvantage and the U.S. HIV Epidemic*, 68 Am. Psych. 197 (2013) (examining the health disparities in the HIV/AIDS epidemic).

82. *See* Shameek Rakshit et al., *How Does Cost Affect Access to Healthcare?*, Peterson-KFF Health Sys. Tracker (Jan. 12, 2024) https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care/.

83. *See* Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 Med. Care Rsch. & Rev. 175, 175 (2021).

effects of cost sharing are especially pronounced for patients who require a high degree of medical care.[84]

For example, higher out-of-pocket costs are correlated with higher rates of patient abandonment of insurer-approved PrEP prescriptions.[85] Due to the financial barrier of cost sharing, people vulnerable to HIV will interrupt or ration their medication[86] and falsely believe that they are fully protected when they are not, if not be deterred from otherwise seeking PrEP. Vulnerable individuals may also forgo other necessary preventive healthcare expenses due to cost, like required quarterly laboratory testing and/or physician visits.[87] This will result in a significant increase in preventable HIV infections which will stymie the meaningful, sustained decline in HIV transmission rates that the United States has fostered in the last few years.s

---

84. *See* Elise Gould, Econ. Pol'y Inst., *Briefing Paper No. 358, Increased Health Care Cost Sharing Works as Intended* 2 (2013), https://files.epi.org/2013/increased-health-care-cost-sharing-works.pdf.

85. *See* Dean et al., *supra* note 43, at 43.

86. *See*, *e.g.*, Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 Risk Mgmt. & Healthcare Pol'y 35, 40 (2014) (finding that high drug costs were one of the most common reasons for patient nonadherence).

87. *See* Varney, *supra* note 41. The cost of mandatory quarterly laboratory testing and doctor's appointments to control for the potential risks of PrEP use, including kidney issues, can cost up to fifteen thousand dollars per year without insurance. *See id.* Even with insurance, people at risk of HIV may be charged over a thousand dollars per year for these required services. *See id.*

The effects of out-of-pocket costs on HIV/AIDS-related care are indicative of the deterrent effects of out-of-pocket costs on critical preventive healthcare services at large. By contrast, the no-cost-sharing requirement for preventive services has led to a defined and promising increase in the utilization of select preventive services, including colon cancer screenings, vaccination administrations, use of contraception, and chronic disease screening.[88] Thus, no cost sharing for preventive care will further national public health efforts, diminishing financial barriers to access and utilization of this pivotal care.

B. The USPSTF's Designation of Evidence-Based Preventive Care Measures like PrEP for No-Cost Coverage Successfully Decreases Disease Prevalence and Incidence.

Increased uptake of evidence-based preventive healthcare measures has been associated with dramatic improvements in individual and public health.[89] The USPSTF[90] is tasked with "improv[ing] the health of people

88. *See generally* Off. of Health Pol'y, U.S. Dep't Health & Hum. Servs., *Access to Preventive Services Without Cost-Sharing: Evidence from the Affordable Care Act* (2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf (examining the impact of the Affordable Care Act's no-cost-sharing requirement on patients' access to preventative care).

89. *See*, *e.g.*, U.S. Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—United States, 2001–2010*, 60 Morbidity & Mortality Wkly. Rep. 619, 619–21 (2011), https://www.cdc.gov/mmwr/pdf/wk/mm6019.pdf.

90. The USPSTF is comprised of sixteen national experts in prevention, evidence-based medicine, and primary care, and has

nationwide by making evidence-based recommendations on effective ways to prevent disease & prolong life."[91] USPSTF-recommended preventive care includes dozens of lifesaving services such as PrEP to prevent HIV, screenings to detect cancer and infectious diseases, and medications to prevent cardiovascular disease.[92] Some preventive care recommendations are geared toward certain populations based on age, family history, and other risk factors.[93] For example, early detection of cancer and linkage to care can significantly improve health outcomes and save lives.[94]

---

employed rigorous methodology to formulate recommendations based on comprehensive scientific research, data, and evidence for over forty years. *See About the USPSTF*, U.S. Preventive Servs. TASK FORCE, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf [https://perma.cc/X27T-GAE6].

