

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

August 29, 2019

Dear Acting Director Vought:

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 maternal and 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 National Institutes of Health (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) 2021 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 21 Minimum Funding Level <i>(Highest of FY19 enacted or House proposed FY20)</i>	Recommended Funding Level
State Department		
PEPFAR	\$4,370	\$5,500
Global Fund	\$1,560	\$1,560
USAID		
HIV/AIDS	\$330	\$350
Malaria	\$755	\$819.3
Maternal and Child Health	\$850	\$900
Neglected Tropical Diseases	\$106	\$125
Nutrition	\$145	\$250
Tuberculosis	\$310	\$400
Global Health Security	\$100	\$172.5
<i>of which Emergency Response Fund</i>	\$100	\$100
Family Planning in all accounts	\$750	\$1,660
CDC		
Center for Emerging Zoonotic and Infectious Diseases	\$644.6	\$699.3
Center for Global Health	\$523.6	\$642
<i>of which Global Public Health Protection</i>	\$133.2	\$208.2
Division of Tuberculosis Elimination	\$152.3	\$195.7
NIH		
National Institute of Allergy and Infectious Diseases	\$5,808.3	\$5,808.3
Office of AIDS Research	\$3,200	\$3,450
Fogarty International Center	\$84.9	\$84.9
BARDA		
Pandemic Influenza	\$566.7	\$566.7
Emerging Infectious Diseases		\$250
		\$250
DoD	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 breakthroughs such as antiretroviral drugs for HIV/AIDS, new vaccines and treatments for Ebola, game changing short-

course preventative therapies for TB, 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 percent 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. As evidenced by the past 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 has supported the development, introduction, and scale-up of affordable health products that save lives and lowers health treatment costs in low- and middle-income countries. Through partnerships with nonprofit and private-sector organizations, USAID has contributed to impressive health breakthroughs:

- USAID supported clinical trials for a new drug, pretomanid, that was recently approved by the US Food and Drug Administration for use as part of a combination therapy for highly-drug resistant forms of TB. The prognosis for extensively drug-resistant TB (XDR-TB) has historically been worse than Ebola with a survival rate below 40 percent. In clinical trials, this new treatment had a success rate of around 90 percent, offering hope for patients with XDR-TB in the United States and around the world.
- USAID supported the development of child friendly TB medicines that have been scaled up quickly to address the global burden of pediatric TB, which takes the lives of 500 children every day. Enough treatment courses have already been ordered to cover half the world's children with TB.
- USAID supported the development of MenAfriVac®, a low-cost meningitis A vaccine. Since its introduction in 2010, the vaccine has been introduced in 22 countries in the African meningitis belt, virtually eliminating meningitis A epidemics wherever it has been used. By 2020 MenAfriVac® is expected to protect than 400 million people in the meningitis belt from devastating disease.
- USAID helped develop several innovative antimalarials, including new pediatric treatments which are critical for ensuring children have safe, effective medicine for this debilitating disease. For just one of these new medicines, Coartem Dispersible®, 385 million treatments have been distributed in 50 countries, 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 monthly dapivirine microbicide ring for HIV prevention, which is now awaiting a regulatory decision.

- USAID provides crucial support for the STREAM trial (The Evaluation of a Standard Treatment Regimen of Anti-tuberculosis Drugs for Patients with Multidrug Resistant TB), a large, multicenter clinical trial that has been fundamental in the development of global treatment guidelines, and the optimization of safer and shorter drug regimens for treating MDR-TB.
- The USAID Center for Innovation and Impact (CII) applies business-minded approaches to accelerate the research, development, and scale-up of health innovations and leverages funding from the private-sector and other sources. USAID CII is a core partner of the Saving Lives at Birth Grand Challenge program which identifies and accelerates interventions to protect mothers and newborns in low-resource settings. Over 120 promising innovations have been advanced through this program, including a rapid-results, portable HIV test and easy-to-use, pre-measured, at-home treatments for HIV/AIDS. Through Saving Lives at Birth, USAID has leveraged a \$20 million US government investment to attract more than \$150 million in additional funding.
- Since its founding, USAID has supported research to develop innovative solutions to tackle malnutrition, which still contributes to more than 40 percent of preventable childhood deaths, as well as blindness, cognitive and physical impairment, weakened immunity, and maternal hemorrhage during childbirth. USAID successes include scaling up evidence-based food technology solutions such as micronutrient supplements, fortified foods, and biofortified, nutrient-rich staple food crops to benefit millions of women and young children. USAID-funded nutrition research has also helped to reduce mother-to-child transmission of HIV.

