United States Court of Appeals

for the

Fifth Circuit

Case No. 23-10326

BRAIDWOOD MANAGEMENT, INCORPORATED; JOHN SCOTT KELLEY; KELLEY ORTHODONTICS; ASHLEY MAXWELL; ZACH MAXWELL; JOEL STAMES,

Plaintiffs-Appellees/Cross-Appellants,

JOEL MILLER; GREGORY SCHEIDEMAN,

Plaintiffs-Cross-Appellants,

v.

XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services, in his official capacity as Secretary of Health and Human Services; UNITED STATES OF AMERICA; JANET YELLEN, Secretary, U.S. Department of Treasury, in her official capacity as Secretary of the Treasury; JULIE A. SU, Acting Secretary, U.S. Department of Labor, in her official capacity as Secretary of Labor,

Defendants-Appellants/Cross-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS, IN DISTRICT NO. 0539-4:4:20-CV-283, HONORABLE REED CHARLES O'CONNOR, U.S. DISTRICT JUDGE

CONSENT MOTION TO FILE BRIEF AS AMICI CURIAE

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CONSENT MOTION TO FILE BRIEF AS AMICI CURIAE

Pursuant to Federal Rule of Appellate Procedure 29 and Fifth Circuit Rule 29, Proposed *Amici* move for leave to file the attached brief in support of Defendant-Appellant's appeal from the District Court's decision.

The proposed *Amici* submit this brief to inform the Court about the harmful impact the District Court's decision will have on the nation's goal to curb, and ultimately end, the HIV epidemic. The Proposed *Amici* organizations include thousands of physicians and other healthcare providers with expertise in the treatment and prevention of HIV, government and public officials from every state responsible for stopping the HIV epidemic, and policy experts who understand the demographics and dynamics of the epidemic. Specifically:

A. **The HIV Medicine Association of the Infectious Diseases Society of America ("HIVMA")** is an organization of medical professionals who practice HIV medicine. HIVMA represents the interests of HIV health care providers and researchers and their patients by promoting quality in HIV care and by advocating for policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

B. **The National Alliance of State & Territorial AIDS Directors ("NASTAD")** is a leading nonpartisan nonprofit association that represents public health officials who administer HIV and hepatitis programs in the United States and

around the world. NASTAD's mission is to end the intersecting epidemics of HIV, viral hepatitis, and related conditions.

ARGUMENT

Today we have the medical tools to end the HIV epidemic. HIV pre-exposure prophylaxis ("PrEP") is an extraordinary medical breakthrough. It is a safe and effective medication that prevents HIV transmission by close to 100 percent. The FDA first approved PrEP in 2012, and the United States Preventive Services Task Force gave it an "A" rating based on the highest quality scientific evidence in 2019. The challenge is that too few people who are vulnerable to HIV infection are currently taking PrEP.

The arc of progress since the harrowing early decades of the epidemic has been extraordinary—but it remains incomplete. The proposed *Amici* submit this brief to emphasize that the outcome of this case will have a deep impact on whether that arc continues or, instead is stymied and reversed. Make no mistake: the District Court's decision, and the resulting re-imposition of cost-sharing for PrEP, will cause tens of thousands of new but preventable HIV infections, erode or even reverse progress to date, and undermine public health efforts to end the HIV epidemic. The consequences to individual health are profound as well. Even with effective antiretroviral treatment, people diagnosed with HIV today live with an incurable and

highly stigmatized health condition that also increases the risk of other life-threatening diseases.

Whether to grant a motion for leave to participate as *amicus curiae* is within the Court's discretion. *See Richardson v. Flores*, 979 F.3d 1102, 1106 (5th Cir. 2020) (noting granting leave to file an *amici* brief is within the Court's discretion). Where, as here, *amici curiae* demonstrate sufficient interest in the case and their brief is relevant to the issues raise in the case, courts typically grant leave to file as *amicus curiae*. *See Lefebure v. D'Aquilla*, 15 F.4th 670, 676 (5th Cir. 2021) (quoting *Neonatology Assocs., P.A. v. Comm'r of Internal Revenue*, 293 F.3d 128, 133 (3rd Cir. 2002) ("[W]e would be 'well advised to grant motions for leave to file amicus briefs unless it is obvious that the proposed briefs do not meet Rule 29's criteria as broadly interpreted.'").

This Court should grant Proposed *Amici's* motion for leave because the proposed brief is timely and useful. Proposed *Amici's* motion is timely because it is filed "no later than 7 days after the principal brief of the party being supported is filed." Fed. R. App. P. 29(a)(6). Additionally, the brief will be useful to this Court because it provides information explaining the critical importance of HIV pre-exposure prophylaxis, the progress we have made in the fight to end this epidemic, and the very real consequences of the District Court's decision: tens of thousands of

new, preventable HIV infections, billions of dollars in medical costs, reversal of progress to date, and undermining public health efforts to end the HIV epidemic.

Counsel for the parties have consented to this motion and to the filing of the attached *amicus curiae* brief.

Pursuant to the Federal Rule of Appellate Procedure 29(a)(4)(E), Proposed *Amici* states that no counsel for any party authored the proposed brief in whole or in part, and no person or entity other than *Amici* and counsel made a monetary contribution intended to fund the preparation or submission of this brief.

Accordingly, Proposed *Amici* respectfully request that this Court grant leave to file the attached proposed brief.

June 27, 2023

Respectfully Submitted,

/s/ Andrew H. DeVoogd

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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2023, a true and correct copy of the foregoing Motion to file Consent to File Brief for Amici were served via electronic filing with the Clerk of Court and all registered ECF users.

Dated: June 27, 2023

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CERTIFICATE OF COMPLIANCE

This motion has been prepared using 14-point, proportionately spaced, serif typeface, in Microsoft Word. Excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), this motion contains 784 words.

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BRIEF FOR *AMICI CURIAE* THE HIV MEDICINE ASSOCIATION OF THE INFECTIOUS DISEASE SOCIETY OF AMERICA AND THE NATIONAL ALLIANCE OF STATE & TERRITORIAL AIDS DIRECTORS

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SUPPLEMENTAL STATEMENT OF INTERESTED PARTIES

Pursuant to Fifth Circuit Rule 29.2, the undersigned counsel of record certifies that the following listed persons and entities, in addition to those already listed in the parties' briefs, have an interest in the outcome of this case. These representations are made in in order to assist the judges of this court in evaluating possible disqualification or recusal.

Amici curiae on this brief:

1. **The HIV Medicine Association ("HIVMA")** is part of the Infectious Diseases Society of America ("IDSA") and is not separately incorporated. IDSA is also an amicus in this case. The IDSA is a non-profit, tax-exempt organization. Neither HIVMA nor IDSA has any parent company, and no publicly held company has any ownership interest of any kind in either organization.

2. **The National Alliance of State and Territorial AIDS Directors ("NASTAD")** is a non-profit, tax-exempt organization. NASTAD has no parent company, and no publicly held company has any ownership interest in it of any kind.

