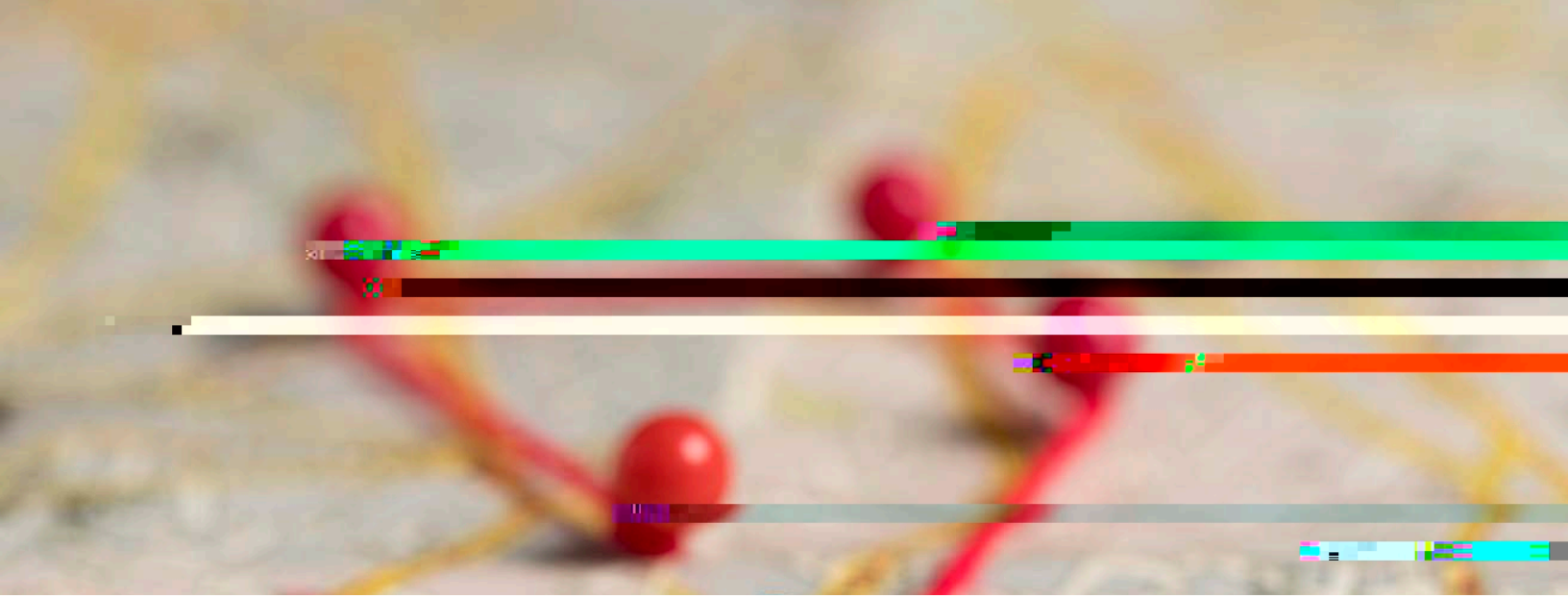

ACT NOW: END AIDS i a na ional coali ion of comm ni -ba ed o gani a ion , heal h depa men , and na ional o gani a ion commi ed o ending AIDS a an epidemic in he Uni ed S a e . The coali ion ho lea ning collabo a i e o ha e ke p ac ice ; o k o ha e Ending he Epidemic (E E) become pa of he na ional di co e i h ke deci ion make ; and ppo heal h depa men ac o he co n i h echnical a i ance

the pandemic has, and may continue to have, an impact on C dimpact on 1xx38.2CIDvehavct ntincaxx37.8CID for yearsan icor

who see far more investment in law enforcement than they do in public health, education, housing, and other services that have been shown to positively affect health outcomes, including reducing the incidence of HIV. Calls have even been made for the Centers for Disease Control and Prevention (CDC) and other public health entities to officially declare racism a public health issue and take steps to address the ways white supremacy adversely impacts the lives of Black, Latinx, Native American/Indigenous, Middle Eastern, and Asian-Pacific Islander communities. But with an administration that has actively courted favor with white nationalist groups, any efforts by public health agencies and researchers to educate impacted communities on the positive role that biomedicine can play in addressing disparities have become increasingly complicated. In short, a confusing and uncoordinated COVID-19 response (that disproportionately impacted Black, Latinx, and Native American communities) combined with the apparent impunity of law enforcement to kill Black citizens has undermined trust in the government and made ending the HIV epidemic even more challenging.

