

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

September 7, 2018

Dear Director Mulvaney:

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 30 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; ending malaria, tuberculosis (TB), and neglected tropical diseases (NTDs); ending preventable child deaths; and preventing epidemics. It has also shown to have a significant return on investment for the United States—creating jobs and economic growth at home, expanding US R&D capacity, leveraging private sector and other funding, promoting cost-savings in health 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 reducing health treatment costs** around the world.
  - This includes 11 new products for malaria, 10 for TB, 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 not have happened independently.

**As you develop the fiscal year (FY) 2020 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), and the Biomedical Advanced Research and Development Authority (BARDA)—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 are as follows:

In millions	FY 20 Minimum Funding Level <i>(Highest of House or Senate from FY19)</i>	Recommended Funding Level
<b>State Department</b>		
PEPFAR	\$4,370	\$5,500
Global Fund	\$1,350	\$1,600
<b>USAID</b>		
HIV/AIDS	\$330	\$350
Malaria	\$755	\$755
Maternal and Child Health	\$845	\$900
Neglected Tropical Diseases	\$106	\$125
Nutrition	\$145	\$250
Tuberculosis	\$302	\$400
Family Planning in all accounts	\$632.6	\$1,660
<b>CDC</b>		
Center for Emerging Zoonotic and Infectious Diseases	\$617.57	\$699.27
Center for Global Health	\$488.62	\$642
<i>Of which Global Public Health Protection</i>	\$108.2	\$208.2
<b>NIH</b>		
National Institute of Allergy and Infectious Diseases	\$5,506.19	\$5,506.19
Office of AIDS Research	\$3,000	\$3,450
Fogarty International Center	\$78.15	\$78.15
<b>BARDA</b>		
	\$520 for BARDA	\$536.70*
Pandemic Influenza Program	\$250	\$250*
Emerging Infectious Disease Program	\$250*	\$250*
<i>* these numbers represent the amounts currently in the House version of the reauthorization of the Pandemic and All Hazards Preparedness Act</i>		
<b>DoD</b>		
	Robust agency-wide funding for global health R&D	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 that we sustain and

continue to build on this leadership. According to a survey conducted by Research!America, 93% of Americans believe it is important for the United States to maintain global leadership in research to improve health.

In addition, as our world becomes more interconnected, it's 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 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.

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### **US Agency for International Development**

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 several innovative antimalarials, including new pediatric treatments—critical to ensuring children have safe, effective medicine for this debilitating disease. For just one of these new medicines, Coartem Dispersible®, some 350 million treatments have been distributed, saving the lives of more than 875,000 children.
- USAID is an important partner in the development of microbicides and supported clinical trials for the Dapivirine vaginal ring for HIV prevention, which is now under regulatory review. Trials found that the ring cut a women's risk of HIV infection by approximately 30 percent, and follow-up studies suggest it can reduce risk by 75 percent or more with near-perfect 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 \$150 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 cuts to USAID's global health R&D activities on the magnitude proposed in the President's FY19 budget were to come to fruition, we might see the following results:**

- 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 a study that is providing approximately 900 women early access to a promising microbicide ring while it is under regulatory review and halting preparations, such as clinical access programs and market introduction planning, 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 the development of effective next generation vaccine candidates.

Cuts to USAID TB funding will risk our ability to meet the goals set forward in the National Action Plan for Combating Multidrug-Resistant Tuberculosis; USAID is already facing a risk of not meeting the next milestones in expanded treatment access and any new cuts would put this at further risk. Cuts could also put at risk late-stage clinical trials supported by USAID aimed at finding new drug regimens to treat TB, including the STREAM, ZeNix, and SimpliciTB trials and could delay access to new TB regimens that are on the verge of registration in the US—offering simple, less-expensive options to treat drug resistant TB in the US and abroad. TB is the number one infectious disease killer globally; there were 10.4 million new TB cases and 1.7 million deaths from TB in 2016. Approximately 490,000 of these cases were multidrug-resistant.

- Cuts to USAID malaria funding would put at risk the global malaria elimination goals. A cut would slow down progression of the most promising malaria drug pipeline in history, halting the development of medicines to address key unmet needs including addressing multi-drug resistance, potentially leading to an eventual reversal of 15 years of progress in the fight against malaria.

