

hiv medicine association Senate Appropriations Committee Hearing: Biomedical Research: Keeping America's Edge in Innovation Statement of the HIV Medicine Association Submitted for the Record by Colleen Kelley, MD, MPH April 30, 2025

Chair Susan Collins and Ranking Member Patty Murray and distinguished members of the Senate Appropriations Committee, thank you for hosting this important hearing on keeping our nation's edge in biomedical research. I appreciate the opportunity to submit this statement for the record as the Chair of the HIV Medicine Association. HIVMA represents more than 6,000 physicians, researchers and other health care professionals who work on the frontlines of the HIV epidemic in Maine and Washington and communities across the country. We are grateful for the Senate Appropriations Committee's longstanding bipartisan support for the National Institutes of Health (NIH), for the National Institute of Allergy and Infectious Diseases (NIAID), Office of AIDS Research (OAR), the National Institute on Drug Abuse (NIDA), and the John C. Fogarty International Center (FIC).

This hearing comes at a critical time when our country's unparalleled leadership and investments in biomedical research are at serious risk. We urge you to protect the investments in biomedical research that Congress intentionally and thoughtfully built up over decades to support the infrastructure and scientific workforce necessary to fuel the innovative research that has propelled discoveries to prevent, treat and cure illnesses and diseases to the benefit of all Americans.

In order to sustain biomedical research innovation, we recommend that Congress take the actions listed below.

- **Reject cuts and provide robust funding for NIH, NIAID, OAR, NIDA, and FIC in FY2026.** Cuts to NIH funding will put all Americans health at risk, compromise global health security and be costly in terms of healthcare expenses and loss of economic activity in communities across the country.
- Urge the Administration to, without delay, resume the funding and peer review processes at NIH to end costly delays or disruptions in research. Recent actions that include significant delays and instability and uncertainty in the grant review process are unravelling our nation's research enterprise. The integrity and rigor of the NIH's peer review process is important to ensuring tax-payer dollars are well spent. Delays and disruptions in the process will have long-term impacts on the pace of new discoveries and on the economic benefits that discoveries produce.
- Ensure that any changes to NIH operations are informed by a congressional reform process, with meaningful opportunities for input from researchers, clinicians, patients and the public. Any major structural changes to the NIH's institutes and centers should be done with input from Congress and the communities who conduct and benefit from research.

- Ensure that any changes to funding facilities and administrative (F&A) costs are informed by Congress and other stakeholders to ensure adequate support for the infrastructure needed to support research. The workforce and infrastructure that is critical to conducting research and keeping the lights on are not currently budgeted directly in grants. Any changes to how F&A costs are covered must sustain the infrastructure needed to conduct and sustain research.
- Conduct robust oversight to ensure that NIH funds are spent as Congress intended and grants are awarded according to longstanding best practices. This will ensure that the best science is funded and not terminated or redirected in a capricious manner or based upon political retribution. The termination of nearly 800 NIH grants, with roughly a third of them being HIV-related, has devastated the HIV scientific workforce and comes at a pivotal time of critical innovations in HIV prevention and treatment options that have the potential to actually end the HIV epidemic. A failure to reverse these terminated grants will cost us decades of progress, as the funding and work already invested in highly promising studies that have been abruptly aborted will be lost.
- Ensure that our country maintains our ethical obligations to participants in NIHsupported research and clinical trials and that study participants are not harmed by the abrupt termination of clinical trials. Study participants take health risks for advancing medical science not only for their own possible benefit but also altruistically for the benefit of others. The termination of any research grants or clinical trials in the U.S. and internationally must be conducted with due process to ensure that participants are transitioned to other forms of treatment or prevention if they will lose access to services when the study ends. For people with HIV, tuberculosis and other infectious diseases conditions – they are at serious risk of death if treatment disruptions or discontinuations occur.
- Restore the ability to enroll participants in TB and HIV clinical trials in parts of the world where these infections are common. Clinical trials done in South Africa have improved the care of Americans with HIV or who have HIV exposures as well as of Americans who have tuberculosis (a growing number). These trials have led to treatments to prevent HIV transmission from a mother to her infant; new therapies to prevent HIV through pre-exposure prophylaxis; and novel measures to treat cancer and heart disease. In addition, these trials have directly led to new therapies for tuberculosis, including multi-drug-resistant TB; new approaches to preventing tuberculosis; and novel TB vaccines.

Investments in HIV Research Saves Lives and Lowers Healthcare Costs

HIV is a powerful example of the immense value of NIH-supported research, the agency's unique role in drug development and the multiplier effect of HIV and other biomedical discoveries. Research supported by NIH transformed HIV from a fatal disease to a chronic, easily managed condition for those with access to antiretroviral treatment averting millions of deaths and dramatically reducing healthcare expenditures for those already infected and by preventing new HIV transmissions.