June 27, 2023

Respectfully Submitted,

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Bragdon v. Abbott,
524 U.S. 624 (1998) ... 10

Doe v. Mutual of Omaha,
No. 1:16-cv-11381 (D. Mass. July 18, 2018) ... 12

Statutes & Other Authorities:

A. David Paltiel, et al., *Increased HIV Transmissions with Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of* Braidwood Management v. Becerra, 10(3) Open Forum Infectious Diseases, Mar. 16, 2023 ... 15, 17, 18, 20

Aaron O'Neill, *Number of Military Fatalities in all Major Wars Involving the United States from 1775 to 2023*, STATISTA (Apr. 11, 2023) ... 13

AIDSVu, *Deeper Look: PrEP* ... 16

Amy R. Baugher, et al., *Prevalence of Internalized HIV-Related Stigma Among HIV-Infected Adults in Care, United States, 2011-2013*, AIDS BEHAV. 2600, 2605 (2017) ... 25

Anthony Fauci et al., *Ending the HIV Epidemic: A Plan for the United States*, 321 JAMA 844, 844 (2019) ... 15

C. Everett Koop, Address at Cardozo High School (Feb. 25, 1988) ... 6

CDC, Advance Report of Final Mortality Statistics, 1993 (1996) (Table 7) ... 7

CDC, Advance Report of Final Mortality Statistics, 1994 (1996) (Table 7) ... 7

CDC, *AIDS and Opportunistic Infections*, (May 20, 2021) ... 8

CDC, *CDC Statement on FDA Approval of Drug for HIV Prevention*, NCHHSTP NEWSROOM (July 16, 2012) ... 12

CDC, Deaths: Final Data for 1996 (1998) (Table 8) ... 7

CDC, Deaths: Final Data for 1997 (1999) (Table 8) ... 7

CDC, *HIV Declines Among Young People and Drive Overall Decrease in New HIV Infections* (May 23, 2023)..14, 15, 16

CDC, *HIV in the Southern United States* (Sept. 2019)..14

CDC, HIV in the United States by Race/Ethnicity: HIV Incidence (Apr. 12, 2022) 15

CDC, *How Effective Is PrEP?*, (June 6, 2022)...12

CDC, *Lifetime Risk of HIV Diagnosis* (February 23, 2016)..................................15

CDC, Nat'l Ctr. for Health Statistics, National Vital Statistics Sys., Mortality 2018-2021, CDC WONDER Online Database 21

CDC, Report of Final Mortality Statistics, 1995 (1997) (Table 7)...........................7

Chia-Ching J. Wang & Joel M. Palefsky, *HPV- Associated Anal Cancer in the HIV/AIDS Patient*, 177 HIV/AIDS-ASSOCIATED VIRAL ONCOGENESIS: CANCER TREATMENT & RSCH. 183 (2018)...........................23

Cindy Ruskin, The Quilt: Stories from the NAMES Project, 34-35 (Pocket Books 1988)...26

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 1, 2 (2023) 15

Dominik Stelzle et al., *Estimates of the Global Burden of Cervical Cancer Associated with HIV*, 9 LANCET GLOB. HEALTH e161 (2021)......................23

Elizabeth Kastor, *AIDS Chronicle: A Public Death*, WASH. POST, Aug. 14, 1985 9

Emile Camille Noubissi et al., *Diabetes and HIV*, 18 CURRENT DIABETES REPS. 1 (2018)..23

Eugene McCray & Jonathan Mermin, *National Gay Men's HIV/AIDS Awareness Day Dear Colleague Letter*, CDC (Sept. 27, 2017)...................11

Fanta Duguma et al., *Diabetes Mellitus and Associated Factors Among Adult HIV Patients on Highly Active Anti-Retroviral Treatment*, 12 HIV/AIDS – RSCH & PALLIATIVE CARE 657 (2020) 23

Gregory M. Herek & Eric K. Glunt, *An Epidemic of Stigma: Public Reactions to AIDS*¸ 43 AM. PSYCH. NO 11 886 (1988)..................................9

Gregory M. Herek & John P. Capitanio, *Public Reactions to AIDS in the United States: A Second Decade of Stigma*, 83 AM. J. PUB. HEALTH 574, 574 (1993)..........10

Gregory M. Herek et al., *HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991–1999*, 92 AM. J. PUB. HEALTH 371, 375 (2002)..........10

Henry Masur, *HIV-Related Opportunistic Infections Are Still Relevant in 2015*, 23 TOPICS IN ANTIVIRAL MED. 116, 116 (2015)..........21

Henry Masur, *Recurring and Emerging Questions Related to Management of HIV-Related Opportunistic Infections*, 26 TOPICS IN ANTIVIRAL MED. 79 (2018)..........21

HIV.gov, *U.S. Statistics: Fast Facts* (Oct. 27, 2022)..........13

Howard Grossman, *AIDS-The Dark Years,* 8 MEDGENMED 57 (2006)..........11

Janice M. Leung, *HIV and Chronic Lung Disease*, 17 CURRENT OP. IN HIV & AIDS 1 (2022)..........22, 23, 24

John Paul Brammer, *Three Decades Later, Men Who Survived the 'Gay Plague' Speak Out*, NBCNEWS (Dec. 1, 2017)..........6, 7

Kaiser Fam. Found., *KFF Health Tracking Poll – March 2019* 15 (2019)..........24

Kaiser Fam. Found., *National Survey of Young Adults on HIV/AIDS* 2 (2017)..........25

Kaylee B. Crockett et al., *Experiences of HIV-Related Discrimination and Consequences for Internalised Stigma, Depression, and Alcohol Use*, 34 PSYCH. HEALTH 1 (2019)..........25, 26

Keith Sigel et al., *Lung Cancer in Persons with HIV*, 12 CURRENT OP. IN HIV & AIDS 31 (2017)..........23

Letter from Debra Birnkrant, Director, Division of Antiviral Drug Products, Office of Drug Evaluation IV, Ctr. for Drug Evaluation & Rsch., to Martine Kraus, Director, Regulatory Affairs, Gilead Sciences, Inc. (Aug. 2, 2004)..........12

Marc A. Pitasi et al., *Stigmatizing Attitudes Toward People Living with HIV Among Adults and Adolescents in the United States*, 22 HIV & BEHAV. 3887, 3890 (2018)..........24

Matthew S. Freiberg et al., *HIV Infection and the Risk of Acute Myocardial Infarction*, 173 JAMA INTERNAL MED. 614, 614 (2013) 23

Maureen Foertsch McKinney, *AIDS at 40: The Epidemic Emerges in Illinois*, NPR Illinois (Dec. 8, 2021)..6, 8, 9

Meredithe McNamara et al., *Braidwood Misreads the Science: the PrEP Mandate Promotes Public Health for the Entire Community* 6 (2023)...11, 12, 19

Michael M. Lederman et al., *Residual Immune Dysregulation Syndrome in Treated HIV Infection*, 119 Advances in Immunology 51 (2013) 22, 24

Mike Thomas, *Arson Cause of Fire at Rays – Boys Start School Today,* ORLANDO SENTINEL (Sept. 23, 1987) 9

Nat'l Insts. of Health, Ctrs. for Disease Control & Prevention, HIV Med. Ass'n, and Infectious Diseases Soc'y. of Am., *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV* A1 (2023) 20, 21

