

Treatment Action Group Testimony to United States Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for Fiscal Year 2022 Appropriations

Organization: Treatment Action Group

Prepared for: Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies

Agency: Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention

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June 24, 2021

Treatment Action Group (TAG) thanks the esteemed members of the subcommittee for the opportunity to submit testimony regarding funding for the government's End the HIV Epidemic (EHE) at the U.S. Centers for Disease Control (CDC) Division for HIV Prevention (DHAP) for fiscal year 2022 (FY22) appropriations. TAG is an independent, activist, and community-based research and policy think tank committed to racial, gender, and LGBTQ+ equity; social justice; and liberation, fighting to end HIV, tuberculosis (TB), and hepatitis C virus (HCV). We work closely with community partners and stakeholders in the jurisdictions funded by the federal government's EHE initiative towards an inclusive, community-centered approach to end the HIV epidemic across our country.

TAG requests that the Subcommittee exceed the President's budget proposal for the CDC EHE initiative of an \$100 million increase in FY22 with an additional increase of \$96 million to a total of \$196 million for DHAP ETE. In particular these resources would be critical to expand EHE efforts, advance and expand vital community partnership activities, and mitigate the impact of the COVID-19 pandemic among the hardest-hit jurisdictions.

While there has been immense progress in the HIV epidemic with rates declining from 37,500 new infections in 2015 to 34,800 infections in 2019 – much work remains on truly ending the epidemic in the hardest-hit jurisdictions and populations in the U.S.ⁱ HIV rates are not evenly distributed across the nation and continue to be primarily skewed towards the Southern states as the bulk of new diagnosesⁱⁱ. Even more concerning, HIV disparities continue to severely persist among the Black and Latinx communities. We see these troublesome trends particularly among Black and Latinx gay and bisexual men, as well as Black women. Black communities represent 13% of the U.S. population, but make up 44% of new diagnoses.ⁱⁱⁱ Similarly, Latinx communities

represent 18% of the U.S. population and account for 30% of new HIV diagnoses.^{iv} HIV comparably disparages Native American community, people of trans experience, and people who use drugs with stark disparities.

It is of no surprise that social determinants of health deeply impact these communities. These include housing, food security, employment and economic justice, as well as undoing numerous policies that violate the human rights of these communities and limit their ability to seek treatment and care. Criminalization for example is intertwined with the HIV epidemic, with many states continuing to have arcane laws that do not align with science and only further stigmatize communities of people living with, and vulnerable to HIV. Without addressing the myriad of social, economic and legal needs of communities impacted by HIV through a combination of targeted resources and a human-rights policies, reaching the vision for ending the epidemic across all communities will remain unclear and unattainable.

The previous administration ambitiously approached this challenge of ending the HIV epidemic once and for all, by redoubling U.S. efforts and formulating the landmark EHE initiative that would direct federal resources towards 57 jurisdictions hardest-hit by HIV through CDC and HRSA. While Congress, has responded in lockstep with bipartisan increases to EHE since its inception, we believe that the COVID-19 pandemic has significantly impacted efforts at the community-level, requiring a significant scale up in assistance to these jurisdictions.

Organizations and partners involved in the ACT NOW:END AIDS coalition– of which TAG is a cofounder– report significant impact upon services and outreach efforts to communities impacted by HIV. The lack of swift and robust federal guidance on COVID-19 to HIV organizations in the early stages of the pandemic led to many organizations having to decide between either risking the safety of their staff by continuing essential services, or temporarily closing programs. Additionally, many already financially strained organizations struggled to obtain the technologies necessary for telemedicine and many reported that clients- especially low-income, and unstably housing individuals- could not access these tools. Such delays led to clients missing care and contributed to an overall sense of burnout among HIV professionals.