Despite these emerging challenges, the United States no has the tools and capabilit to end the HIV epidemic at home. COVID-19 has presented us ith an opportunit to address the longstanding problems in our healthcare s stem and public health infrastructure that have made ending HIV as an epidemic elusive for man ears. Facing these s stemic challenges to end the COVID-19 pandemic ould support our efforts to end the HIV epidemic. Improving our HIV prevention, treatment, and care infrastructure ma also support efforts to end COVID-19 as a pandemic. We must also urgentl seek to eliminate the related s ndemics of opioid use, viral hepatitis, STIs, and TB. The undersigned call on the U.S. government to further scale-up resources and enact ne legislative and regulator changes to achieve the goal of ending the HIV epidemic in the United States b 2025 as laid out b the Department of Health & Human Services (HHS) in 2019.

Though there is no vaccine or cure, highly effective antiretroviral therapy, taken as treatment or prevention, provides a means to end our HIV epidemic by dramatically reducing new HIV cases, ending AIDS deaths, and eliminating disparities in access to quality HIV prevention and treatment. We now know that for people living with HIV, retention in HIV treatment that suppresses viral load to an undetectable level both sustains optimal individual health and eliminates the risk of sexual transmission of the virus. Successful HIV prevention for HIV-negative individuals is available through a combination of sexual health education, routine HIV screening, wide-scale access to both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for those who need it, and syringe access and other harm reduction services. Comprehensive insurance coverage of these interventions is also an essential preventive health care service.

Calls have even been made for the Centers for Disease Control and Prevention (CDC)... to o cially declare racism a public health issue.

U.S. innovation and leadership on HIV have laid the foundation for decisive action to end the epidemic. Numerous federal government departments, agencies, and programs are involved in the domestic HIV/AIDS response; together they provide disease surveillance, prevention, care, support services, and research. The Centers for Disease Control and Prevention (CDC) leads U.S. surveillance and prevention activities, which are carried out in conjunction with state and local health departments and community-based organizations (CBOs). Federal health care programs including Medicaid, Medicare, the Ryan White HIV/AIDS Program, Community Health Centers, and the Veterans Administration provide care, treatment, and supportive services. The Housing Opportunities for Persons with AIDS (HOPWA) program, as well as other safety net services available through the Department of Housing and Urban Development (HUD), provides essential access to affordable housing for low-income people living with, affected by, or made vulnerable to HIV by an unequal distribution of resources and systemic gaps in access to health care services. The Social Security Administration's income programs for those who are disabled—Supplemental Security Income (SSI) and Social Security Disability Insurance (SSDI)—are important sources of support and financial stability. The passage of the Patient Protection and Affordable Care Act (ACA) in March 2010 provided new opportunities for expanding health care access, prevention, and treatment services for millions of people in the U.S., including many people living with or vulnerable to HIV, while also offering key nondiscrimination efforts.

A variety of other departments and programs also play key roles in this work. The Departments of Justice Civil Rights Division, Education, Labor, Transportation, Defense, Agriculture, the Bureau of Prisons, and others all have crucial roles to play in ending new HIV transmissions in the U.S. and supporting the health of people living with HIV.

We can change the trajectory of the U.S. HIV epidemic by setting and meeting the ambitious but achievable goal of reaching a 95/95/95 framework for HIV care (95 percent of people living with HIV are aware of their HIV status, 95 percent of diagnosed individuals are retained in care, and 95 percent of individuals on antiretroviral therapy are virally suppressed), significantly increasing access to combination prevention for people who are HIV negative and taking concrete action to ensure that no population or region is left behind. But we must bring all available treatment and prevention tools to scale now to have the necessary impact on the epidemic. Failure to act swiftly at the required scale and across all affected communities and populations will result in more HIV transmissions, more HIV-related morbidity and mortality, continued health inequities, and increased health care costs.

Through the joint effort of community, all levels of government, and industry, we can harness the progress made over the last three decades to achieve a once unthinkable goal. Experience and research show us that a focus on the six pillars detailed below will provide the guidance, framework, and direction needed to drastically reduce new HIV cases, improve the length and quality of the lives of people living with HIV, and effectively address the related opioid, viral hepatitis, STI, and TB syndemics. In doing so, we can dramatically reduce overall costs in both lives and health care dollars.

