GHTC
global health technologies coalition

advancing **innovation** to save lives

The Honorable Mick Mulvaney
Director, Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Ave., NW
Washington, DC 20503

August 28, 2017

Dear Director Mulvaney:

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 25 nonprofit organizations advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools for neglected diseases and health conditions—we write to highlight the critical role of US programs that support global health research and development (R&D) and encourage your continued support for this important work.

US investment in the development of new vaccines, drugs, devices, diagnostics, and other health technologies is essential to addressing some of the world's most pressing health challenges—achieving an AIDS-free generation; curbing the spread of malaria, tuberculosis (TB), and neglected tropical diseases (NTDs); and ending preventable child deaths. It has also shown to have a significant return on investment for the United States—creating jobs and economic growth at home, leveraging private sector and other funding, promoting cost-savings in heath treatment and services, and protecting American health and security.

- US investments in global health R&D between 2007 and 2015 have supported **42 new technologies that are saving lives and saving health treatment costs** around the world.
    - This includes 11 new products for malaria, 10 for tuberculosis, 2 for HIV/AIDS, and 4 for Ebola
- **89 cents** of every US government dollar directed to global health R&D was **invested within the United States**.
- Between 2007 and 2015, **US government investment in global health R&D injected $12 billion into the American economy**. This investment is estimated to have **created nearly 200,000 new jobs and generated an additional $33 billion in economic output**.
- Every $1 NIH spends on basic research generates an additional $8.38 of industry investment over the next eight years. This means that **by 2023, the US government's 2015 investment in global health basic research alone will spur nearly $4 billion in additional industry investment** in global health research that would have not happened independently.

As you develop the FY 2019 budget, we urge you to recognize this success, and protect and sustain global health R&D investments at agencies within the US Department of Health and Human Services (HHS)—including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Biological Advanced Research and Development Authority (BARDA), and the Food and Drug Administration (FDA)—the Department of State, the US Agency for International Development (USAID), and the Department of Defense (DoD).

Global health R&D is a "best buy" for the United States, from a strategic and humanitarian perspective. Our recommendations, and the real-world, tangible impact of cuts to programs that support global health R&D follow:

In millions	Minimum Funding Level *(FY17 enacted unless otherwise specified)*	Recommended Funding Level
State Department		
PEPFAR	$4,320	$5,160
Global Fund	$1,350	$1,350
USAID		
HIV/AIDS	$330	$350
Malaria	$755	$755
Maternal and Child Health	$814.50	$900
Neglected Tropical Diseases	$100	$125
Nutrition	$125	$259
Tuberculosis	$241	$450
Family Planning in all accounts	$607.5	$1,500
CDC		
Center for Emerging Zoonotic and Infectious Diseases	$584	$699.27
Center for Global Health	$435.10	$691
Of which Global Health Security Agenda		$199
NIH		
National Institute of Allergy and Infectious Diseases	$5,005.81 *(FY18 House)*	$5,005.81
Office of AIDS Research	$3,000	$3,225
Fogarty International Center	$73.35 *(FY18 House)*	$73.35
BARDA		$520 Robust funding that encourages work in neglected infectious diseases
DoD		Robust agency-wide funding for global health R&D

The United States has long played a leading role in research and innovation for new technologies to combat global health challenges. Global health research at US agencies has supported such breakthroughs as antiretroviral drugs for HIV/AIDS, improved diagnostics for infectious diseases, new maternal health technologies, and a new vaccine to combat malaria. It is critical to sustain and build on this leadership: more than 80 percent of Americans say that it is important for the United States to work to improve health globally through R&D.

In addition, as our world becomes more interconnected, it is clear that global health R&D provides direct benefits to US citizens, and that the health of Americans is dependent on the health of populations abroad. Evidenced by the recent Zika and Ebola epidemics, health crises overseas can become health crises at home, and protecting the well-being of Americans requires a globally-focused, whole-of-government approach. Purposeful, coordinated investment in global health R&D is not only critical to combating health threats abroad, but also to promoting global health security.