In addition to the direct impact upon services for PLHIV and communities vulnerable to HIV, we have noted a significant shift in human resources and public health personnel detailed to the COVID-19 pandemic. CDC HIV program staff are also contributing significantly to the nation's COVID-19 response. The pandemic has caused severe disruptions to care and treatment activities of the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP). According to research from the Kaiser Family Foundation, nearly 700 CDC staff (with 1,125 cumulative deployments) from NCHHSTP have been detailed and deployed to the COVID response since the early days of the pandemic.^v This is primarily due to the Center staff's expertise in infectious diseases. HIV public health practitioners from the CDC are drawn upon for the COVID-19 pandemic, primarily for their expertise in centering communities in prevention efforts and their ability to form key relationships, conduct outreach, while grounding public health prevention work in respect for human rights. However, scarce public health resources and personnel corresponds to a shift away from EHE efforts.

Furthermore, HIV community contributions to the COVID-19 response have been significantly extended through HIV/AIDS research investments at the National Institutes of Health (NIH) as well. For example, HIV research first piloted the use of mRNA as a vaccine platform for HIV prevention. These previous investments in HIV vaccine research boosted the development of widely disseminated COVID-19 vaccines that increasingly leveraged the well-developed research infrastructure of HIV research.^{vi}

In sum, the programmatic and research contributions of HIV have been invaluable to the nation's COVID-19 response. But the shift in HIV sector resources leaves EHE efforts in peril and limited in reaching its ambitious goals for treatment and prevention of HIV. Due to our weakened public health infrastructure that COVID-19 leaves in its wake, without significantly targeted and expanded resources, HIV disparities will continue to be deeply entrenched in our nation's historically disenfranchised and marginalized communities. We urge the subcommittee to maximize resources to backfill the contributions of the HIV sector and launch our HIV response with the same level of vigor that we saw with the COVID-19.

To that end, we request an allocation of at least \$196 million in FY22 for CDC DHAP EHE Plan to begin to align the necessary resources to mitigate the effects of COVID-19 upon struggling HIV programs and shore-up the necessary HIV infrastructure. We applaud the administration's and Congressional attention towards rooting out systemic racism, and believe that these investments will go a long way to begin addressing HIV as health disparity that primarily affects communities of color.

Thank you for the members of the subcommittee for this opportunity to submit testimony in support of CDC DHAP ETE initiative. We hope you will take action and recommit to realizing the end of the HIV epidemic with urgent, new resources.

ⁱ Health Resource and Services Administration. HIV Data and Trends. HIV.gov. <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>

ⁱⁱ Ibid

ⁱⁱⁱ U.S. Centers for Disease Control and Prevention. Racial and Ethnic HIV Rates – African Americans and Hispanic/Latinos. Division of HIV/AIDS Prevention. <https://www.cdc.gov/hiv/group/raciaethnic/africanamericans/index.html>

^{iv} Ibid

^v Dawson L, Kates J. Issue Brief: Key Questions on HIV and COVID-19. Kaiser Family Foundation. 20 May 2021. <https://www.kff.org/coronavirus-covid-19/issue-brief/key-questions-hiv-and-covid-19/>

^{vi} Chibbaro L. HIV Research Sped the Develop of the COVID-19 Vaccine. Washington Blade. 23 June 2021 <https://www.washingtonblade.com/2021/06/23/hiv-research-sped-development-of-covid-vaccine/>

Treatment Action Group Testimony to United States Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for Fiscal Year 2022 Appropriations

Organization: Treatment Action Group

Prepared for: Senate Subcommittee on Labor, Health and Human Services, Education and Related Agencies

Agency: Department of Health and Human Services, U.S. Centers for Disease Control and Prevention, Division of Tuberculosis Elimination