Revery P. Barnes et al., *HIV Infection and Risk of Cardiovascular Diseases Beyond Coronary Artery Disease*, 19 CURRENT ATHEROSCLEROSIS REPS. 1 (2017)..22

Rob Roth, *Cleve Jones Reflects on Life in San Francisco during the 1980s AIDS Crisis*, KTVU (June 21, 2019)..3, 6

Robin Marantz Henig, *Five-Star Surgeon General*, SAN FRANCISCO EXAMINER, Oct. 18, 1987 ....5, 6

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 NO 11 737, 738 (2005) 10

Skip Hollandsworth, *AIDS: Seven Days in the Crisis*, D MAG., Mar. 1, 1988 9

Southern State AIDS Directors Work Group, *Southern States Manifesto*, (2003)..14

Steven G. Deeks et al., *The End of AIDS: HIV Infection as a Chronic Disease*, 382 Lancet 1525 (2013)...22, 24

Surgeon General Visits Falwell's Campus with Message of Safe Sex, SEATTLE GAY NEWS, Feb. 20, 1987 5

Thomas Ferraro, *Surgeon General Makes His Mark on the Nation*, THE INDIANAPOLIS STAR, Dec. 27, 1987 5

U.S. Dep't of Health & Hum. Servs., *Understanding AIDS: A Message From The Surgeon General* (1988) 6

U.S. Dep'ts of Lab., Health and Hum. Servs., & the Treasury, *FAQs About Affordable Care Act Implementation Part 47* 3 (2021) 13

U.S. Preventive Services Task Force, Draft Recommendation Statement: Prevention of HIV Infection: Pre-Exposure Prophylaxis (Dec. 13, 2022) 12-13

U.S. Preventive Services Task Force, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (June 11, 2019) 12

White House Office of National AIDS Policy: National HIV/AIDS Strategy for the United States: Updated to 2020 (July 2015) 24

William Chris Woodward, *Can You Explain AIDS and How It Affects the Immune System? How does HIV Become AIDS?*, SCI. AM., NOV. 8, 1999 8

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) 19

INTEREST OF THE *AMICI CURIAE*[1]

The HIV Medicine Association of the Infectious Diseases Society of America

The HIV Medicine Association of the Infectious Diseases Society of America (the "HIVMA") is an organization of medical professionals who practice HIV medicine. HIVMA represents the interests of HIV health care providers and researchers and their patients by promoting quality in HIV care and by advocating for policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.

The National Alliance of State & Territorial AIDS Directors

The National Alliance of State & Territorial AIDS Directors ("NASTAD"), founded in 1992, is a leading nonpartisan non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S. and around the world. NASTAD's mission is to end the intersecting epidemics of HIV, viral hepatitis, and related conditions. As a national leader in health department mobilization, NASTAD encourages the use of applied scientific knowledge and community engagement as a method of reducing the incidence of HIV and hepatitis in the United States ("U.S"), its territories, and around the world. NASTAD's

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[1] All parties have consented to the filing of this brief. We certify that this brief was not authored in whole or in part by counsel for any of the parties and that no one other than *Amici* and their counsel have contributed money for this brief.

programmatic teams interpret and influence policies, conduct trainings, offer technical assistance, and provide advocacy mobilization for U.S. health departments and ministries of health around the world to improve health outcomes for people living with and at risk for HIV and hepatitis.

INTRODUCTION

Infectious, incurable, and, prior to the advent of highly effective antiretroviral medicines, almost always lethal, the HIV[2] epidemic has presented a unique public health challenge. As one of the few survivors of HIV from the 1980s recounted of the early years of the epidemic, "[i]t was a time of great sorrow and overwhelming terror."[3] In those early years, a diagnosis was followed by painful and debilitating opportunistic infections not seen in healthy young people. The average time to death was just one year. Over time the epidemic has disproportionately affected populations and regions of the country with the greatest inequities in access to healthcare. And no other disease has evoked the fear, misunderstanding, and discrimination as that associated with HIV.

It would have been unfathomable to the hundreds of thousands of young Americans who died in the first three decades of the HIV epidemic—and to the parents, children, spouses, partners, friends, and caretakers who survived them—that there would one day be a fully effective daily pill that prevents HIV transmission

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[2] HIV, the human immunodeficiency virus, is a retrovirus that is the causative agent of Acquired Immune Deficiency Syndrome ("AIDS"), which is the advanced stage of HIV disease.

[3] Rob Roth, *Cleve Jones Reflects on Life in San Francisco during the 1980s AIDS Crisis*, KTVU (June 21, 2019), https://www.ktvu.com/news/cleve-jones-reflects-on-life-in-san-francisco-during-the-1980s-aids-crisis. All website links cited in this brief were last accessed on June 26, 2023.

by close to 100 percent. Yet, HIV pre-exposure prophylaxis ("PrEP") is just that: an extraordinary medical breakthrough. The FDA first approved PrEP in 2012, and the United States Preventive Services Task Force ("USPSTF") gave it an "A" rating based on the highest quality scientific evidence in 2019. Once considered unthinkable early on, we now have the medical tools to curb, and eventually end, the HIV epidemic. The challenge is that too few people who are vulnerable to HIV infection are currently taking PrEP.

The *Amici* organizations include thousands of physicians and other healthcare providers with expertise in the treatment and prevention of HIV; government public officials from every state responsible for stopping the epidemic; and policy experts who understand the demographics and dynamics of the epidemic. The arc of progress since the harrowing early decades of the epidemic has been remarkable—but it remains incomplete. The *Amici* submit this brief to emphasize that the outcome of this case will have a deep impact on whether that positive arc continues or, instead is stymied and reversed.

Make no mistake: the District Court's decision, and the resulting re-imposition of cost-sharing for PrEP, will cause tens of thousands of new but preventable HIV infections,[4] erode or even reverse progress to date, and undermine public health efforts to end the HIV epidemic. The consequences to individual health are profound

[4] *See infra* Section II(a).

as well. Even with effective antiretroviral treatment, people diagnosed with HIV today have an incurable and highly stigmatized health condition that also increases the risk of other life-threatening diseases.

ARGUMENT

I. FOUR DECADES AFTER THE DEVASTATING HIV EPIDEMIC BEGAN, OUTCOMES ARE NO LONGER NEARLY UNIVERSALLY FATAL: WE NOW HAVE MEDICAL SOLUTIONS TO END THE EPIDEMIC.