Each US agency involved in global health R&D occupies a unique niche in the fight against global disease, and provides skills and leadership that are complementary in scope. Together they support the development, scale-up, and introduction of affordable health products, policies, and practices that promote healthy populations in low- and middle-income countries, and in the United States.

US Agency for International Development (USAID)
Global health R&D at USAID has supported the development, introduction, and scale-up of affordable health products that are saving lives and lowering health treatment costs in low- and middle-income countries. Through partnerships with nonprofit and private sector organizations, USAID has contributed to impressive health breakthroughs, including those detailed below:

- USAID supported the development of MenAfriVac®, a 50-cent meningitis A vaccine. Since its introduction in 2010, the vaccine has prevented 673,000 cases of meningitis A, averted 378,000 deaths, and saved 63,000 children from life-long disability. By 2020, this 50-cent vaccine is projected to save $9 billion dollars in treatment costs for meningitis A.
- USAID helped develop two new pediatric treatments for malaria—critical to ensuring children have safe, effective medicine for this debilitating disease. For just one of these new medicines, over 300 million treatments have been distributed, saving the lives of an estimated 750,000 children.
- USAID is an important partner in the development of microbicides, supporting clinical trials for Dapivirine vaginal ring for HIV prevention. Trials show that the ring can cut a women's risk of HIV infection by approximately 30 percent, and higher levels with increased use.
- USAID's Center for Accelerating Innovation and Impact applies business-minded approaches to accelerate the research, development, and scale-up of health innovations, and also leverages private sector and other funding. The Saving Lives at Birth Grand Challenge program identifies and accelerates interventions to protect mothers and newborns in low-resource settings. Innovations advanced through this contest include a rapid-results, portable HIV test and easy-to-use, pre-measured, at-home treatments for HIV/AIDS. From an initial $20 million US government investment, Saving Lives at Birth has attracted over $110 million in additional funding.

USAID also supports work in other areas of R&D, including research toward an HIV/AIDS vaccine and R&D for new diagnostics for infectious diseases. The agency has a vital track record in the development of reproductive health technologies, which have saved and improved the lives of millions of women and their families.

If funding for USAID's global health R&D activities is cut, the impact will be significant. Some, but not all, of the impacts from cuts proposed in President's Fiscal Year 2018 budget follow:

- Cuts to USAID's HIV/AIDS programming, including a zeroing of the microbicides account will threaten continued development of promising new tools to prevent HIV transmission in young women, including stalling or canceling a study that is providing approximately 1,100 women

early access to a promising microbicide ring while it is under regulatory review and halting plans for wide-scale rollout of this new, discreet HIV prevention tool for women in Africa.
    - HIV/AIDS remains the leading cause of death for women ages 15-44 worldwide and new, women-centered prevention tools are vital to ending the HIV/AIDS epidemic.

- Zeroing funding for the International AIDS Vaccine Initiative (IAVI) and HIV vaccine development will stall or stop critical research toward the development of a preventive HIV vaccine, including stopping 10 promising vaccine candidates from progressing into the clinic, and 3 of these into efficacy trials. It will also halt research with populations at the center of the HIV/AIDs epidemic, which is providing important clues about how the virus mutates to inform development of effective next generation vaccine candidates.
    - A 70% effective HIV/AIDS vaccine could prevent nearly 5 million new HIV infections over a decade. Every $1 invested in HIV/AIDS vaccine research is projected to return between $2-67 in cost savings.

- Cuts to tuberculosis (TB) funding, including cuts to the TB drug facility will risk our ability to respond to the growing threat of drug resistant tuberculosis (TB), including retreating from a public private partnership (PPP) with Johnson & Johnson to deliver Bedaquiline, the first new drug to treat TB in more than 50 years. This novel PPP is helping patients in nearly 100 countries access new life-saving medication and curb the epidemic of multidrug resistant (MDR) TB.
    - In 2015 TB became the world's leading infectious disease killer–claiming 1.5 million lives. It costs $494,000 to treat a single case of extensively drug resistant TB with current tools.