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June 24, 2021

Treatment Action Group (TAG) thanks the esteemed members of the subcommittee for the opportunity to submit testimony regarding funding for the U.S. Centers for Disease Control and Prevention (CDC) Division of Tuberculosis Elimination (DTBE) for fiscal year 2022 (FY22) appropriations. TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis (TB), and hepatitis C virus (HCV). TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. **Together with a broad coalition of stakeholders in the TB advocacy community, TAG requests that the Subcommittee appropriate \$225 million to CDC DTBE for FY22, in particular to expand critical TB research activities at the TB Trials Consortium (TBTC) and mitigate the impact of the COVID-19 pandemic on struggling TB programs across our country.**

TAG works in close partnership with TB program practitioners and researchers across the country to advance the collective goal of eliminating TB through comprehensive, safe, and effective TB prevention and treatment. TB cases continue to be reported in every state in the United States (US) every year, with 8,916 cases reported in 2019.ⁱ It is estimated that approximately 13 million people in the US are currently living with latent TB infection, which can progress to active and contagious disease if left untreated.ⁱⁱ TB trends in the US are also influenced by many of the same social determinants of health that determine other health disparities – including poverty, lack of access to healthcare, overcrowded housing and homelessness, and other structural factors.ⁱⁱⁱ This leaves many of the most vulnerable and marginalized members of our society at greater risk of being exposed to TB and developing active disease.

The state and local TB programs that are on the frontlines of preventing and treating TB are engaged in critical work, and they rely on the support of the CDC DTBE for guidance and funding. One important way DTBE supports state and local TB programs is through its research initiatives, including the TBTC. Housed within DTBE, the TBTC is a unique partnership between CDC, health departments, academic research institutions, and trial sites throughout the US and across the globe.^{iv} TBTC's research is mandated to be programmatically relevant to health departments, meaning that investments in this research network are some of the most cost-effective of any federal research program. Tax payers' investments in the work of the TBTC have supported dozens of studies of critical import to advancing the field and improving TB treatment and prevention for people and communities affected by TB at home and abroad.

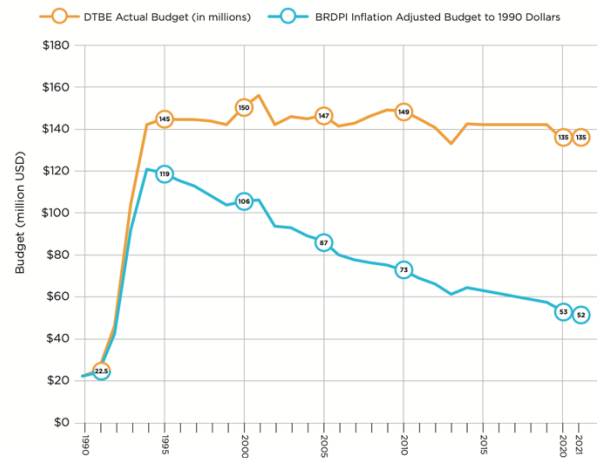
This research is sorely needed to advance more tolerable and effective options for TB prevention and treatment. Current treatment guidelines for drug-sensitive TB have been the same for almost four decades, leaving programs and patients reliant on a regimen made up of four drugs taken for 6–9 months requiring long periods of isolation and management of difficult side effects necessitating intensive treatment monitoring. However, promising results from a pivotal phase III trial, TBTC's Study 31 demonstrated that a different combination of medicines enables treatment for drug-sensitive TB to be shortened to just four months without compromising any efficacy.^v This groundbreaking finding has the potential to dramatically improve rates of treatment completion, drive down TB transmission, and allow TB patients to return to their loved ones and support themselves more quickly than ever before.^{vi} Study 31 and prior TBTC research at DTBE has had profound global health security implications, where TB was the world's leading cause of death to an infectious disease prior to COVID-19. Research at CDC's TBTC has been the basis for public health treatment and prevention guidelines developed by the World Health Organization (WHO) that are critical for country TB programs where TB is particularly endemic and claims 1.6 million lives a year.