Pillar 1: Commit to End the U.S. HIV Epidemic and Eliminate HIV Health Disparities

To end the U.S. HIV epidemic, we must use all the powerful tools available, hold ourselves accountable for results, and ensure that no person or community is left behind.

Set Public Health Goals to End the U.S. HIV Epidemic by 2025

Experience has demonstrated that time-bound public health goals drive progress, promote accountability, and unite stakeholders. We must set and meet benchmarks, modernize our national HIV surveillance system, and develop a real-time dashboard of key metrics to track the epidemic, gauge our progress, and better prioritize resources, if we are going to end the U.S. HIV epidemic.

Mathematical modeling, detailed starting on page 7 of this Roadmap, indicates that achieving the 95/95/95 HIV care framework by the year 2025, coupled with PrEP scale-up, will significantly reduce HIV incidence and prevalence in the U.S.

Compared with the scenario of simply continuing current efforts:

- Achieving the 95/95/95 care framework and 40 percent PrEP coverage by the year 2025 would have the greatest impact on HIV incidence and prevalence, reducing the number of new HIV cases occurring during the years 2019 to 2030 by approximately 353,000 persons.
- Achieving the 95/95/95 framework by the year 2030 would reduce the number of new HIV cases occurring during the years 2019 to 2030 by approximately 210,500 persons. Increasing uptake of PrEP to achieve 40 percent coverage of persons vulnerable to HIV would further amplify these gains, bringing the total of averted new HIV cases between now and 2030 to 292,500 persons.

Additional resources will be required to achieve these programmatic service delivery goals. Without such rapid scale-up, however, the U.S. HIV epidemic will continue to outrun the response, increasing the long-term need

covers 52 percent of all people living with HIV in the U.S., and, as a non-insurance payer of last resort, fills in payment gaps for people living with HIV who are also enrolled in Medicaid, Medicare, and/or private insurance.

In terms of federal expenditures, Medicare is the largest federal funder of HIV care and treatment at $10 billion per year, followed by Medicaid at $5.9 billion, and then the Ryan White HIV/AIDS Program at $2.3 billion. Further, Medicaid expansion and private insurance reforms under the ACA have allowed tens of thousands of people living with and vulnerable to HIV to access comprehensive, affordable coverage for the first time. The commitment to and innovative use of state and local resources to fill gaps and cover costs excluded by federal funding streams is also vital.

Sustain and Expand Vital Health Insurance Programs

Equitable, sustained access to adequate health coverage is the fundamental building block for ending the U.S. HIV epidemic:

- Medicaid is the largest source of insurance coverage for people with HIV, estimated to cover more than 40 percent of people with HIV in care.3 Expanded and sustained access to Medicaid coverage across the country, as defined by the ACA, must be a top priority if we are to end HIV as an epidemic. This means protecting and expanding Medicaid as a health care safety net program in every state, ensuring the stability of the Medicaid program, and rejecting state proposals that would harm people living with HIV, such as rolling back benefits, restricting access for lifesaving medications, imposing work requirements as a condition of continued coverage, or requiring additional cost-sharing beyond the federal limits on low-income beneficiaries.
- The Medicare program is also a critical resource for ending the epidemic, covering 20 percent of people living with HIV in care. Most people with HIV on Medicare are under age 65 and qualify as disabled beneficiaries, and a significantly higher percentage of them are dually-eligible for Medicaid than in the overall Medicare population. With the implementation of the Medicare Part D prescription drug benefit in 2006, Medicare assumed an even more critical role for people living with HIV: Seventy-seven percent of Medicare beneficiaries living with HIV qualify for Part D prescription drug subsidies.
- The ACA's consumer protections that include prohibiting insurers from denying coverage due to pre-existing conditions, premium setting based on community rating, nondiscrimination protections, guaranteed coverage of essential health benefits, premium and cost-sharing assistance, and annual caps on out-of-pocket costs are all critical to improving access to health care coverage and services for people with HIV and must be maintained.
- Ensuring that people living with HIV can get the care their doctors prescribe requires that all public and private health insurance plans include consumer protections for pres[seven per)ting