91. *Id.*

92. *See A & B Recommendations*, U.S. Preventive Servs. TASK FORCE, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations [https://perma.cc/9B4K-K5N6]; Trisha Pasricha & Lawrence Friedman, *How Well Do Colonoscopies Prevent Colon Cancer? What You Need to Know*, Harv. Health Publ'g (Oct. 18, 2022), https://www.health.harvard.edu/blog/how-well-do-colonoscopies-prevent-colorectal-cancer-what-you-need-to-know-202210182834; *The HIV/AIDS Epidemic in the United States: The Basics*, KFF https://www.kff.org/hivaids/fact-sheet/the-hiv-aids-epidemic-in-the-united-states-the-basics/ (Oct. 9, 2024).

93. *See About the USPSTF*, *supra* note 90.

94. *See* Am. Cancer Soc'y, *Cancer Facts & Figures 2022* 2 (2022), https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2022/2022-cancer-facts-and-figures.pdf. Between 1991 and 2019, the age-adjusted cancer death rate in the United States decreased by thirty-two percent. *See id.*

The USPSTF's recommendations reflect "thousands of scientific studies every year on a range of preventive services" that result in publicly available information about which preventive-care services are recommended, for whom, and why.[95] Early detection and treatment through recommended screenings is also important for infectious diseases, such as Hepatitis C. If left untreated, Hepatitis C can cause life-threatening complications including liver cancer and liver failure, but with early diagnosis and treatment, antiviral medications can cure the disease in more than ninety-five percent of patients.[96] Hepatitis C screening, as recommended by the USPSTF, helps people with the virus connect to treatment and avoid life-threatening complications, while promoting public health by enabling patients to take precautions to prevent transmission.[97]

Another prominent example of the United States' commitment to preventive care is its immunization

---

95. *USPSTF: The Primary Care Clinician's Source for Prevention Recommendations*, U.S. Preventive Servs. TASK FORCE, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/task-force-resources/primary-care-clinicans-source-factsheet (May 2021) [https://perma.cc/69CP-KFB2].

96. *See Hepatitis C Basics*, CDC (Jan. 31, 2025), https://www.cdc.gov/hepatitis-c/about/index.html [https://perma.cc/4XAJ-3WC9]; *Hepatitis C*, World Health Org. (Apr. 9, 2024), https://www.who.int/news-room/fact-sheets/detail/hepatitis-c [https://perma.cc/Y6EE-YUS3].

97. *See Hepatitis C Virus Infection in Adolescents and Adults: Screening*, U.S. Preventive Servs. TASK FORCE (Mar. 2, 2020), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening [https://perma.cc/W4KE-DTNN].

policy. Lauded as one of the ten greatest public health achievements of the 2010s, the immunization policy currently targets twenty-one dangerous, preventable communicable diseases.[98] In a similar vein, the Vaccines for Children ("VFC") program was created to cover immunization costs for children of socioeconomically disadvantaged families otherwise unable to afford such preventive care.[99] As a result of the VFC program, "[a]mong children born during 1994–2023, routine childhood vaccinations will have prevented approximately 508,000,000 cases of illness, 32,000,000 hospitalizations, and 1,129,000 deaths, resulting in direct savings of $540 billion and societal savings of $2.7 trillion."[100]

USPSTF's recommendation of PrEP aligns with the Task Force's broader framework of mitigating public health risks through early, evidence-based intervention.[101] Limiting access to PrEP both jeopardizes individual health and weakens the broader public health strategy for

---

98. *See* U.S. Ctrs. for Disease Control & Prevention, *supra* note 89, at 619; *Vaccines by Disease*, CDC (Aug. 14, 2024), https://www.cdc.gov/vaccines/hcp/by-disease/index.html.

99. *See* Fangjun Zhou et al., *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program—United States, 1994–2023*, 73 Morbidity & Mortality Wkly. Rep. 682, 682 (2024), https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7331a2-H.pdf.

100. *Id.* at 685.

101. *See* Michael J. Barry, et al., *Putting Evidence into Practice: An Update on the US Preventive Services Task Force Methods for Developing Recommendations for Preventive Services*, 21 Annals Fam. Med. 165, 170 (2023); *About the USPSTF*, *supra* note 90.

disease prevention. The strength of preventive care efforts lies in a comprehensive approach, which recognizes that disease prevention must be tackled through a combination of measures addressing various health risks to keep the population as a whole healthy.[102]