While these results are certainly cause for celebration, much work remains to be done to translate these findings into real public health impact and ensure the availability of shorter treatment regimens to all TB patients and programs. Many other areas of research are also still on the horizon, including better TB prevention options and tools for children and pregnant people. Some of this research is already underway through other TBTC studies.^{vii} The recent process by TBTC to solicit research proposals (i.e. TBTC re-competition) sets up this heralded research network for the next 10 years of programmatically-relevant research that could include many of these pressing priorities for TB R&D. But this progress is marred by decades of insufficient federal funding for DTBE, which limits the ambition and scientific integrity of how TBTC can approach its research agenda. In turn, the historical lack of funding to DTBE limits the possibilities of implementation of such research through state and local TB programs.

Decades of stagnant appropriations for DTBE have led to the Division currently being funded at nearly the same level as it was in fiscal year 1994 (see right figure on impact of inflation). Factoring in the rate of inflation over that period, that stagnant funding level has drastically reduced the purchasing power of DTBE.^{viii} In addition, the costs of TB diagnosis and treatment have steadily risen, especially for drug-resistant forms of TB which can now cost up to several hundred thousand dollars to treat per person.^{ix} As a direct result, DTBE has been forced to do more with less, necessitating difficult decisions about resource allocation to its lifesaving programmatic and research initiatives.

Impact of Inflation on Flat DTBE Funding

Figure 2: CDC DTBE Overall Budget (FY 1990 - FY 2021)



Without sufficient funding to bolster our nation's TB programs, implementation of U.S.-led TB treatment strategies and interventions made possible through publicly funded research at TBTC, remains severely limited.

The COVID-19 pandemic has worsened these capacity constraints. According to a survey of TB program staff in the US, 87% of respondents reported that they or their colleagues had been either partially or completely reassigned to work on COVID-19.^x In many cases, these reassignments were indefinite, and state and local TB programs continue to operate under reduced capacity and temporary leadership. Many TB clinics, hospitals, and other resources were also designated exclusively for use in the COVID-19 pandemic response, as they were uniquely outfitted for airborne isolation. The expertise of TB public health clinicians, researchers and practitioners in particular, are drawn upon in the COVID-19 response for their critical experience in addressing an airborne infection.

Some of the impacts of the pandemic are not yet visible. TB case reporting dropped by 20% in 2020 compared to 2019. Unprecedented barriers to accessing testing and care stemming from COVID-19 health service disruptions and the reallocation of TB staff and resources from conducting contact tracing, community outreach, and TB treatment monitoring, to COVID-19 response efforts are likely the major causes of this steep drop in TB notifications.^{xi} The impacts of this reduced capacity to prevent and respond to TB cannot be overstated, and the costs of recovering from such impacts will be much higher than current funding levels allow.

Stagnant funding, and the additional damage wrought by the COVID-19 pandemic, also threaten TB research and development efforts at DTBE. In the aforementioned recent TBTC "re-competition" process for the next 10-year funding cycle, four of the prominent academic institutions that housed some of the crucial leadership for TBTC's most promising studies were excluded in the subsequent cycle due to shrinking research dollars to expand this highly successful clinical trials network.^{xii} The collective TB expertise held within these institutions is irreplaceable. Higher funding levels for DTBE and its research initiatives, such as TBTC, are vital to retain the invaluable experience necessary to complete study enrollment, data collection, analysis, publication, and translation into policy. Furthermore, expanded resources would position TBTC

to embark on a new era of clinical research led by these partners, building on its success shortening treatment and prevention of TB and looking to future opportunities, such as the possibility of TBTC trialing novel TB vaccines. However, without an increase in funding, this experience will be lost, taking with it the promise of TB research breakthroughs like those shown in TBTC Study 31, which demonstrated the first effective short course TB treatment in over 40 years^{xiii}.