It is also critical to recognize that cuts to USAID global health accounts threaten progress in saving lives and supporting healthy populations around the world, in addition to the direct costs to global health R&D. Cuts proposed in the President's FY18 budget proposal could result in some of the following backslides:

- 280,100 additional new HIV infections year and 96,100 additional HIV deaths each year.
- 31,300 additional maternal, newborn, and child deaths each year.
- Over 20 million bed nets not being distributed, which would mean an additional 40.5 million people could be at risk of malaria.

We strongly recommend that you fund the Global Health Programs account under the State Department and USAID at a minimum of FY 2017 enacted levels and urge the agency to invest in R&D for new global health innovations in each of the disease and condition areas within the account. To this end, we support:

Agency	Minimum Funding Level *(FY17 enacted unless otherwise specified)*	Recommended Funding Level
Global Health Programs at State and USAID		
PEPFAR	$4,320	$5,160
HIV/AIDS (USAID)	$330	$350
Malaria	$755	$755
Maternal and Child Health	$814.50	$900
Neglected Tropical Diseases	$100	$125
Nutrition	$125	$259

Tuberculosis	$241	$450
Family Planning in all accounts	$608	$1,500

Department of Health and Human Services (HHS)
Institutions within HHS—including **the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biological Advanced Research and Development Authority (BARDA)—**make major contributions to the development of new health technologies.

Centers for Disease Control and Prevention
The **CDC** leads global disease surveillance, capacity building, and research in the development of new tools and technologies—such as diagnostics to identify global diseases, including Ebola and the bubonic plague. It is a lead partner in the Global Health Security Agenda (GHSA), a whole-of-government initiative that works to build capacity in 30 low- and middle-income countries to detect global health risks rapidly, prevent them when possible, and respond effectively when they occur.

The **Center for Global Health** is a world expert in global immunization, disease eradication, and public health capacity building, home to the Global HIV/AIDS, Global Immunization, Parasitic Diseases and Malaria, Global Disease Detection and Emergency Response, and Global Public Health Capacity Development programs. Its immunization program has helped reduce the number of new polio cases globally by more than 99 percent between 1988 and 2010. The Field Epidemiology Training Program has trained more than 31,000 epidemiologists in 72 countries on how to detect and rapidly respond to infectious disease outbreaks, which greatly contributed to Nigeria's ability to contain the 2014 Ebola outbreak.

Ongoing research and development at the **Center for Emerging Zoonotic and Infectious Diseases** includes new rapid diagnostic tests for the plague and rabies. The center also serves as an international reference hub for vector-borne viral and bacterial diseases.

If funding for CDC's global health R&D activities is cut, the impact will be significant. Some, but not all, of the impacts from cuts proposed in President's Fiscal Year 2018 budget follow:

- Cuts to CDC's TB programming will stop a groundbreaking study of a new CDC-developed latent TB treatment that will reduce activation and transmission of TB in the US.
    - About 1/3 of the world's population is infected with latent TB, and we still do not understand what causes the disease to activate in some individuals and not others.

- Cuts to CDC's global HIV/AIDS programming will halt the detection and study of HIV drug resistance and the development of new, superior diagnostic tests that can be used domestically and internationally.
    - New diagnostics for drug resistant HIV are critical to identifying resistance to new classes of drugs and placing individuals on effective therapy. Without proper detection, drug resistant HIV strains will increase, which are costlier and more difficult to successfully treat.
- HIV cuts will also halt the development of new test to simultaneously diagnose HIV infections and distinguish between recent and long term HIV infection, and eliminate false positive HIV diagnoses.

    - Identifying recent HIV infection is an important step toward targeting HIV treatment and HIV prevention approaches to the most at risk individuals.

- Cuts to CDC's global health protection and global disease detection accounts will cease innovation in diagnostic testing and advanced laboratory services needed to identify new and emerging pathogens, including ending advanced laboratory collaboration in 3-4 of 10 priority countries, which will allow new pathogens to spread undetected and lead to costly delays in the world's ability to detect them in new areas and populations.
    - Since 2005, CDC's 10 Global Disease Detection Centers have discovered 12 previously unknown pathogens and organisms for the first time anywhere in the world.