In 1987, the Surgeon General during the administration of President Ronald Reagan, Dr. C. Everett Koop, predicted that HIV would "become 'the most devastating epidemic since the Black Death.'"[5] "I think that the response of our young people [to the threat of HIV] will determine whether we as a civilization survive or don't," he said.[6] "Where else have you ever seen a fatal disease for which

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[5] Robin Marantz Henig, *Five-Star Surgeon General*, SAN FRANCISCO EXAMINER, Oct. 18, 1987, at 23. Dr. Koop was the Surgeon General of the United States from 1981 to 1989. Notably, Dr. Koop personally opposed homosexuality and premarital sex, and urged sexual abstinence or monogamous relationships as the best ways to prevent HIV. *Surgeon General Visits Falwell's Campus with Message of Safe Sex*, SEATTLE GAY NEWS, Feb. 20, 1987; Thomas Ferraro, *Surgeon General Makes His Mark on the Nation*, THE INDIANAPOLIS STAR, Dec. 27, 1987, at F-4. Despite this, in a 1987 interview, he explained that he could not "let his personal morality interfere with his 'moral bottom line'-helping people avoid a sexually transmitted disease that is 100 percent fatal." Henig, *supra*, at 23. At a time of governmental silence about HIV, Dr. Koop became a well-known (and in some senses controversial) figure because of his frank discussion of the way HIV is spread, his call for HIV prevention education as early as elementary school, his promotion of condom use, and his pleas for compassion towards those with HIV. SEATTLE GAY NEWS, *supra*.

[6] Henig, *supra* note 5 at 23 (alteration in original).

there was no vaccine, for which there was no treatment, and which is spread by something everybody likes to do and doesn't like to be told not to do?"[7] In a message mailed to every American, Dr. Koop declared that "AIDS is one of the most serious health problems that has ever faced the American public."[8]

This was not hyperbole. A doctor who established the AIDS ward at a Chicago hospital recounted that "[t]he average life span in the early days of AIDS was about a year."[9] Cleve Jones, who created the idea of the AIDS Memorial Quilt, recalls: "It was not unusual to see people [in San Francisco] collapse and die in the street."[10] Nelson Vergel, a Houston man who tested positive in 1985, said the epidemic felt like being in a war and "bombs were dropping and one might hit me eventually."[11]

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[7] *Id*. Dr. Koop told an audience of high school students in 1988: "AIDS is virtually fatal: 93 percent of the people who were diagnosed as having AIDS back in 1981 have since died of the disease. In medicine, a death rate of 93 percent is as bad as a rate of 100 percent." C. Everett Koop, Address at Cardozo High School (Feb. 25, 1988) (transcript available at https://profiles.nlm.nih.gov/spotlight/qq/catalog/nlm:nlmuid-101584930X635-doc). Although death during that period was so prevalent as to seem unavoidable, there are, in fact, long-term survivors of the 1980s, many of whom have given accounts of that harrowing time.

[8] U.S. Dep't of Health & Hum. Servs., *Understanding AIDS: A Message From The Surgeon General* (1988), https://stacks.cdc.gov/view/cdc/6927.

[9] Maureen Foertsch McKinney, *AIDS at 40: The Epidemic Emerges in Illinois*, NPR Illinois (Dec. 8, 2021), https://www.nprillinois.org/health-harvest/2021-12-07/aids-at-40-the-epidemic-emerges-in-illinois.

[10] Roth, *supra* note 3.

[11] John Paul Brammer, *Three Decades Later, Men Who Survived the 'Gay Plague' Speak Out*, NBCNews (Dec. 1, 2017), https://www.nbcnews.com/feature/nbc-out/three-decades-later-men-who-survived-gay-plague-speak-out-n825621.

Mark King of Los Angeles remembers his dilemma about whether to take the newly licensed test for HIV in 1985:

> If you could take a test that would tell you if you would be alive in two years, would you take it? . . . Everyone [he] knew who had been diagnosed had gone to the hospital and died.[12]

People in their 20s and 30s became caretakers of their sick and dying friends and partners. Many endured the trauma of losing entire friendship networks. Underscoring the nearly universal fatality rate of the disease, over the span of two years in the mid-1990s HIV was the leading cause of death for all Americans between the ages of 25 and 44.[13] For the same age groups, HIV was the leading cause of death for all African-Americans from 1993-1997[14] and for African-American women from 1993 until 1996.[15]

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[12] *Id.*

[13] Ctrs. for Disease Control & Prevention ("CDC"), Advance Report of Final Mortality Statistics, 1994 (1996) (Table 7) ("1994 Report"), at 23, https://www.cdc.gov/nchs/data/mvsr/supp/mv45_03s.pdf; CDC, Report of Final Mortality Statistics, 1995 (1997) (Table 7) ("1995 Report"), at 23, https://www.cdc.gov/nchs/data/mvsr/supp/mv45_11s2.pdf.

[14] CDC, Advance Report of Final Mortality Statistics, 1993 (1996) (Table 7) ("1993 Report"), at 22, https://www.cdc.gov/nchs/data/mvsr/supp/mv44_07s.pdf; 1994 Report, *supra* note 13 at 30; 1995 Report, *supra* note 13 at 30; CDC, Deaths: Final Data for 1996 (1998) (Table 8) ("1996 Report"), at 33, https://www.cdc.gov/nchs/data/nvsr/nvsr47/nvs47_09.pdf; CDC, Deaths: Final Data for 1997 (1999) (Table 8) ("1997 Report"), at 34, https://www.cdc.gov/nchs/data/nvsr/nvsr47/nvs47_19.pdf.

[15] 1993 Report, *supra* note 14 at 25; 1994 Report, *supra* note 13, at 33; 1995 Report, *supra* note 13 at 33; 1996 Report, *supra* note 14 at 36.

Death from AIDS was often preceded by what one doctor described as "almost like slow, slow torture . . . [s]ome of the problems people develop are just horrendous,"[16] often resulting from HIV-associated opportunistic infections. Prior to the advent of effective treatment, HIV infection resulted in a progressive destruction of the body's lymphatic and immune systems resulting in a myriad of viral, bacterial, and fungal infections not seen in an immunocompetent host.[17] Harrowing stories of this slow torture depict a man at Parkland Hospital who "looks like a concentration camp victim . . . curled fetus-like in the bed" weighing ninety-eight pounds; a 37 year-old man with stabbing pain in his throat, raw sores in his mouth, with dark lesions of Kaposi's sarcoma who dropped from 150 to 90 pounds; or a 64 year-old

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[16] McKinney, *supra* note 9 (quoting a Chicago doctor: "I think people either don't know or have forgotten what an awful disease HIV can be. It's one thing to develop a fatal illness and die quickly … But this is almost like slow, slow torture. Some of the problems people develop are just horrendous.").