USAID 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 FY20 budget were to come to fruition, we might see the following results:

- Eliminating funding for USAID’s HIV/AIDS programming would risk millions of lives and threaten drastic backsliding of progress made. It would also threaten continued development of promising new tools to prevent HIV transmission in young women, including halting preparations—such as clinical access programs and market introduction planning—for wide-scale rollout of the dapivirine vaginal ring, a new, discreet HIV-prevention tool for women in Africa which is now awaiting a regulatory decision. HIV/AIDS remains the leading cause of death for women ages 15 to 44 worldwide and new, women-centered prevention tools are vital to ending the HIV/AIDS epidemic.
- Eliminating funding for the International AIDS Vaccine Initiative (IAVI) could stall or stop research toward the development of an HIV vaccine including four promising vaccine candidates in preclinical work, four candidates in clinical trials, and two candidates in efficacy trials.
- Cuts to USAID TB funding would make it unlikely that we achieve the goals set out in the National Action Plan for Combating Multidrug-Resistant Tuberculosis and the recently launched USAID Global Accelerator to End Tuberculosis to combat the world’s leading infectious killer. There were 10 million new TB cases and 1.6 million deaths from TB in 2017. Approximately 458,000 of these cases were multidrug-resistant, and decreased investments could hamper the global response to counter greater drug resistance with emerging tools. For instance, cuts could impede scientific progress being advanced by late-stage clinical trials supported by USAID aimed

at finding new drug regimens to treat drug-resistant 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 United States—offering simpler, less-expensive options to treat drug resistant TB in the United States and abroad. Without adequate USAID funding and new tools, it is unlikely we will reach our national or global milestones toward the end of TB.

- Cuts to USAID malaria funding would put at risk the global malaria elimination goals. A cut could slow down progression of the most promising malaria drug pipeline in history, halt the development of medicines to address key unmet needs including multi-drug resistance, the development of next generation bed nets to fight insecticide resistance, and reverse 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 FY20 budget proposal could result in some of the following backslides:

- More than 220,000 additional new HIV infections and 483,000 additional HIV-related deaths each year.
- 135,000 additional preventable maternal, newborn, and child deaths.
- Over 27 million bed nets 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.

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

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 more than 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 CDC is an integral part of the global health R&D ecosystem. For example, CDC has developed an HIV rapid test that can diagnose HIV in minutes and distinguish recent from long-standing HIV infection. This test, now commercialized by two manufacturers, is being integrated into routine HIV testing services in 17 PEPFAR-supported countries to establish a real-time HIV surveillance and response system. CDC has also been testing an innovative new technology, the Measles-Rubella Box. The technology, developed by scientists from the University of Toronto, has the potential to confirm active measles and rubella infections in the field to stop outbreaks faster.

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 10,000 epidemiologists in 65 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 and is today bolstering Uganda's public health defenses against the ongoing Ebola epidemic in neighboring Democratic Republic of the Congo (DRC).

Ongoing research and development at the **Center for Emerging Zoonotic and Infectious Diseases** includes new rapid diagnostic tests for the plague, yellow fever, and rabies. Early in the Zika outbreak, NCEZID scientists developed a new test called the Trioplex that detects Zika virus, dengue, and chikungunya in a single test. The Center also serves as an international reference hub for vector-borne viral and bacterial diseases.

CDC's **Division of Tuberculosis Elimination** houses the Tuberculosis Trials Consortium (TBTC), a collaboration of researchers from the CDC and other domestic and international partners who conduct programmatically relevant research on the diagnosis, clinical management, and prevention of TB infection and disease. Over the past decade, TBTC patient enrollment has been shifting to predominantly international sites located across Peru, Spain, South Africa, Uganda, Kenya, Vietnam, and China (Hong Kong). TBTC clinical trials—which have enrolled more than 14,000 patients and volunteers over the past 20 years—have supported the development and implementation of new life-saving TB technologies and significantly improved global TB treatment and prevention guidelines.

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 FY20 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 one-quarter 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.
- 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.

- For instance, funding for the Division of Parasitic Disease and Malaria has remained unchanged since 2004 except for a modest increase in FY18. With inflation, its 'purchasing power' has diminished by at least 20 percent since 2004, eroding its scientific core capacity.

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 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 research on new HIV/AIDS interventions, including the use of HIV/AIDS drugs as a form of prevention as well as treatment—a strategy that now forms the foundation of “Ending the HIV Epidemic: A Plan for America,” the goal announced by President Trump in the 2019 State of the Union to end the HIV epidemic in the United States within ten years.