It is also important to stress that cuts to CDC global health accounts in general—which includes no new dedicated funds to support implementation of the Global Health Security Agenda—will have a significant impact on global health and American health security. Some, but not all of the impacts, include:

- Stopping training of "disease detectives" in 15 priority countries, which will result in outbreaks that last longer, spread further, and affect more people.
- Inability to mobilize emergency response support teams to provide technical assistance during disease outbreaks, services that were critical to containing Ebola in West Africa and preventing the spread of the virus to the United States.

National Institutes of Health

NIH leads US government work in global health R&D, excelling in basic research that advances new drugs, diagnostics, and other tools for neglected diseases and conditions. We have seen the incredible success of NIH-funded studies for new HIV/AIDS interventions, including evidence that certain HIV/AIDS drugs can prevent the disease, as well as treat it.

For over six decades, the **National Institute of Allergy and Infectious Diseases (NIAID)** has supported research to better understand, treat, and prevent infectious diseases of global health importance. For example, through a public-private partnership, NIAID supported the development of an innovative diagnostic for TB—the Cepheid Xpert® MTB/RIF test—which in clinical trials fully identified 98 percent of TB cases in less than two hours.

The **Office of AIDS Research** has led the NIH's groundbreaking work in HIV/AIDS R&D for the past 30 years. NIH researchers first identified the HIV virus as the cause of AIDS, developed the first blood test for HIV/AIDS, and created strategies to prevent mother-to-child transmission of the disease. One study estimates that 14.4 million life-years have been gained since 1995 by the use of HIV/AIDS therapies developed as a result of NIH-funded research.

The **Fogarty International Center** serves as a critical link between researchers in the United States and the developing world, supporting collaboration in research, training, and fellowships to address critical health challenges in more than 100 countries.

If funding for NIH's global health R&D activities is cut, the impact will be significant. Some, but not all, of the impacts from cuts proposed in President's Fiscal Year 2018 budget follow:

- Elimination of the Fogarty International Center will cease critical research partnerships overseas that have been vital to containing the Ebola outbreak in West Africa and building a scientific knowledge base to develop effective Zika countermeasures.
- Across-the-board cuts of 23 percent to NIAID will threaten progress in basic research for neglected and infectious diseases, including limiting pioneering research in in vector-borne diseases that is pivotal to developing a Zika vaccine, and research needed to develop new HIV/AIDS vaccine technologies aimed at stopping the virus before it can enter human cells.
- An 18.1 percent cut to the Office of AIDS Research would delay development of an HIV vaccine, cure and desperately needed new prevention interventions. It would also slow the progress being made at NIH to understand how to better treat and care for HIV patients, lead to increased HIV infections, and increase HIV morbidity and mortality in the US and across the globe.

With any increase in overall NIH funding, there should be a proportionate increase for NIAID, the Office of AIDS Research, and the Fogarty International Center.

Biological Advanced Research and Development Authority
Through its mobilization to accelerate the development of medical countermeasures for Ebola and Zika, BARDA is playing an increasingly important role in global health R&D. Thanks to BARDA's unique expertise in late-stage product development for medical countermeasures without robust commercial markets and ability to forge innovative partnerships with the private sector, the authority has advanced at least three Ebola vaccine candidates, at least six diagnostics for Zika, and at least five Zika vaccine candidates in under two years. This work was only possible through one-time, emergency funding. We urge you to provide BARDA with robust funding that allows work in neglected infectious diseases countermeasures and continues this vital work stream with a remarkable record of success.

We strongly recommend that you fund NIH, CDC, and BARDA as robustly as possible and encourage their work in global health R&D. This includes:

Agency	Minimum Funding Level *(FY17 enacted unless otherwise specified)*	Recommended Funding Level
CDC		
Center for Emerging Zoonotic and Infectious Diseases	$584	$699.27
Center for Global Health	$435.10	$691
Of which Global Health Security Agenda		$199
NIH		
National Institute of Allergy and Infectious Diseases	$5,005.81 *(FY18 House)*	$5,005.81
Office of AIDS Research		$3,225
Fogarty International Center	$73.35 *(FY18 House)*	$73.35
BARDA		$520 Robust funding that encourages work in neglected infectious diseases

With any increase in overall NIH funding, there should be a proportionate increase for NIAID, the Office of AIDS Research, and the Fogarty International Center.