[17] 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/. Examples of HIV-associated opportunistic infections include: Kaposi's sarcoma (KS) (KS appears as firm pink or purple lesions on the skin and can be life-threatening when it affects organs inside the body, such as the lung, lymph nodes, or intestines); Pneumocystis pneumonia (PCP) (a lung infection caused by a fungus); Cytomegalovirus (CMV) (a virus that can infect multiple parts of the body and cause pneumonia, gastroenteritis, encephalitis (infection of the brain)), and sight-threatening retinitis; Mycobacterium avium complex (MAC) (life-threatening bacterial infection); and Wasting syndrome (defined as the involuntary loss of more than 10% of one's body weight due to diarrhea, weakness, or fever). CDC, *AIDS and Opportunistic Infections*, (May 20, 2021), https://www.cdc.gov/hiv/basics/livingwithhiv/opportunisticinfections.html.

retired woman hospitalized with pneumocystis pneumonia just months after testing positive.[18] "The bulk of what we were trying to do," one doctor recalled, "[was] buy time for people. And then eventually, it was the patient's decision that it just wasn't worth it anymore."[19]

The HIV epidemic in the United States has been much more than just a medical crisis. No other disease in our history has evoked more fear, misunderstanding, and overt and life-altering discrimination. For example, prominent cultural figures called for drastic, authoritarian measures such as quarantines and even tattooing the words "HIV-positive" on those with HIV.[20] Children with HIV were systematically ostracized from school and community—families who pressed for the rights of their children with HIV to attend school experienced violent backlash and even arson.[21] Doctors, dentists, and other healthcare providers commonly refused to treat patients with HIV based on fears of

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[18] *See* Skip Hollandsworth, *AIDS: Seven Days in the Crisis*, D MAG., Mar. 1, 1988, https://www.dmagazine.com/publications/d-magazine/1988/march/aids-seven-days-in-the-crisis/; Elizabeth Kastor, *AIDS Chronicle: A Public Death*, WASH. POST, Aug. 14, 1985, https://www.washingtonpost.com/archive/politics/1985/08/14/aids-chronicle-a-public-death/72ba10bd-19a3-4e6f-bd76-a35a40708265/.

[19] McKinney, *supra* note 9.

[20] Gregory M. Herek & Eric K. Glunt, *An Epidemic of Stigma: Public Reactions to AIDS*¸ 43 AM. PSYCH. NO 11 886, 887 (1988).

[21] *See* Mike Thomas, *Arson Cause of Fire at Rays – Boys Start School Today,* ORLANDO SENTINEL (Sept. 23, 1987), https://www.orlandosentinel.com/1987/09/23/arson-cause-of-fire-at-rays-boys-start-school-today/.

contagiousness.[22] Discrimination by nursing homes, day care centers, funeral homes, restaurants, gyms, and other public accommodations was rampant.[23]

Myths and stereotypes fueled this discrimination and led people with HIV to fear disclosure of their status. Studies showed that "a disturbingly large proportion of respondents believed that HIV can be transmitted through various kinds of casual contact," including 45.4 percent of respondents who falsely believed that transmission is "likely" if a person with HIV merely "sneezes or coughs on someone else."[24] A 1991 survey showed that "45% [of respondents] said that they would avoid shopping at a grocery store whose owner had AIDS."[25]

Fortunately, both treatment and prevention for HIV have advanced dramatically since the inception of the epidemic. In the late 1990s, the advent of highly active oral antiretroviral medications, comprising a multiple drug regimen, transformed HIV from a disease in which people could quickly progress to

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[22] *See, e.g.*, Bragdon v. Abbott, 524 U.S. 624, 652-53 (1998).

[23] 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 NO 11 737, 738 (2005) (referencing 2003 report of American Civil Liberties Union survey finding that HIV stigma resulted in denials of medical treatment, privacy violations, and refused admittance to nursing homes).

[24] Gregory M. Herek & John P. Capitanio, *Public Reactions to AIDS in the United States: A Second Decade of Stigma*, 83 AM. J. PUB. HEALTH 574, 574 (1993).

[25] Gregory M. Herek et al., *HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991–1999*, 92 AM. J. PUB. HEALTH 371, 375 (2002).

debilitation and death, to a chronic manageable condition.[26] "Viral suppression is the hallmark of successful HIV treatment" and is achieved with consistent adherence to antiretroviral medication.[27] In the face of the nearly universal fatality rates of the early days of the epidemic, it is no exaggeration to say that these medications are "near-miraculous" and, with proper administration, within months render the virus "undetectable" by medical standards.[28]

The use of oral antiretroviral medications that treat HIV has also transformed the ability to prevent transmission of HIV.[29] Pre-exposure prophylaxis, or PrEP, is another extraordinary advance in HIV prevention using an antiretroviral medication. The FDA first approved the antiretroviral medication Truvada in 2004 as a treatment

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[26] Howard Grossman, *AIDS-The Dark Years,* 8 MEDGENMED 57 (2006).

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

[28] Grossman, *supra* note 26.

[29] With respect to people who have HIV and are in treatment, the CDC has concluded based on a series of research studies beginning in 2011 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), https://www.cdc.gov/nchhstp/dear_colleague/2017/dcl-092717-National-Gay-Mens-HIV-AIDS-Awareness-Day.html. This "landmark public health discovery" is known as "U equals U" or "undetectable equals untransmittable." McNamara et al., *supra* note 27, at 6.

for HIV in combination with other medications.[30] The FDA later approved Truvada, taken as a single daily pill, as use for PrEP in 2012.[31]

Public health and medical experts agree that "PrEP is one of the most celebrated biomedical successes in the global fight to end the HIV epidemic."[32] PrEP reduces the risk of HIV infection from sex by over 99%—a truly extraordinary efficacy.[33] In 2019 the USPSTF gave PrEP an "A" rating, meaning that it recommends PrEP as routine preventive care based on the highest quality scientific evidence.[34] Due in large part to its incredible efficacy in preventing the transmission

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[30] Letter from Debra Birnkrant, Director, Division of Antiviral Drug Products, Office of Drug Evaluation IV, Ctr. for Drug Evaluation & Rsch., to Martine Kraus, Director, Regulatory Affairs, Gilead Sciences, Inc. (Aug. 2, 2004), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2004/021752s000_Truvada_Approv.pdf.

[31] CDC, *CDC Statement on FDA Approval of Drug for HIV Prevention*, NCHHSTP NEWSROOM (July 16, 2012), https://www.cdc.gov/nchhstp/newsroom/2012/fda-approvesdrugstatement.html. PrEP works by keeping HIV from penetrating certain cells, called CD4 cells, and making copies of itself. CD4 cells are critical to the functioning of the immune system. Aff. of Kenneth Mayer, M.D., in Support of Pl.'s Mot. for Summ. J., at 7, Doe v. Mutual of Omaha, No. 1:16-cv-11381 (D. Mass. July 18, 2018). Without these CD4 cells, HIV cannot reproduce and make copies of itself. *Id*. Currently, three medications are FDA approved for PrEP, two daily oral medications and an injectable form. McNamara et al., *supra* note 27, at 10.

[32] McNamara et al., *supra* note 27, at 1.

[33] CDC, *How Effective Is PrEP?*, (June 6, 2022), https://www.cdc.gov/hiv/basics/prep/prep-effectiveness.html.

[34] U.S. Preventive Services Task Force, *Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis* (June 11, 2019), https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis#fullrecommendationstart. In 2022 the USPSTF updated its recommendation to include newer PrEP medications. U.S. Preventive Services Task

of HIV—as reflected in the USPSTF's "A" rating—as of June 2020 insurers were required to cover PrEP when medically indicated *without cost sharing*. This meant that prescribed individuals with insurance incurred zero out-of-pocket cost to receive the medicine, thereby lowering one critical barrier to access to the life-saving medicine.[35]

Today, there are 1.2 million Americans with HIV.[36] All told, over 700,000 Americans have died from HIV—more deaths than the combined American casualties of all foreign wars in our nation's history.[37] After many years of plateau, there has in recent years been a modest but meaningful and sustained *decrease* in the

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Force, Draft Recommendation Statement: Prevention of HIV Infection: Pre-Exposure Prophylaxis (Dec. 13, 2022), https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/prevention-human-immunodeficiency-virus-hiv-infection-prep#fullrecommendationstart.

