

Shaun Donovan
 Director, Office of Management and Budget
 Eisenhower Executive Office Building
 1650 Pennsylvania Ave., NW
 Washington, DC 20503

September 27, 2016

Dear Director Donovan:

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 that bring healthy lives within reach for all people—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. We recognize that you face many difficult decisions and are grateful for the administration’s ongoing support for global health R&D. New global health tools and technologies hold promise to dramatically improve the lives of those living in the poorest countries around the world, and we ask for your continued support in fiscal year (FY) 2018.

As you develop the FY 2018 budget, we respectfully urge you to protect and sustain funding for research to develop new global health products and innovations 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 Food and Drug Administration (FDA)—the Department of State, the US Agency for International Development (USAID), and the Department of Defense (DoD). Our recommendations follow:

USAID	(in USD thousands)
Global Health Programs at USAID and Department of State	\$10,421,000
HIV/AIDS (USAID)	\$350,000
PEPFAR	\$4,845,000
Malaria	\$874,000
Maternal and Child Health	\$900,000
Neglected Tropical Diseases	\$125,000
Nutrition	\$250,000
Tuberculosis	\$500,000
Family Planning in all accounts	\$1,200,000
NIH	\$34,100,000
National Institute of Allergy and Infectious Diseases	\$4,960,000
Office of AIDS Research	\$3,225,066
National Center for Advancing Translational Sciences	\$713,000
Fogarty International Center	\$73,030

CDC	\$7,926,110
Center for Emerging Zoonotic and Infectious Diseases	\$699,270
Center for Global Health	\$682,830
<i>of which Global Health Security Agenda</i>	<i>\$199,000</i>
FDA	\$2,9000,000
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 contraceptive 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 abroad 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. Among the most critical functions played by US government agencies are the following:

US Agency for International Development (USAID)

Global health R&D at USAID has supported the development, introduction, and scale-up of affordable health products, as well as policies and practices appropriate for addressing health issues in low- and middle-income countries.

- Through product development partnerships—a unique form of public-private partnership designed to develop new tools for neglected diseases—USAID supports nonprofit product developers in their R&D to improve health conditions around the world. One success of this model has been the development of a low-cost meningitis vaccine, specifically designed for the millions of people in sub-Saharan Africa at risk for this deadly disease. This vaccine—MenAfriVac®—is having real world lifesaving impact: More than 151 million people have been vaccinated since introduction in 2010, and it is expected to save more than \$570 million in treatment costs over the next decade.
- As a vital partner of Medicines for Malaria Venture since 2009, USAID has contributed significantly to the launch of five targeted antimalarial treatments that are already saving lives. The agency, along with the NIH, continues to support the global goal to defeat malaria by funding this product

development partnership that helps address unmet medical needs of malaria-affected people around the world.

- USAID has played a critical role in the development and funding of many contraceptive technologies, including the Mirena® intrauterine system, Paraguard® intrauterine device, contraceptive vaginal ring, female condom, new SILCs diaphragm, and first implantable contraceptive, Norplant®. These technologies have led to global population-level decreases in maternal and infant mortality as women are better able to avoid early and unwanted pregnancies, mother-to-child transmission of HIV is reduced, and child survival increases with healthier spacing of pregnancies.
- USAID's Center for Accelerating Innovation and Impact applies business-minded approaches to accelerate the research, development, and scale-up of health innovations. The Development^X Challenge through the Saving Lives at Birth program is a competitive grant program that challenges public and private innovators to develop groundbreaking 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.
- USAID is an important partner in the development of microbicides, supporting the RING Study in South Africa to evaluate the efficacy of the Dapivirine vaginal ring for HIV prevention. Results of this first study show about 30 percent protection, with higher rates of protection correlated with higher adherence and product use. These results suggest the ring has strong potential as one tool for women to combat HIV.

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.

With decades of experience and a presence in more than 100 countries, USAID has the expertise and broad geographical reach to uniquely support and guide global health R&D activities.

We strongly recommend that you fund the Global Health Programs account under the State Department and USAID at a minimum of \$10.420 billion 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 at minimum:

- **\$350 million in USAID funding for HIV/AIDS**
- **\$4.85 billion for PEPFAR**
- **\$874 million for malaria**
- **\$900 million for maternal and child health**
- **\$125 million for NTDs**
- **\$250 million for nutrition**
- **\$500 million for TB**
- **\$1.2 billion for family planning in all accounts**

We also support funding for USAID's Annual Report on Health-Related R&D and commend its valuable role in detailing the impact of USAID-led global health R&D on the agency's overarching global health objectives.

In addition, we stress the critical contributions of the Center for Accelerating Innovation and Impact in supporting cutting-edge strategies for the development and scale-up of priority global health interventions and ask that the center receive continued support.