- Support implementation of innovative care delivery and payment models through state Medicaid programs, such as coordinated, integrated patient-centered health care programs, incentivize Medicaid programs to enter into data-sharing agreements with state and local departments of health, and require Medicaid programs to adopt HIV viral load suppression performance measures.
- Eliminate the 29-month waiting period before SSDI recipients can obtain Medicare benefits.
- Maintain in the Medicare Part D Formulary an "all drugs, all classes" rule for FDA-approved antiretroviral drugs.
- Extend Medicaid drug rebates to Medicare plans covering dually-eligible, low-income beneficiaries.
- Direct the Center for Medicare deputy administrator to ensure that beneficiaries have access to and a choice of providers, including pharmacies, and prohibit Part D plans from changing pharmacy networks mid-year to ensure continuity of care and treatment.
- Take all necessary legislative action to ensure that the ACA continues in full, including the nondiscrimination protections, and to stabilize the ACA insurance marketplace with sufficient funding for enrollment and marketing activities.

Enhance the Ryan White HIV/AIDS Program

The federal Ryan White HIV/AIDS Program provides comprehensive services for the most vulnerable people living with HIV in the U.S. Almost two-thirds of Ryan White Program participants are living at or below 100 percent of the Federal Poverty Level (FPL), and over 90 percent are living at or below 250 percent of the FPL. Racial and ethnic minorities in every congressional district make up nearly three-quarters of Ryan White Program participants.

About 80 percent of all Ryan White Program participants are covered by some form of health care insurance, including about half who are covered by Medicaid and/or Medicare. However, public and private insurance programs do not always provide the comprehensive array of services required to meet the needs of people living with HIV. These include case management, mental health and substance use treatment, adult dental services, and transportation, legal, and nutritional support services.

About 80 percent of all Ryan White Program participants are covered by some form of health care insurance, including about half who are covered by Medicaid and/or Medicare.

The Ryan White Program, particularly the AIDS Drug Assistance Program, assists with these costs so that low-income people living with HIV can access comprehensive and effective medical care and treatment. To improve the continuum of care and progress toward an end to the U.S. epidemic, continued and enhanced funding for all parts of the Ryan White Program is crucial. Robust funding for the Ryan White Program is particularly important to fill gaps in health coverage for people with HIV in jurisdictions that have not expanded Medicaid, such as several states in the U.S. South.

Recommendations for action:

- Increase funding for the Ryan White Program consistent with a growing epidemic and need, ensuring that the program's funding formulas and structure support integrated efforts to end the HIV epidemic.
- Allow Ryan White Program-funded clinics access to health center reimbursement mechanisms under Medicaid.
- Create flexibility under program income guidance to ensure critical support for HIV services.
- Reduce renewal of benefits paperwork and, with new resources, train and hire more HIV care providers to reduce delays in linkage to care/ARV prescription.

Protect the 340B Drug Pricing Program

Similarly, since 1992 the 340B Drug Pricing Program has provided critical support for HIV services and extends care to many who otherwise would go without. Savings from 340B allow covered entities, including AIDS service organizations, to increase health care services and capacity in their communities, offering more health care delivery locations and hours of operation and an expert workforce. Thanks to the savings covered entities earn through the 340B program, Americans living with and vulnerable to HIV benefit from lifesaving treatment, preventive health care, substance use and mental health services, and chronic disease management.

Recommendation for action:

- Maintain the 340B Program to ensure critical support for HIV services.

Adopt National Strategies to Eliminate Viral Hepatitis, STIs, and Tuberculosis

Sustaining the health of people with and at risk of HIV also requires concrete action to stop the worsening syndemics of viral hepatitis and tuberculosis (TB). People living with HIV are disproportionately affected by viral hepatitis—about one-third are coinfected with either hepatitis B virus (HBV) or hepatitis C virus (HCV)—and HIV coinfection more than triples the risk of liver disease, liver failure, and liver-related death from HCV. With new highly effective curative treatments for HCV and treatment and a vaccine for HBV, we have the means to eliminate viral hepatitis as a public health threat in the United States. The risk of developing TB from latent infection is also significantly increased for people living with HIV, and TB is the leading cause of death for people living with HIV globally. Decades of declines in federal and state funding for TB prevention and control have led to the deterioration of public health infrastructure and limited the capacity of TB programs to provide prevention, treatment, and monitoring efforts and to prevent and respond to outbreaks, especially to emerging drug-resistant strains. TB is preventable, treatable, and curable, but putting the U.S. back on the track of TB elimination will require national leadership, resources, and political will.

People living with HIV are disproportionately a ected by viral hepatitis... and HIV coinfection more than triples the risk of liver disease, liver failure, and liver-related death.