In order to avert further devastating impacts on TB programs, prevention, care, and research, increased funding for CDC DTBE is critically important. **TAG requests that the subcommittee appropriate \$225 million - an increase of \$90 million - to safeguard the lifesaving progress that DTBE has made against TB in the US, sustain and grow the government's vital TB research agenda at TBTC by retaining critical R&D expertise, and to bring us closer to the elimination of TB once and for all, here and abroad.** We thank you for your support of public health programs and research, and we look forward to working with you to ensure the health of all those impacted by TB in the US and around the world.

ⁱ U.S. Centers for Disease Control and Prevention. U.S. TB Statistics. Division of TB Elimination.

<https://www.cdc.gov/tb/statistics/default.htm>

ⁱⁱ Ibid

ⁱⁱⁱ Ibid

^{iv} U.S. Centers for Disease Control and Prevention. Tuberculosis Trials Consortium. Division of TB Elimination.

<https://www.cdc.gov/tb/topic/research/tbtc/default.htm>

^v Dorman SE, Nahid P, Kurbatova EV, Goldberg SV, Bozeman L, Burman WJ, Chang KC, Chen M, Cotton M, Dooley KE, Engle M, Feng PJ, Fletcher CV, Ha P, Heilig CM, Johnson JL, Lessem E, Metchock B, Miro JM, Nhung NV, Pettit AC, Phillips PPJ, Podany AT, Purfield AE, Robergeau K, Samaneka W, Scott NA, Sizemore E, Vernon A, Weiner M, Swindells S, Chaisson RE; AIDS Clinical Trials Group and the Tuberculosis Trials Consortium. High-dose rifapentine with or without moxifloxacin for shortening treatment of pulmonary tuberculosis: Study protocol for TBTC study 31/ACTG A5349 phase 3 clinical trial. *Contemp Clin Trials*. 2020 Mar;90:105938. doi: 10.1016/j.cct.2020.105938. Epub 2020 Jan 22. PMID: 31981713; PMCID: PMC7307310. <https://pubmed.ncbi.nlm.nih.gov/31981713/>

^{vi} Treatment Action Group. TAG Statement: Finally a New Four Month Treatment for Drug Susceptible TB. 2020 October. <https://www.treatmentactiongroup.org/statement/finally-a-new-four-month-treatment-for-drug-susceptible-tb/>

^{vii} U.S. Centers for Disease Control and Prevention. Tuberculosis Trials Consortium – Research Projects. Division of TB Elimination. <https://www.cdc.gov/tb/topic/research/tbtc/projects.htm>

^{viii} Treatment Action Group. The TB Research Engine That Could: Sustaining the Success of the Tuberculosis Trials Consortium in Turbulent Times. 2021 April. <https://www.treatmentactiongroup.org/publication/the-tb-research-engine-that-could/>

^{ix} U.S. Centers for Disease Control and Prevention. CDC Fact Sheet: The Costly Burden of Drug Resistant TB Disease in the U.S.. National Center for HIV, Hepatitis, STD, and Tuberculosis Prevention – Newsroom. <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/costly-burden-dr-tb-508.pdf>

^x Stop TB Partnership. The Impact of COVID-19 on the TB Epidemic: A Community Perspective. Geneva: March 2021

<https://spark.adobe.com/page/xJ7pygvhrIAqW/>

^{xi} Deutsch-Feldman M, Pratt RH, Price SF, Tsang CA, Self JL. Tuberculosis — United States, 2020. *MMWR Morb Mortal Wkly Rep* 2021;70:409–414. DOI:

https://www.cdc.gov/mmwr/volumes/70/wr/mm7012a1.htm?s_cid=mm7012a1_w

^{xii} Treatment Action Group. The TB Research Engine That Could: Sustaining the Success of the Tuberculosis Trials Consortium in Turbulent Times.