[35] In 2021 the U.S. Department of Health and Services issued a clarification that the mandate to cover PrEP medication without cost sharing also included ongoing quarterly labs for blood work, associated office visits, and other ancillary services recommended in connection with PrEP use. U.S. Dep'ts of Lab., Health and Hum. Servs., & the Treasury, *FAQs About Affordable Care Act Implementation Part 47* 3 (2021), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-47.pdf.

[36] HIV.gov, *U.S. Statistics: Fast Facts* (Oct. 27, 2022), https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics/.

[37] Aaron O'Neill, *Number of Military Fatalities in all Major Wars Involving the United States from 1775 to 2023*, STATISTA (Apr. 11, 2023), https://www.statista.com/statistics/1009819/total-us-military-fatalities-in-american-wars-1775-present/ (demonstrating that the combined casualties of all American wars from 1775-2023, other than the Civil War, is 684,585).

number of annual new HIV infections: estimated annual new infections dropped from 36,500 infections in 2017 to about 32,100 infections in 2021.[38]

The epidemic, however, reflects stark disparities and inequities. It is (and has been) geographically concentrated in the South, a shift in demographics that began over 20 years ago.[39] Eight of the 10 states with the highest rates of new diagnoses are in the South, as are nine of the 10 metropolitan areas with the highest rates of HIV.[40] Even though just 38% of the U.S. population lives in the region, according to the Centers for Disease Control, Southern states account for over half of new HIV cases annually.[41]

The epidemic's racial disparities are startling and unacceptable. In a sobering call to action in 2016, the CDC released risk estimates projecting that "[i]f current HIV diagnosis rates persist, about 1 in 2 [B]lack men who have sex with men and 1 in 4 Latino MSM in the United States will be diagnosed with HIV during their

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

[39] A "Southern States Manifesto" declared in 2002: "There is an emergency underway in the southern states… Over the last decade, the HIV/AIDS and STD epidemics continue to increase in every southern locality, particularly among poor, disenfranchised, and minority populations… [t]he face of HIV/AIDS is becoming increasingly rural, female, black and heterosexual." Southern State AIDS Directors Work Group, *Southern States Manifesto*, at 6-8 (2003).

[40] CDC, *HIV in the Southern United States* 1 (Sept. 2019), available at https://www.cdc.gov/hiv/pdf/policies/cdc-hiv-in-the-south-issue-brief.pdf.

[41] *Id.*; *see also* CDC, *HIV Declines Among Young People, supra* note 38.

lifetimes."[42] In data reflecting the racial categorization of 2019 and 2021 diagnoses, Black people accounted for the largest number of diagnosed HIV cases and Latino people reported the second highest number.[43] And despite the misconception that HIV is a risk faced only by men who have sex with men, "[a]bout one-fifth of new HIV infections in 2021 were among women, and over half of those were among Black women."[44] Transgender women and people who inject drugs are also disproportionately vulnerable to HIV.[45]

PrEP is a key pillar of the strategy to end the HIV epidemic.[46] The challenge is that far too few people vulnerable to infection are currently taking PrEP. In 2021,

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[42] CDC, *Lifetime Risk of HIV Diagnosis* (February 23, 2016), https://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html.

[43] CDC, HIV in the United States by Race/Ethnicity: HIV Incidence (Apr. 12, 2022), https://www.cdc.gov/hiv/group/racialethnic/other-races/incidence.html; CDC, *HIV Declines Among Young People, supra* note 38.

[44] CDC, *HIV Declines Among Young People, supra* note 38.

[45] A. David Paltiel, et al., *Increased HIV Transmissions with Reduced Insurance Coverage for HIV Preexposure Prophylaxis: Potential Consequences of* Braidwood Management v. Becerra, 10(3) Open Forum Infectious Diseases, Mar. 16, 2023, at 3.

[46] The United States Department of Health and Human Services has rolled out the Ending the HIV Epidemic ("EHE") initiative that seeks to curtail new HIV infections by 90% by 2030. Anthony Fauci et al., *Ending the HIV Epidemic: A Plan for the United States*, 321 JAMA 844, 844 (2019), https://jamanetwork.com/journals/jama/fullarticle/2724455. PrEP is a critical instrument for achieving EHE's objectives, acting as both a preventative measure and a means to empower individuals to take charge of their health outcomes. 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 1, 2 (2023), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-023-15563-5.

less than a third of the 1.2 million people who could benefit from PrEP were prescribed it. Although still woefully inadequate in view of the medicine's overwhelming efficacy, this actually represents a significant increase from 13% in 2017.[47] Mirroring stark disparities in infection rates, acute racial disparities are also evident in access to PrEP. The majority of people who could benefit from PrEP for HIV prevention are Black or Hispanic/Latino.[48] In 2021, however, the CDC estimates that only 11% of Black people 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.[49] Geographic disparities compound this delta in access to HIV prevention medication. More than half (52%) of new HIV infections in 2021 were in the U.S. South.[50] The states with the highest unmet need for PrEP are Alabama, West Virgina, South Carolina, and Mississippi.[51]

The District Court's decision threatens to impede, erode, and even reverse the sustained, but incomplete, progress that has been made towards increasing PrEP use and reducing HIV infections. The harm caused will "be borne disproportionately by

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[47] CDC, *HIV Declines Among Young People, supra* note 38.
[48] *Id*.
[49] *Id*.
[50] *Id*.
[51] AIDSVu, *Deeper Look: PrEP*, https://aidsvu.org/resources/deeper-look-prep/ (last visited June 22, 2023).

racial and ethnic sociodemographic groups at particularly high risk for HIV infection."[52]

II. IF NOT REVERSED, THE CONSEQUENCES OF THE DISTRICT COURT'S DECISION WILL UNDERMINE YEARS OF PROGRESS TOWARDS ENDING THE HIV EPIDEMIC AND CAUSE PROFOUND HARM.

a. Giving Effect to the District Court's Decision Will Result in Increased HIV Transmissions.

Among the 30% of people vulnerable to HIV currently taking PrEP, some will inevitably cease treatment because of the new out-of-pocket costs for both the medication and the necessary quarterly laboratory testing and physician visits. Some will interrupt or ration their medication and falsely believe that they are fully protected when they are not. Others still will be deterred from initiating PrEP in the first instance. Simply put, the District Court's decision *will cause* a significant increase in preventable HIV infections at an historic public health moment when the United States is finally seeing modest but meaningful and sustained declines in HIV transmission rates.

A recent epidemiological analysis confirmed that the District Court's decision 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

[52] Paltiel, *supra* note 45, at 3.

US."[53] The same recent study analyzed data from the CDC and HIV prevention clinical trials to "estimate the expected additional HIV transmissions" that will arise from the District Court's decision.[54] To arrive at a "conservative estimate" seeking to "represent a lower bound on the potential impact of this decision,"[55] the study authors restricted their analysis to the expected HIV incidence among only men who have sex with men ("MSM") in a single year.[56] With these cautious parameters, the authors predict an additional 2,057 primary HIV infections *in the first year alone*.[57] The predicted first-year increase of 2,057 primary HIV infections in MSM alone as a result of the decision below will result in at least $863 million additional health care costs.