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 of the magnitude proposed in the President's FY19 budget proposal could result in some of the following backslides:

- More than 261,000 additional new HIV infections and 119,200 HIV-related deaths each year.
- 1,970,000 children and 78,583 mothers not saved due to budgets [cuts](#) from 2018 to 2019.
- Over 27 million bednets not being distributed, which would mean an additional 54 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 the minimum funding levels recommended above 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.**

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## **Department of Health and Human Services**

Institutions within HHS—including **CDC, NIH, and 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 implementer in the Global Health Security Agenda, a partnership of over 60 nations that works to build capacity in 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, and is 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 since 1988. 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.** Cuts of the magnitude proposed in the President's FY19 budget proposal could result in some of the following backslides:

- Cuts to CDC's TB program will stop the evaluation of novel diagnostics to detect latent TB infection (LTBI) and delay clinical research on a CDC-developed LTBI treatment that will reduce activation and transmission of TB in the United States.
  - About 1/3 of the world's population has LTBI, and implementation of CDC LTBI research—from diagnostics to treatment—is needed to prevent active TB disease from occurring.
- 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 tests to simultaneously diagnose HIV infections and distinguish between recent and long-term HIV infection, and eliminate false positive HIV diagnoses.
  - Identifying recent HIV infections 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 stall innovation in diagnostic testing and the advanced laboratory services needed to identify new and emerging pathogens, including ending advanced laboratory collaboration in 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 11 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 will have a significant impact on global health and American health security. Some, but not all impacts, include:

- Stopping training of “disease detectives” in 17 priority countries, which will result in outbreaks that last longer, spread farther, and affect more people.
- Inability to mobilize emergency response support teams to provide technical assistance during disease outbreaks, services critical to containing Ebola in West Africa and preventing the spread of viruses such as Ebola 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 the use of HIV/AIDS drugs as a form of prevention as well as treatment.

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, automated diagnostic for TB—the Cepheid Xpert® MTB/RIF test—which is simple to use and provides results in less than 2 hours, compared to traditional methods which can take weeks. It also supported the developing and testing of the investigational Ebola vaccine deployed during the 2018 Ebola outbreak in the Democratic Republic of Congo.

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.** Cuts of the magnitude proposed in the President’s FY19 budget proposal could result in some of the following backslides:

- Any cuts to the Fogarty International Center will affect 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.
- Cuts of 9 percent to NIAID will threaten progress in basic research for neglected and infectious diseases, would limit pioneering research on vector-borne diseases that is pivotal to developing a Zika vaccine, innovative antimalarials, and research needed to develop new HIV/AIDS vaccine technologies aimed at stopping the virus before it can enter human cells.

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’s efforts to protect U.S. health security interests are shown, by necessity, to play an increasingly important role in advancing global health R&D. Thanks to BARDA’s unique expertise in late-stage product development for medical countermeasures without robust commercial markets and its ability to forge innovative partnerships with the private sector, by summer 2017 the authority had advanced at least three Ebola vaccine candidates, at least six diagnostics for Zika, and at least five Zika vaccine candidates in under two years. However, this work was only possible through one-time, emergency funding. We urge you to provide BARDA with robust annual funding that supports the development of countermeasures to address threats from emerging infectious diseases and continues this vital work stream.

**As noted in the chart above, we strongly recommend that you fund NIH, CDC, and BARDA as robustly as possible and encourage their work in global health R&D. 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. We support the minimum funding levels recommended above for CDC—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 the utmost importance and requires increased, sustainable funding. As we look towards PAHPA reauthorization, we support the House authorized bill to establish an Emerging Infectious Disease program at BARDA for R&D activities with respect to emerging infectious diseases. We also support investment in BARDA’s work on AMR and pan flu.**

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### **Department of Defense**

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 healthcare resources and improve our diplomatic relationships with other nations. For example, a new single-dose treatment approved this year for a 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 HIV 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 as well as for the Congressionally Directed Medical Research Programs (CDMRP) 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.**

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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.

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 has **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 Jamie Bay Nishi at [jnishi@ghtcoalition.org](mailto:jnishi@ghtcoalition.org) or (202) 540-4393, if you have questions or need any additional information.



Sincerely,