^{xiii} U.S. Centers for Disease Control and Prevention. Landmark TB Trial Identifies Shorter-Course Treatment Regimen. National Center for HIV, Hepatitis, STDs, and Tuberculosis Prevention – Newsroom. 21 October 2020 <https://www.cdc.gov/nchhstp/newsroom/2020/landmark-tb-trial-media-statement.html>

Federal AIDS Policy Partnership Research Work Group Testimony to United States Senate Subcommittee on Labor, Health and Human Services, Education, and Related Agencies for Fiscal Year 2022 Appropriations

Organization: AVAC and Treatment Action Group on behalf of the Federal AIDS Policy Partnership's Research Work Group

Prepared for: Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies

Agency: Department of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases and the Office of AIDS Research

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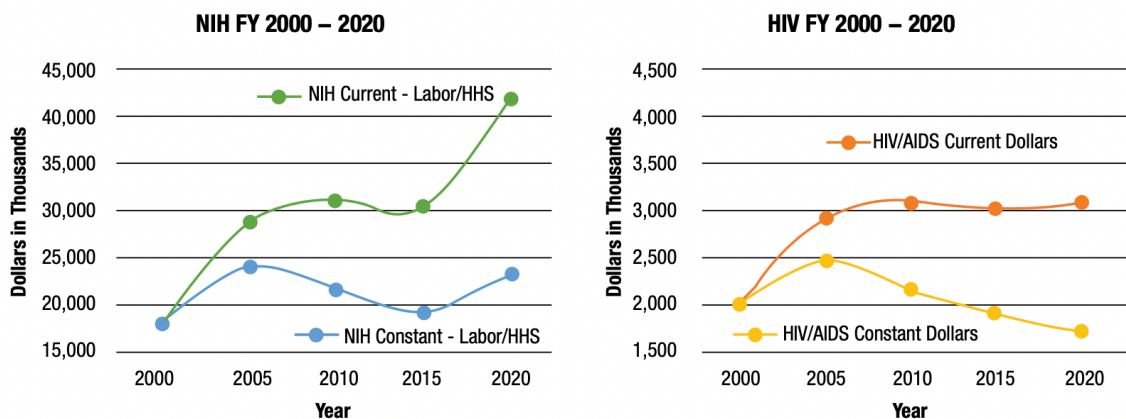
On behalf of the Federal AIDS Policy Partnership's Research Working Group, we thank Chairwoman Senator Murray, Ranking Member Senator Blunt, and members of the subcommittee for the opportunity to submit testimony to the Senate LHHS Subcommittee on Fiscal Year 2022 (FY 2022) Appropriations for the National Institutes of Health (NIH) in regards to protecting, strengthening, and expanding our nation's HIV/AIDS research agenda. The Research Work Group (RWG) of the Federal AIDS Policy Partnership (FAPP) is a coalition of more than 60 national and local HIV/AIDS research advocates, patients, clinicians and scientists from across the country. Our goal is to advance and support U.S. leadership to accelerate progress in the field of HIV/AIDS research. **The FAPP RWG urges the subcommittee to recommend a FY 2022 budget request level of at least \$46.1 billion for the NIH consistent the request of the Ad Hoc Group for Medical Research. We also ask that \$3.845 billion be allocated for HIV research at the NIH in FY 2022, which is the research need identified by the Office of AIDS Research in their Congressionally mandated FY 21 Professional Judgment Budget.**

Public investments in health research via NIH have paid enormous dividends in the health and wellbeing of people in the U.S. and around the world, particularly for people living with, or vulnerable to, HIV. NIH funded AIDS research has supported innovative basic science for better drug therapies, and evidence-based behavioral and biomedical prevention interventions which have saved and improved the lives of millions. NIH funding has contributed to over 210 approvals for a range of novel therapeutics between 2010 through 2016, with new anti-infectives for HIV and HCV receiving the second largest fraction of those approvals. Additionally, NIH support was crucial in the development of pre-exposure prophylaxis (PrEP), an HIV prevention tool that is upwards of 99% effective in preventing sexual transmission. NIH-supported HIV research is now critical to advancement of possible treatments and several vaccines against COVID-19.