It is, of course, alarming that after just one year a predicted 2,057 Americans would end up with an incurable, life-threatening, life-altering, and highly

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[53] *Id*.

[54] *Id*. at 1.

[55] *Id*. at 3.

[56] The study restricted attention to the short-term, one year following the District Court decision. It did not take into account the additional primary HIV transmissions that will continue to accumulate beyond the first year. Nor did it account for the secondary transmissions that will result from those primary cases. It restricted attention to MSM and did not consider the many other populations at high risk for HIV. Finally, the study authors note that they likely underestimated the number of individuals using private health insurance. *Id*. at 3. The authors predicted that the suspension of the Affordable Care Act provisions would lower PrEP coverage from 28% to 10% of indicated MSM. *Id*. at 1.

[57] *Id*. at 1.

stigmatized disease as a result of the District Court's order. But the damage would not be limited to only those individuals:

> HIV is a *population-level threat*, not just an individual infection. Anyone with HIV who has detectable viral load can transmit the virus to their sexual partners, who in turn can infect others.[58]

Data underscore this point: for every 100 people with HIV in the United States there will be 92 secondary transmissions.[59] Unlike the incidence of other serious and prevalent diseases like cancer, heart disease, or diabetes, the reality of HIV infectiousness necessarily means that those 2,057 additional cases will not stand in isolation.

One year with 2,057 preventable new infections is predicted to lead to an additional 1,892 secondary infections. And these 3,949 people with HIV will cost the healthcare system a staggering $1.66 billion. Because the model applied in the study is static, it is reasonable to predict that subsequent years will see similar new infections that otherwise would not have occurred. Extending the static one-year model, along with secondary transmissions, just five years into the future paints a bleak picture: approximately 20,000 people with HIV and costing the United States

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[58] McNamara et al., *supra* note 27 at 14 (emphasis added).

[59] 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). Put another way, the effective reproduction number for HIV in the United States is 0.92, the value that represents secondary transmissions attributable to a single person with HIV over the rest of their lifetime. *Id*.

healthcare system over $8 billion. All of this could be prevented absent the District Court's re-imposition of cost barriers to accessing PrEP.

While this snapshot evinces the dynamics of conservatively calculated compounded infections over time, it still does not fully show the lifetime impact from one year of increased transmissions. This is because secondary transmissions invariably lead to subsequent tertiary cases—and beyond.

If allowed to stand, the District Court's order *will* result in new but preventable infections. With those infections come truly massive healthcare costs in terms of dollars, to say nothing of the devastating and immeasurable impact on human life.

b. People Continue to Die of HIV-Related Illness and Complications in the United States.

With this increased HIV transmission comes the likelihood of increased deaths from HIV. Despite the availability of antiretroviral medication that effectively suppresses HIV viral replication, the CDC estimates that 13% of people are unaware of their HIV infection and 34% of Americans who are aware of their HIV infection are not effectively virally suppressed.[60] These individuals are susceptible to the same

[60] Nat'l Insts. of Health, Ctrs. for Disease Control & Prevention, HIV Med. Ass'n, and Infectious Diseases Soc'y. of Am., *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV* A1 (2023), https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-oi/guidelines-adult-adolescent-oi.pdf [hereinafter CDC 2023 Guidelines]. Barriers to testing and viral suppression include systemic lack of access to healthcare and HIV-related stigma and disproportionately affect Black and Latino gay men and transgender women. *See* Paltiel, *supra* note 45, at 3.

devastating opportunistic infections that were prevalent in the early decades of the epidemic.[61] Opportunistic infections "continue to cause preventable morbidity and mortality in the United States."[62] In fact, in 2021 alone 4,977 people in the United States died of HIV.[63] Continued progress in reducing HIV transmission is essential to further reduction in the number of HIV-related opportunistic infections and deaths. Yet the District Court's decision, if left to stand, will have exactly the opposite effect.

c. HIV, Even with Early Diagnosis and Viral Suppression, Increases the Risk of Heart Attack, Stroke, Cancers, Diabetes, and Other Debilitating and Life-Threatening Conditions.

The *Amici* celebrate that today people with HIV are able to live well while managing a chronic disease if they can access and adhere to lifelong antiretroviral

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[61] CDC 2023 Guidelines, *supra* note 60; *see also* Henry Masur, *Recurring and Emerging Questions Related to Management of HIV-Related Opportunistic Infections*, 26 TOPICS IN ANTIVIRAL MED. 79, 79 (2018) ("[A] large number of patients remain at risk for OIs because they are diagnosed at late stages of HIV disease, fail to stay in treatment, or fail to maintain viral suppression."); Henry Masur, *HIV-Related Opportunistic Infections Are Still Relevant in 2015*, 23 TOPICS IN ANTIVIRAL MED. 116, 116 (2015) ("[T]he absolute number of patients with OIS and the rates of associated mortality remain high, particularly in large urban settings in the United States.").

[62] CDC 2023 Guidelines, *supra* note 60.

[63] CDC, Nat'l Ctr. for Health Statistics, National Vital Statistics Sys., Mortality 2018-2021 on CDC WONDER Online Database, https://wonder.cdc.gov/controller/saved/D158/D321F152 (queried on Jun. 22, 2023).

medication. Notwithstanding these advances in treatment, even well-controlled HIV disease presents increased risks of serious, life-threatening medical complications.

Despite its extraordinary efficacy in suppressing viral load, antiretroviral treatment unfortunately "does not fully restore immune health."[64] HIV is a disease of immune system dysregulation and chronic inflammation.[65] And even with antiretroviral treatment, this attendant immune dysregulation and chronic inflammation increases the risk of a myriad of complications, such as cardiovascular disease and cancers.[66] The multitude of comorbidities in people with HIV "suggests that increased lifespan ahead has not necessarily translated into optimal health span."[67] There remain negative health effects associated with antiretroviral-treated HIV.

For example, people with HIV are at higher risk than age-matched controls for all types of cardiovascular disease, including acute myocardial infarction (heart attack), heart failure, stroke, and arrhythmias.[68] In a comprehensive analysis involving over 27,000 people with HIV conducted by the Veterans Administration,

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[64] Steven G. Deeks et al., *The End of AIDS: HIV Infection as a Chronic Disease*, 382 Lancet 1525, 1525 (2013).

[65] *Id.*; Michael M. Lederman et al., *Residual Immune Dysregulation Syndrome in Treated HIV Infection*, 119 Advances in Immunology 51, 52 (2013).

[66] Deeks et al., *supra* note 64, at 1525-26; Lederman et al., *supra* note 65, at 52-55.

[67] Janice M. Leung, *HIV and Chronic Lung Disease*, 17 CURRENT OP. IN HIV & AIDS 1, 1 (2022).