Department of Health and Human Services (HHS)

Under the purview of HHS, three significant institutions—the **National Institutes of Health (NIH)**, the **Centers for Disease Control and Prevention (CDC)**, and **Food and Drug Administration (FDA)**—make major contributions to the development of new health technologies.

- **NIH** is the largest funder of global health R&D in the world. 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.
 - The **National Center for Advancing Translational Science** plays an important role in improving the translational research pipeline for global health innovations and helps ensure new treatments and cures for diseases get delivered faster.
- The **CDC** performs another critical function, leading 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 leader 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.
- Through the **Global Health Security Agenda** and other global health security efforts, the CDC shares expertise and works to improve the global capacity to prevent, detect, and respond to diseases around the world, including through R&D for new technologies.
- The **FDA** also serves a vital role, ensuring that safe and effective new tools to prevent, diagnose, and treat global diseases reach those who are most in need, and supporting a stronger global regulatory system. These efforts help improve the health of those living in the poorest countries of the world, protect the lives of Americans from emerging threats, and even benefit the local US economy through the creation of academic, manufacturing, and research jobs.

We strongly recommend that you fund NIH, CDC, and FDA as robustly as possible. This includes at minimum:

- **\$34.10 billion for NIH**
 - **\$4.96 billion for the National Institute of Allergy and Infectious Diseases**
 - **\$3.1 billion for the Office of AIDS Research**
 - **\$713 million for the National Center for Advancing Translational Sciences**
 - **\$73 million for the Fogarty International Center**
- **\$7.926 billion for the CDC**
 - **\$699.27 million for the Center for Emerging Zoonotic and Infectious Diseases**
 - **\$682.83 million for the Center for Global Health**
- **\$2.9 billion for the Food and Drug Administration**

Our funding request for the CDC Center for Global Health includes a meaningful increase to support global health security programming, including the agency’s participation in the Global Health Security Agenda. While 30 partner countries have been identified for GHSA, funding only exists to implement programs in the first set of 11 countries, and this funding expires in FY 2019. To fully implement GHSA and fulfill the ambitious goals of the initiative, at least \$199 million—roughly equivalent to one year’s spending at previously allocated levels—must be specifically designated to the program. This funding should be separate from CDC’s other programs in support of global health security, including the Global Disease Detection program, the Global Public Health Capacity Development program, and the Field Epidemiology Training Program, which must remain robustly funded priorities.

In addition, 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. Accordingly, our request for the CDC Center for Global Health budget reflects a ten percent increase 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. The request also includes \$14 million to be dedicated to global TB programming—an expanding area of work for the center without a dedicated funding stream.

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.

- 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.

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 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.

We strongly recommend that you fund these accounts within DoD as robustly as possible 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 an important component of the wide spectrum of R&D needed to ensure that appropriate, affordable, and effective health technologies reach those who need them most. These efforts are critical to protecting lives and must not be slowed or halted.

Ongoing investments in the development of new vaccines, drugs, diagnostics, devices, and other health technologies have the potential to greatly accelerate efforts to address HIV/AIDS, TB, malaria, reproductive health, diarrheal disease, and other less well-known diseases such as leishmaniasis, dengue fever, schistosomiasis, hookworm, and Chagas disease. Specifically:

- New therapies to treat drug-resistant TB have the potential to reduce the price of TB treatment by 90 percent, increasing access to treatment and cutting health system costs dramatically.
- A 70 percent effective HIV/AIDS vaccine could prevent nearly five million new HIV infections over a decade, once introduced to a segment of the population in low- and middle-income countries.
- Investments in new contraceptives and microbicides, including multipurpose prevention technologies, that are more effective, longer-acting, protect against HIV and other STIs, and result in fewer side effects would help to meet needs of the 222 million women who have unmet need for contraception, reduce the 80 million unintended pregnancies globally each year, and continue to reduce maternal and child deaths globally.

- An economic model for a therapeutic Chagas disease vaccine indicates that on an annual basis it could prevent cardiac complications among the estimated 40,000 new cases and prevent 10,000 deaths.

Investments in innovations such as these can ensure that the progress made in global health over the past several years—thanks to increased support from the United States—is not reversed.

In addition to bringing lifesaving tools to those who need them most, global health R&D is a smart economic investment for the United States. Investment in global health R&D drives job creation, spurs business activity, and benefits academic institutions: **nearly 64 cents of every US dollar spent on global health R&D goes directly to US-based researchers.**

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. 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.

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,



American Society of Tropical Medicine and Hygiene



Drugs for Neglected Diseases *initiative*



Elizabeth Glaser Pediatric AIDS Foundation



Global Alliance to Prevent Prematurity and Stillbirth



Global Health Council



HarvestPlus



International AIDS Vaccine Initiative



Infectious Diseases Society of America



International Partnership for Microbicides



PATH



Population Council



RESULTS



Sabin Vaccine Institute



Treatment Action Group



TB Alliance



UPMC Center for Health Security



Washington Global Health Alliance