Like the preventive measures discussed above, PrEP is highly effective in protecting individuals against HIV transmission.[103] When taken as prescribed, PrEP decreases the likelihood of acquiring HIV from sexual contact by approximately ninety-nine percent—a feat with profound implications.[104] For couples where one partner is HIV-positive, for example, PrEP can protect the HIV-negative partner while trying to conceive, and the baby during pregnancy and while breastfeeding.[105] Ultimately, ensuring continuous and widespread access to PrEP has the potential to result in 139,296 person-years of HIV treatment averted as well as medical cost savings of more than $4.25 billion over ten years.[106]

---

102. *See National Health Initiatives, Strategies & Action Plans*, CDC (May 16, 2024), https://www.cdc.gov/public-health-gateway/php/communications-resources/national-health-initiatives-strategies-action-plans.html (listing the numerous national preventive care initiatives that collectively set forth the "strategic priorities to tackle the most significant health challenges faced by the nation").

103. *See Pre-Exposure Prophylaxis*, HIV.gov, https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis (Feb. 7, 2025).

104. *See id.*

105. *See id.*

106. Memorandum on the Updated HIV Incidence Assumptions for the PrEP Cost Calculator from Sophia D'Angelo,

Such gains are at risk of reversal, however, if no-cost access to preventive measures is not guaranteed and upheld.

CONCLUSION

The elimination of no-cost preventive care measures like PrEP will force the nation into another HIV outbreak despite the existence of preventive measures proven to minimize communicability. While decades of bipartisan efforts to decrease the incidence and prevalence of HIV/AIDS and similar public health crises have monumentally improved public welfare, eradication and continued health promotion are contingent on widespread access to preventive care measures.

President Donald J. Trump stated in his 2019 State of the Union Address that "no force in history has done more to advance the human condition than American freedom. In recent years we have made astonishing progress in the fight against HIV and AIDS. Scientific breakthroughs have brought a once-distant dream within reach. . . . Together, we will defeat AIDS in America."[107] This is only possible if preventive care measures, like PrEP, continue to remain accessible to all Americans.

Laurel Bates, & Amanda Honeycutt, RTI Int'l, to Carl Schmid & Kevin Herwig, HIV+Hepatitis Pol'y Inst. 3 (Nov. 28, 2023) (available at https://hivhep.org/wp-content/uploads/2024/02/PrEP_Cost_HIV_Incidence_Updates_Memo_20231128.pdf).

107. Donald J. Trump, U.S. Pres., State of the Union Address (Feb. 5, 2019) (transcript available at https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-state-union-address-2/).

For the foregoing reasons, *amici* urge this Court to reverse the Fifth Circuit's decision and remand to the District Court for further proceedings.

Respectfully submitted,

Christopher R. Riano
Jacob A. Barrera
Danielle A. Giaccio
Holland & Knight LLP
787 Seventh Avenue,
31st Floor
New York, NY 10019

Amy O'Brien
Curran Butcher
Kaatje S. Greenberg
Holland & Knight LLP
800 17th Street NW,
Suite 1100
Washington, DC 20006

Jose I. Abrigo Jr.
Counsel of Record
Omar Gonzalez-Pagan
Lambda Legal Defense and
Education Fund, Inc.
120 Wall Street, 19th Floor
New York, NY 10005
(212) 809-8585
jabrigo@lambdalegal.org

Karen L. Loewy
Lambda Legal Defense and
Education Fund, Inc.
815 16th Street NW, Suite 4140
Washington, DC 20006

Bennett Klein
Chris Erchull
GLBTQ Legal Advocates
& Defenders
18 Tremont Street, Suite 950
Boston, MA 02108

Suman Chakraborty
Mintz, Levin, Cohn, Ferris,
Glovsky, and Popeo, P.C
919 Third Avenue
New York, NY 10022

Katie Stewart
Courtney Herndon
Mintz, Levin, Cohn, Ferris,
Glovsky, and Popeo, P.C.
One Financial Center
Boston, MA 02111

February 25, 2025

APPENDIX

TABLE OF APPENDICES

APPENDIX — LIST OF *AMICI CURIAE*

AIDS Foundation Chicago

AIDS Law Project of Pennsylvania

AIDS United

Callen-Lorde Community Health Center

DAP Health

Equality California

Equitas Health

The Human Rights Campaign Foundation

Justice in Aging

Legal Action Center

The LGBT Bar of New York

The Los Angeles LGBT Center

Mazzoni Center

National Alliance of State and Territorial AIDS Directors

PrEP4All

Thrive Alabama

Treatment Action Group

Rhode Island Public Health Institute

San Francisco Community Health Center

Whitman-Walker Health