[68] Revery P. Barnes et al., *HIV Infection and Risk of Cardiovascular Diseases Beyond Coronary Artery Disease*, 19 CURRENT ATHEROSCLEROSIS REPS. 1, 1 (2017).

patients with HIV, even those managing their HIV well, had nearly 1.5 times the risk of having a heart attack compared to HIV-negative individuals.[69] A meta-analysis of 24 studies showed that women with HIV have a six-fold higher risk of developing cervical cancer relative to their counterparts without HIV, and an estimated 5% of all cervical cancers are attributable to HIV.[70] The incidence of anal cancer in MSM with HIV is 80 times higher than men in the general population.[71] The risk for both chronic obstructive pulmonary disease and lung cancer remains significantly higher in people with HIV.[72] Both HIV disease and exposure to antiretroviral medication significantly increase the prevalence of diabetes mellitus in people with HIV.[73] The spectrum of additional health risks also includes liver disease, kidney disease, bone diseases such as osteoporosis and osteopenia, neurocognitive disorders, and

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[69] Matthew S. Freiberg et al., *HIV Infection and the Risk of Acute Myocardial Infarction*, 173 JAMA INTERNAL MED. 614, 614 (2013).

[70] Dominik Stelzle et al., *Estimates of the Global Burden of Cervical Cancer Associated with HIV*, 9 LANCET GLOB. HEALTH e161, e161 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7815633/.

[71] Chia-Ching J. Wang & Joel M. Palefsky, *HPV- Associated Anal Cancer in the HIV/AIDS Patient*, 177 HIV/AIDS-ASSOCIATED VIRAL ONCOGENESIS: CANCER TREATMENT & RSCH. 183, 194 (2018).

[72] Leung, *supra* note 67, at 1; Keith Sigel et al., *Lung Cancer in Persons with HIV*, 12 CURRENT OP. IN HIV & AIDS 31, 31 (2017).

[73] Fanta Duguma et al., *Diabetes Mellitus and Associated Factors Among Adult HIV Patients on Highly Active Anti-Retroviral Treatment*, 12 HIV/AIDS – RSCH & PALLIATIVE CARE 657, 658 (2020), https://www.dovepress.com/getfile.php?fileID=63352; Emile Camille Noubissi et al., *Diabetes and HIV*, 18 CURRENT DIABETES REPS. 1, 1 (2018).

additional non-AIDS related cancers such as Hodgkin's lymphoma.[74] Given the varied medical complications that result from an HIV infection, prevention in the first instance is essential.

d. People with HIV Live with a Highly Stigmatized and Feared Health Condition.

The deeply rooted stigma directed at people with HIV, and the self-stigmatization that follows, persists today and harms both the individuals and public health.[75] Although somewhat improved compared to past decades, the stigma remains evident. In a 2019 Kaiser Family Foundation survey, thirty-seven percent of respondents reported that they would be somewhat or very uncomfortable sharing a living space with someone who has HIV.[76] One in five respondents reported that they would be somewhat or very uncomfortable either working with or having a close friendship with a person with HIV.[77] Four decades after the onset of the HIV

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[74] Deeks et al., *supra* note 64, at 1526-27; Leung, *supra* note 67, at 1; Lederman et al., *supra* note 65, at 52.

[75] "Stigma is an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable." White House Office of National AIDS Policy: National HIV/AIDS Strategy for the United States: Updated to 2020 (July 2015) at 41; *see also, e.g.*, Marc A. Pitasi et al., *Stigmatizing Attitudes Toward People Living with HIV Among Adults and Adolescents in the United States*, 22 HIV & BEHAV. 3887, 3890 (2018) ("Nearly 1 in 5 adults and 1 in 3 adolescents reported fear of" people with HIV.).

[76] Kaiser Fam. Found., *KFF Health Tracking Poll – March 2019* 15 (2019), https://files.kff.org/attachment/Topline-KFF-Health-Tracking-Poll-March-2019.

[77] *Id.*

epidemic, most people with HIV struggle with the fear that others will learn their HIV status.[78]

HIV-related stigma continues to be fueled by lingering ignorance about the nature and risk of HIV transmission. For example, a 2017 Kaiser Family Foundation survey found that "[m]ore than a third incorrectly believe HIV can be spread through everyday items, such as plates and glasses (38%) or toilets (38%)."[79] And, "[m]ajorities are misinformed in thinking HIV can be transmitted by spitting (54%) or kissing (58%)."[80]

HIV-related stigma creates both individual and societal harm. The "[c]onsequences of HIV stigma . . . include higher levels of depression . . . problematic alcohol use" and other "maladaptive forms of coping" which "translate to poorer . . . disease progression [and] greater health burden."[81] The impact of HIV-

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[78] *See* Amy R. Baugher, et al., *Prevalence of Internalized HIV-Related Stigma Among HIV-Infected Adults in Care, United States, 2011-2013*, AIDS BEHAV. 2600, 2605 (2017). ("Almost two-thirds [of people receiving HIV care in the United States] said that it was difficult to tell others about their HIV infection."). HIV-related stigma can be made more complicated by other stigmas. Researchers working for the CDC have shown through survey data that "[o]verall, women and transgender persons had higher stigma scores than men and, compared to non-Hispanic whites, all other racial/ethnic groups had higher stigma scores." *Id.*

[79] Kaiser Fam. Found., *National Survey of Young Adults on HIV/AIDS* 2 (2017), https://files.kff.org/attachment/Report-National-Survey-of-Young-Adults-on-HIV/AIDS.

[80] *Id.*

[81] Kaylee B. Crockett et al., *Experiences of HIV-Related Discrimination and Consequences for Internalised Stigma, Depression, and Alcohol Use*, 34 PSYCH. HEALTH 1, 2, 8, 9 (2019).

related stigma also results in poorer adherence to treatment.[82] Lack of adherence to antiretroviral medication not only undermines individual health, but also leads to higher viral replication and an increased risk of transmitting HIV to sexual partners.[83] The damaging physical and psychological consequences of HIV-related stigma further underscore the urgent need to continue working towards reducing the number of people who contract HIV, which will be nearly impossible should the District Court's decision stand.

CONCLUSION

The AIDS Memorial Quilt contains 110,000 panels, each panel commemorating one of the over 700,000 Americans who have lost their lives in this epidemic. As one woman reflected about a panel she sewed for a friend who died in 1984: "The saddest thing, I believe, for Roger Lyon . . . was how unfair it was to have to die without knowing how it—AIDS—is all going to end."[84] PrEP is a vital biomedical tool that stops the spread of HIV. In reviewing the District Court's injunction, this Court should take account of the four decades of advances aimed at bringing this epidemic to a close.

[82] *Id.* at 9.
[83] *See supra* Section I.
[84] Cindy Ruskin, The Quilt: Stories from the NAMES Project, 34-35 (Pocket Books 1988).

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CERTIFICATE OF SERVICE

I hereby certify that on June 27, 2023, a true and correct copy of the foregoing Brief for Amici Curiae were served via electronic filing with the Clerk of Court and all registered ECF users.

Upon acceptance by the Court of the e-filed document, 7 paper copies will be filed with the Court within the time provided in the Court's rules via Federal Express.

Dated: June 27, 2023

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This brief has been prepared using 14-point, proportionately spaced, serif typeface, in Microsoft Word. Excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), this brief contains 6,480 words.

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