Recommendations for action:

- Fully implement and resource the National Viral Hepatitis Action Plan 2017–2020 and establish, implement, and resource the Viral Hepatitis National Strategic Plan 2021–2025.
- Support local, state, and national TB elimination efforts, including implementing and resourcing the National Action Plan to Combat Multidrug-Resistant TB.
- Fully implement and resource the Sexually Transmitted Infections National Strategic Plan for the U.S. 2021–2025.

Pillar 3: Prevent Ne HIV Transmissions

While we work to diagnose and treat all Americans living with HIV, we also must work to prevent exposure. We know that biomedical, behavioral, and structural interventions used in concert can successfully and significantly reduce HIV transmission. Routine and voluntary universal HIV testing is a gateway to HIV prevention for those who test negative; effective treatment for people living with HIV suppresses viral load to undetectable levels,

eliminating sexual transmission. Both groups benefit from interventions to address behavioral and structural factors that increase the risk of acquiring and transmitting HIV.

However, there are still an estimated 40,000 new cases in the U.S. each year, and while rates of new cases are declining in some communities, there are increases or no change in communities where resources for prevention and care are limited. The Southern U.S. is particularly affected, accounting for over 50 percent of the estimated new cases while representing only 37 percent of the U.S. population.

Reduce New HIV Cases Through Evidgdsé-Bsesd Combnatinn)V CPevention

Stop the Opioid, Injection Drug, and Crystal Meth Use Crises

The overdose crisis and attendant increases in injection drug use are driving a significant increase in the rate of new viral hepatitis infections and threatening to reverse the substantial gains since 1990 in reducing HIV rates among people who inject drugs. In addition, many jurisdictions around the country have reported spikes in methamphetamine use. Community-based harm reduction, overdose prevention, and syringe services programs have consistently demonstrated the greatest impact and are the most cost-effective interventions available to reverse the overdose and infectious disease crises devastating our communities. Widespread, free, and low-barrier access to all forms of Medication Assisted Treatment (MAT) for those who seek it must be a critical component of federal, state, and local strategies to address the opioid epidemic.

Recommendation for action:

- Develop, implement, and resource a National Harm Reduction Strategy with particular focus on overdose and infectious disease prevention (recommendations are detailed in this Roadmap starting on page 58), ending criminalization and promoting the rights and dignity of people who use drugs (recommendations are detailed in this Roadmap starting on page 61), and structural interventions and social determinants of health (recommendations are detailed in this Roadmap starting on page 63).

Reduce the Syndemic of Sexually Transmitted Infections

The U.S. is experiencing a historic rise in rates of sexually transmitted infections (STIs)—another indication of a

Pillar 4: Address Social and Structural Barriers to Effective HIV Prevention and Care

Biomedical treatment and prevention alone will not end the U.S. HIV epidemic. Structural factors including poverty, discrimination, lack of employment and educational opportunities, housing and food insecurity, untreated or undertreated mental health and substance use challenges, and limited transportation infrastructure contribute to poor health outcomes. Other structural contributors to the U.S. HIV epidemic include the criminalization of HIV nondisclosure, exposure, and/or transmission, nonviolent drug violations, and adult consensual sex work; interpersonal violence; the burden of disproportionate incarceration and entanglement with the criminal justice system for young men of color and transgender persons; and barriers to prevention and care services for new immigrants. For many persons living with or vulnerable to HIV, successful prevention and care requires culturally competent services to address these barriers, and evidence demonstrates that interventions to ensure adequate housing, food, transportation, and other critical enablers of health care are both essential and cost-effective.

Ensure Availability of Essential Services That Support Health, Prevention, and Retention in Care and That These Services Integrate the Innovations That Resulted from COVID-19

The federal government has a unique opportunity and responsibility to expand efforts to assure availability of essential services that support health, HIV prevention, and retention in care, including programs that address poverty, unemployment, criminal justice involvement, and other social factors that drive the ongoing U.S. HIV epidemic, as well as programs and supports that address homelessness, hunger, and other unmet subsistence needs that are powerful barriers to effective HIV care and treatment.

This includes the need to address disparities in health care and other structural drivers of the HIV epidemic across U.S. regions and communities.

Additionally, the innovation to HIV treatment and care that was introduced as a result of COVID-19 must continue to evolve even after the pandemic is under control. This includes increased and uninterrupted access to telemedicine, greater supplies of prevention or treatment medication, swifter prescription refill times, syringe exchange, as well as HIV prevention/treatment medication delivery.