HIV research advances at the NIH hold the potential to end the AIDS epidemic, as well as update prevention approaches and improve outcomes along the treatment cascade – a cornerstone of the initiative to End the HIV Epidemic in the U.S. In addition, the average age of people living with HIV in the United States is increasing, so it also remains critically important to make substantial investments in research on co-morbidities and new antiretroviral therapies. NIH research is critical to ensuring that aging population stays healthy and virally suppressed.

Since 2003, funding for NIH HIV research has failed to keep up with our existing research needs - damaging the success rate of approved grants and leaving very little money to fund promising new research – despite increases to the overall NIH budget. According to the Biomedical Research and Development Price Index (BRDI) - which calculates how much the NIH budget must change each year to maintain purchasing power - between FY 2003 and FY 2020, the NIH budget in constant dollars according to BRDI will have declined by almost half.

Inflation Effect on Research Purchasing Power



Note: The above funding does not include COVID-19 appropriations.
 Source: Biomedical Research and Development Price Index (BRDPI).

Investment by the NIH has transformed the HIV epidemic from a terrible, untreatable disease to a chronic condition that can be managed through once-a-day drug regimens. Now is the time to

increase investment for the NIH to finish the job and end the HIV epidemic through strategic, science-based interventions. NIH funding of HIV/AIDS research provides an example of innovation at work where investment in basic and translational research, working in partnership with industry and community, can move quickly to develop solutions. NIH investments in HIV/AIDS research add value by seeding ideas later taken up in industry partnerships and creating innovation incubators for important medical advances with significant health impact.

Federal support for HIV/AIDS research has also led to new treatments for other diseases, including cancer, COVID-19, heart disease, Alzheimer's, hepatitis, osteoporosis, and a wide range of autoimmune disorders. Several HIV/AIDS treatments have been researched as treatments for the novel coronavirus – saving months of research time and, in the process, potentially countless lives. Coronavirus vaccine research is now ongoing using platforms and technology, such as Ad26 and mRNA, previously developed for use as an HIV vaccine.

Robust funding for NIH overall enables research universities to pursue scientific opportunity, advance public health, and create jobs and economic growth. NIH funding puts approximately 300,000 scientists to work at research institutions across the country. According to NIH, each of its research grants creates or sustains six to eight jobs and NIH-supported research grants and technology transfers have resulted in the creation of thousands of new independent private sector companies.

The race to find better treatments and a cure for cancer, Alzheimer's, heart disease, HIV/AIDS, and other diseases, and for controlling global epidemics like AIDS, tuberculosis, coronavirus, and malaria, all depend on a robust long-term investment strategy for health research at NIH. There can be no innovation without reliable and adequate research funding. Congress should ensure the nation does not delay vital HIV/AIDS research progress. We must protect HIV/AIDS research funding to sustain research capacity and maintain our worldwide leadership in HIV/AIDS research and innovation.

To that end, we urge the subcommittee to consider a needed increase to the overall FY 2022 budget request level of at least \$46.1 billion for the National Institutes of Health (NIH) consistent with the request of the Ad Hoc Group for Medical Research. While this increase may get us closer to meeting the OAR By-Pass Budget Estimate for FY 2022, we ask the committee direct that increased funding be allocated for HIV research at the NIH in FY 2022. We urge the subcommittee to consider approaches to ensure the HIV research budget receives increases alongside other important and intersecting biomedical research at NIH.

In conclusion, the RWG calls on Congress to continue the bipartisan federal commitment towards combating HIV as well as other chronic and life-threatening illnesses by increasing funding for NIH in FY 2022. A meaningful commitment towards maintaining the U.S. pre-eminence in HIV research and fostering innovation cannot be met without prioritizing the research investment at NIH that will lead to tomorrow's lifesaving vaccines, treatments, and cures that are needed to end the HIV epidemic here and abroad. Thank you for the opportunity to provide these written comments.