Sustained investments in HIV research led to the development of antiretroviral therapies that are highly effective at suppressing HIV to undetectable levels in the body and <u>innovative treatment</u> <u>options</u> to improve uptake of HIV treatment, such as once a day combination pills or monthly or bimonthly injections. Offering treatment options that work for people with HIV is important for their health and to stop HIV transmission. When people with HIV are on effective treatment, they <u>do not</u> transmit the virus to others. Today more than <u>one million lives</u> a year are saved by antiretroviral

treatment worldwide. Early <u>studies</u> focused on the benefits in the United States found that HIV treatment had saved 3 million years of life by 2006.

The rapid evolution of HIV therapies facilitated the development of pre-exposure prophylaxis (PrEP) options that are 99% effective at preventing HIV acquisition. In the U.S., only <u>36% of the 1.2 million</u> people who could benefit from PrEP are receiving it. Every HIV case prevented saves at least <u>\$500,000</u> or more in lifetime healthcare costs. An <u>exciting new PrEP option</u> that is anticipated to be approved by the Food and Drug Administration in June 2025 is a twice a year injection that was found to be 100% effective in studies conducted in South Africa with NIH and industry support. These studies would not have been possible without NIH funding.

Benefits Well Beyond HIV, including for cancer, aging and cardiovascular disease

Research into HIV and other infectious diseases has informed – and will continue to inform – our approach to other diseases, such as cancer, cardiovascular disease, neurologic conditions like dementia, and premature frailty. <u>HIV research</u> has played an important role in the development of PD-1 inhibitors – an important new approach to cancer immunotherapy that has revolutionized cancer treatment. HIV research spurred the development of curative treatment for hepatitis C, a chronic liver disease that leads to cirrhosis, liver cancer and death and affects an estimated 58 million people globally. HIV research is shedding light on mechanisms and prevention of cardiovascular disease and frailty that occur prematurely in people with HIV; these insights from HIV research will improve the health of *all* Americans.

Healthier and Stable Communities and Economies

NIH funding is critical to supporting biomedical research in <u>Maine</u> and in <u>Washington</u> that will improve the lives and address health issues affecting residents in both states and across the nation. In 2024, Maine received \$125 million in NIH funding, which supported 1,468 jobs and \$286 million in economic activity. Washington received \$1.26 billion in NIH grant funding, which supported 12,250 jobs and \$3.09 billion in economic activity.

In 2024, every dollar NIH invested in biomedical research <u>yielded \$2.56</u> in economic activity. Every <u>state and nearly every congressional district</u> benefits from NIH funding. A <u>recent study</u> found that in 2024 NIH awarded \$36.94 billion in grants to researchers in all 50 states and the District of Columbia supporting 407,782 jobs and \$94.58 billion in new economic activity.

Publicly funded basic research also fuels innovation in the private sector. NIH investments play a role in the <u>development of nearly all of the drugs</u> approved by the Food and Drug Administration. A publicly funded research dollar – <u>stimulates an additional \$8.38</u> of industry research and development investment after eight years.

What's at Stake

An analysis completed by the eminent scientific journal <u>Nature</u> found that as of April 7, 2025 NIH had terminated approximately 770 grants, of which nearly 29% were HIV-related and more than half focused on LGBTQ and transgender populations – both heavily impacted by HIV in the U.S. Discontinuing studies that evaluate interventions in different population groups will be a major setback to the HIV response because we will not know how to effectively reach those most in need. It also will be costly and inefficient because we will not know the effectiveness of the interventions with different groups based on gender, race/ethnicity, sexual orientation and other factors. Institutes and centers focused on minority groups and infectious diseases also have been most heavily impacted by the grant terminations. Infectious diseases and chronic diseases are integrally linked; infectious diseases have been shown to cause a range of important chronic diseases, including type 1 diabetes, cancer, liver disease, asthma and inflammatory bowel disease. By supporting a comprehensive research agenda that addresses both we can control infectious diseases and dramatically reduce the toll of chronic diseases on all Americans. In addition, seniors and other people with chronic diseases, such as cancer and cardiovascular disease, are at increased risk for serious illness and death from infections, and a growing number of people who use drugs are at risk for serious complications and death that require greater attention and study. HIV itself is now a chronic condition that, until we find a cure, requires lifelong treatment to prevent comorbidities and death.

If the threats to NIH-funded research continue, we will see spikes in new HIV infections, a resurgence in deaths from AIDS and tuberculosis, and tremendous increase in healthcare costs.

Conclusion

HIVMA appreciates the Committee's attention to sustaining America's leadership in biomedical research. We urge you to please protect the progress that has been made in improving the health of Americans as a result of Congress' sustained investments in NIH. Our country needs robust FY2026 funding for NIH. We hope that you will work with the Administration, physicians, researchers, people affected by HIV and other stakeholders to ensure that NIH and the critical research the agency supports continues to transform the lives of Americans and bolster health security at home and abroad.