Recommendations for action:

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Provide Federal Leadership to End HIV Criminalization

Laws that criminalize HIV exposure, non-disclosure, transmission, and behaviors that can transmit HIV, despite evidence that this does not impact HIV transmission, are systemic structural barriers that create stigma and discrimination and infringe on the civil rights of people living with HIV.

It is time to eliminate HIV-specific and -related laws that are outdated, do not reflect current scientific understanding, and are at odds with well-tested and effective public health strategies.

It is time to eliminate HIV-specific and -related laws that are outdated, do not reflect current scientific understanding, and are at odds with well-tested and e ective public health strategies.

Recommendations for action:

- Support and pass legislation to end HIV criminalization via the REPEAL (Repeal Existing Policies that Encourage and Allow Legal) HIV Discrimination Act.
- Decriminalize sex work.
- Repeal the Stop Enabling Sex Traffickers Act (SESTA) and the Allow States and Victims to Fight Online Sex Trafficking Act (FOSTA) and pass anti-trafficking legislation that does not conflate human trafficking with consensual adult sex work.
- With community input, review the uses of HIV molecular surveillance and the research on its efficacy in helping reduce transmissions, and create and publish guidelines restricting the access local, state, and federal policing and law enforcement agencies have to said data.

Pillar 5: Maintain U.S. Leadership in Lifesaving Research

In the last four decades, HIV/AIDS research has been responsible for the dramatic transformation of HIV from a uniformly fatal diagnosis to one that can be managed over a near-normal lifespan. Innovations such as highly effective antiretroviral therapy and PrEP combined with strategies to address health disparities and structural drivers give us the tools to bring HIV below epidemic levels in the U.S. However, additional research advances will support maximizing the implementation of existing tools and developing new modalities to sustainably end the HIV epidemic in the U.S. and worldwide.

As such, a robust research agenda is an indispensable part of our ability to end the domestic and global epidemics. The federal government must support groundbreaking research within the National Institutes of Health and other publicly-funded research bodies to develop a preventive vaccine, microbicides, a cure for HIV, new HIV treatments, new approaches to PrEP, and implementation science to support scaling up treatment and prevention, including by addressing co-morbidities and related health disparities.

Recommendations for action:

- Make sustained, multi-year increases to HIV/AIDS biomedical research in line with reaching the Office AIDS Research (OARs) annual Professional Judgement Budget recommendations.
- Increase resources for other HIV/AIDS research activities, including implementation science, across all levels of government; leverage the Centers for AIDS Research (CFAR) national network to enhance collaboration with local AIDS service organizations and community-based organizations to support implementation science within communities; and continue existing HIV research cohorts.

- Expand ethical research on treatment, prevention needs, and implementation among vulnerable populations such as youth, people of color, pregnant and lactating women, people of trans experience, and people who use drugs.
- Establish a federally-supported Structural Interventions Research Committee within the Office of AIDS Research to advance coordination, communication, and furthering of cross-government research.
- Use existing mechanisms to recruit and train new HIV investigators, especially from the most impacted and underrepresented communities.

Pillar 6: Support the Meaningful Involvement of People Living ith and Vulnerable to HIV

No complex health crisis can be resolved without the leadership of affected communities and centering vulnerable individuals within the heart of the response.

The communities and constituencies affected by HIV/AIDS across the United States, Puerto Rico, U.S. Virgin Islands, and all other territories include people living with HIV/AIDS, people of color, transgender and cisgender women and men, queer-identified and gender nonconforming individuals, sex workers, immigrants with and without documentation, people in U.S. jails, prisons, and immigration detention centers, people who use drugs, people living with mental health challenges, people living with physical and intellectual disabilities, people of all religious practices, all languages, all ages, and in all regions. Many daily confront stigma, transphobia, homophobia, unemployment, economic and food insecurity, homelessness, lack of health care, violence, discrimination, criminalization, racism and whitein .8ro

Conclusion

We have made substantial progress in responding to the HIV epidemic. At the beginning of the epidemic, no one could have predicted the incredible success of antiretroviral medications that today permit people with HIV to live healthy, productive, and long lives. In the last decade, the U.S. has created and implemented the first National HIV/AIDS Strategy, launched a federal End the HIV Epidemic plan, developed antiretroviral prevention