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. In 2018 at the UN High-Level Meeting on TB, NIAID announced an ambitious 5-year strategic plan to prioritize and overcome crucial gaps in TB research, including in basic sciences, and strengthen support for emerging technologies across diagnostics, therapeutics, and vaccines to address TB. NIAID supported preclinical research that contributed to the development of pretomanid, a new drug recently approved by the US Food and Drug Administration for use as part of a combination therapy for highly-drug resistant forms of TB. NIAID also developed an Ebola treatment, mAB114, which was found to dramatically improve the survival rate of infected patients in a clinical trial, also conducted by NIAID, carried during the ongoing outbreak in the Democratic Republic of Congo. NIAID also supported the development and testing of investigational Ebola vaccines being used to stem the ongoing outbreak.

The **Office of AIDS Research** has led 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. NIH has also supported development of a promising “mosaic” HIV vaccine candidate, designed to address several HIV strains simultaneously, which is now in large-scale clinical trials in sub-Saharan Africa. Today, as we seek to accelerate progress towards the end of HIV/AIDS in the United States within ten years and stem the tide of the disease globally, continued investment in NIH's HIV research will pay dividends by increasing the effectiveness of our prevention and treatment tools. GHTC supports the proposal included in the House of Representatives' FY20 Labor,

Health and Human Services, Education, and Related Agencies appropriations bill report directing NIH to “to increase funding for HIV/AIDS research by at least the same percentage as the increase in NIH overall funding.”

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 FY20 budget proposal could result in some of the following backslides:

- Cuts of nearly 14 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.
- Any cuts to the Fogarty International Center will affect critical research partnerships overseas that have been vital to addressing global health security threats like Ebola and building a scientific knowledge base to develop effective Zika countermeasures.

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 US 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 the summer of 2017 the authority had helped advanced at least three Ebola vaccine candidates, at least six diagnostics for Zika, and at least five Zika vaccine candidates in under two years. BARDA supported the development of REGN-EB3, one of two Ebola treatments that were recently found to significantly improve survival rates of infected patients during a clinical trials conducted in the DRC. BARDA is also working on a broad-spectrum antiviral called galidesivir, now in phase I human trials, which has the potential to treat a variety of pathogens, including Ebola, Marburg, yellow fever, and Zika. BARDA’s work on naturally-occurring threats, however, has been driven by emergency appropriations for Zika and Ebola, funding now nearly depleted; sustainable increases in funding for BARDA’s work on naturally-occurring threats including emerging infectious diseases, pandemic influenza and antimicrobial-resistant pathogens is needed to fuel continued breakthroughs.

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 at the end of 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. BARDA’s authority to pursue Strategic Initiatives against naturally occurring threats—reinforced in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019—can significantly contribute to our nation’s defenses, but this authority must be supported with robust funding.

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. The Walter Reed Army Institute of Research (WRAIR) and the Naval Medical Research Center (NMRC) contribute significantly to this mission.

For instance, because service members deployed by the US military comprise a majority of the healthy adults traveling each year to malarial regions on behalf of the US government, the US military has taken a primary role in the development of antimalarial drugs. Nearly all the most effective and widely used antimalarials were developed in part by US military researchers, which is a remarkable accomplishment. There is an ongoing need for medicines to evolve and for the development of a vaccine with the latest generation of malaria medicines increasingly facing drug-resistance. We strongly encourage funding for the DoD’s malaria drug and vaccine development programs to continue. 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 also benefit countries with few healthcare resources and improve our diplomatic relationships with other nations. For example, a new single-dose treatment approved in 2018 for a strain of malaria that sickens around 8 million people annually—including US service members—stems from research conducted at DoD and military research centers.

DoD also supports research on global health security threats. For example, WRAIR is leading the first clinical trials for a Marburg vaccine developed by the NIH. Marburg—a deadly cousin of Ebola—is on the World Health Organization’s list of top emerging diseases likely to cause major epidemics. A Marburg vaccine will make it possible to prevent future Marburg outbreaks from becoming epidemics, whether in the United States or abroad.

The DoD also sponsors important HIV research. 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. This research holds promise for ending the HIV/AIDS epidemic at home and abroad.

Finally, DoD has sponsored global health R&D programs that have directly benefited Americans at home. Examples include new thermo-stabilization technologies to improve vaccine supply chains and save lives. These types of technologies increase efficiency for health systems around the world and in the United States.

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.

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 or (202) 540-4393, if you have questions or need any additional information.

Sincerely,