While we support at minimum FY17 enacted levels of funding for CDC, our full recommendation for the CDC Center for Global Health budget reflects a ten percent increase from FY 17 enacted levels to support existing programs, accelerate the development of next generation diagnostics and other health tools, and ensure we are on track to eliminate polio, measles, malaria, NTDs, and TB. It also includes $14 million to be dedicated to global TB programming—an expanding area of work for the center without a dedicated funding stream—and dedicated funding for continued implementation of the Global Health Security Agenda, for which temporary funding will expire in FY19. In a time when drug resistance and the global spread of disease are increasingly in the spotlight, CDC's role to prevent, detect, and respond to global health threats—including through robust R&D for new and improved interventions—is of utmost importance and requires increased, sustainable funding.

Department of Defense (DoD)
The DoD responds to infectious diseases many Americans may never see up close—such as malaria, leishmaniasis, and cholera—but which military service personnel stationed in the developing world experience alongside local communities. Walter Reed Army Institute of Research (WRAIR) and the Naval Medical Research Center (NMRC) contribute significantly to this mission.

While focused on protecting and treating US armed forces, the global health efforts of DoD and its partners include substantial R&D, infrastructure, and capacity building programs that benefit countries with few health care resources and improve our diplomatic relationships with other nations. The most promising candidate for a single-dose treatment for the strain of malaria that sickens hundreds of millions of people annually—including US service members—stems from research conducted at DoD and military research centers. The US Military HIV Research Program led the first vaccine clinical trial that showed a reduction in the risk of HIV infection to humans, which holds tremendous promise for ending the HIV/AIDS epidemic at home and abroad.

DoD's global health R&D programs also benefit Americans at home: New thermo-stabilization technologies developed by DoD improve vaccine supply chains and save lives, while making both global and US health systems more efficient.

As you consider increased funding for DoD, we strongly recommend that you consider increases for these accounts within DoD and protect agency-wide funding for global health R&D. It is also critical to support infectious disease research at WRAIR and NMRC, including their work on chemoprophylaxis, disease surveillance technologies, novel vaccines, and other countermeasures for diseases of military and global health importance.

Each agency's work in global health research and product development is unique, and contributes to a vital whole-of-government response to developing medical technologies urgently needed to save lives around the world, and protect Americans at home. These efforts are critical, and must not be slowed or halted.

Global health R&D is a smart investment for the United States because it saves lives and protects health around the world, and, as highlighted earlier, yields direct economic and health security benefits for

America. In addition, **investments in global health R&D are a net cost-savings** versus continued spending to treat complicated and costly health conditions or respond to global pandemics:

- A **$26 million investment in polio vaccine R&D** in the 1950s have **saved $180 billion** in polio treatment costs in the United States alone.
- It **cost $50 million to develop a low-cost vaccine to combat Meningitis A**. By 2020, the vaccine is **predicted to save $9 billion** in treatment costs.
- **Large-scale disease pandemics are estimated to cost the global economy more than $60 billion** a year, while an investment in **R&D to prevent these pandemics would cost only $1 billion** per year.

Global health research that improves the lives of people around the world—while at the same time supporting US interests, creating jobs, and spurring economic growth at home—is a win-win. We stand ready to work with you to advance US leadership in global health and global health innovation, and ask that support for global health R&D not come at the expense of other humanitarian assistance and development accounts. Now more than ever, policymakers must make smart budget decisions, and we urge you to support this best buy for the American taxpayers.

Please do not hesitate to contact Courtney Carson at ccarson@ghtcoalition.org or (202) 540-4377, if you have questions or need any additional information.

Sincerely,

Aeras

American Society of Tropical Medicine and Hygiene

AVAC: Global Advocacy for HIV Prevention

Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation

FHI 360

Global Health Council

HarvestPlus

Infectious Diseases Society of America

International Partnership for Microbicides

PATH

Population Council

Results

Sabin Vaccine Institute

Treatment Action Group

TB Alliance

Washington Global Health Alliance