



*Advancing innovation to save lives*

September 9, 2014

The Honorable Shaun Donovan  
Director  
Office of Management and Budget  
1650 Pennsylvania Ave, NW  
Washington, DC 20503

Dear Director Donovan:

We, the undersigned organizations are members of the Global Health Technologies Coalition (GHTC)—a group of nearly 30 nonprofit organizations that work together to raise awareness about the role of health technologies in saving lives in the developing world. We are writing today to express our gratitude for the Administration's ongoing support for global health research and development (R&D) programs. We recognize that you face many challenging decisions about US expenditures during these difficult economic times. We also want to take this opportunity to reiterate the importance of continuing the progress realized through US investments in the R&D of vaccines, microbicides, drugs, devices, and diagnostics to address health conditions of those living in some of the poorest countries around the world. **As the Office of Management and Budget develops the fiscal year (FY) 2016 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 for 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).**

As you know, the United States has a legacy of research and innovation for new technologies to combat global health diseases and conditions. Global health research at US government agencies has supported the development and introduction of affordable health products, policies, and practices appropriate for addressing diseases and health issues in developing countries. Each of these agencies occupies a unique niche in the fight against global diseases, providing skills and leadership in areas that complement the scope of other US government agencies. We believe that in today's globalized world, the health of Americans is interdependent with the health of populations abroad; protecting the well-being of Americans requires a global effort. Therefore, it is critical to our nation's public health that all of these agencies work together to combat these deadly diseases. More than 80 percent of Americans say that it is important for the United States to work to improve health globally through R&D. Among the most critical functions played by US government agencies are the following:

□ Throughout USAID's history, global health R&D and innovation at the agency has supported the development and introduction of affordable health products, as well as policies and practices appropriate for addressing diseases and health issues in developing countries. Through product development partnerships—a unique form of public-private collaboration 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 African countries who are at risk for this deadly disease each year. This vaccine is having real world life-saving implications—more than 151 million people have been vaccinated since introduction in 2010, and it is expected to save over \$570 million in the next decade

Additional examples of the vital role USAID plays to develop life-saving technologies include the development of new combination therapies to expand and diversify treatment options for malaria-endemic countries and help delay the onset of resistance to artemisinin (the current frontline drug in the fight against malaria). With USAID support, Medicines for Malaria Venture (MMV) has developed three new artemisinin-based combination therapies. This includes Coartem<sup>®</sup> Dispersible, a pediatric formulation, which, by the end of 2013, had delivered more than 200 million treatments to 50 malaria-endemic countries. Through the agency's Health Tech program, and in partnership with PATH, USAID has supported the development of 85 technologies in partnership with more than 100 private-sector collaborators who have matched federal dollars at least two to one. USAID, a global leader in microbicide R&D, also currently supports the government of South Africa in FACTS 001, a confirmatory trial examining whether 1 percent tenofovir gel can protect women protect women and their partners against HIV and other sexually transmitted infections. USAID supports similar work in other areas of R&D, including research toward an AIDS vaccine, and R&D for new diagnostics and interventions supporting maternal and newborn health. Finally, 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 such activities. **We strongly recommend that you consider funding the Global Health Programs account under the State Department and USAID at least \$10.93 billion and to urge the agency to invest in funding for research to develop new global health products and innovations within each of the disease and condition areas within the account.**

□ Under the purview of **HHS**, three significant institutions—**NIH**, **FDA**, and **CDC**—also 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 through the discovery of evidence that certain HIV drugs can prevent the disease, as well as treat it. The CDC fills an equally critical function, providing global disease surveillance, capacity building, and leading research in the development of new tools and technologies—such as diagnostics to identify global diseases, including the bubonic plague. Through the Global Health Security Agenda,

the CDC is bolstering its leadership by improving the global capacity to prevent, detect, and respond to diseases around the world, including through R&D for new technologies. Finally, 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 these accounts as robustly as possible, including at least \$32 billion for NIH, \$469 million for the CDC's Center for Global Health, \$445 million for the CDC's Center for Emerging Zoonotic and Infectious Diseases, and \$2.78 billion for the FDA.**

□ **The DoD** and the US military services' medical research operations respond 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. For instance, the most promising candidate for a single-dose treatment for the form of relapsing malaria that affects hundreds of millions of people annually—including US service personnel—stems from research conducted at DoD. 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 and training programs that benefit countries with few healthcare resources and improve our diplomatic relationships with partner nations. DoD's global health R&D programs also benefit Americans at home; for instance, new thermo-stabilization technologies make both global and US health programs more efficient, improving vaccine supply chains while saving lives. **We strongly recommend that you fund these accounts as robustly as possible and protect agency-wide funding for global health R&D.**

The work of each agency in product development is an important component of the wide spectrum of research needed to ensure that appropriate, affordable, and effective vaccines, drugs, diagnostics, and other tools 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, and reproductive health technologies have the potential to greatly accelerate efforts to address HIV/AIDS, tuberculosis (TB), malaria, diarrheal disease, pneumonia, and other less well-known diseases such as leishmaniasis, dengue fever, schistosomiasis, hookworm, and Chagas disease, as well as increasing family planning options. A new partially effective TB vaccine, delivered to just 20 percent of adult and adolescent populations in high-burden countries and to at-risk groups in low-incident settings, could potentially avert up to 50 million new TB cases by 2050. Recent projections show that even a 60 percent effective HIV vaccine could prevent more than five million new HIV infections over a decade, once introduced to a segment of the population in low- and middle-income countries. Shorter TB treatment regimens currently under development have the potential to reduce significantly the cost of treatment. Additionally, an effective vaccine for human hookworm infection has been shown to be highly cost-effective and could avert up to 3.23 million disability-adjusted life years if used worldwide in endemic areas. Similarly, a recently published 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. Such investments can ensure that the progress made in the past several years—thanks to increased support from the United States—is not reversed.

This research not only improves people’s lives around the world; it is also a smart economic investment for the United States because it drives job creation, spurs business activity, and benefits academic institutions. Around 64 cents in every dollar spent by the US government on global health R&D goes directly to US-based researchers.

In these times of fiscal constraint, we understand the unique pressures that you face in setting priorities for our nation and recommending levels of associated funding. 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 here at home—is an important priority for the nation. We ask that support for global health R&D not come at the expense of other humanitarian assistance and development accounts.

We must bolster and sustain the United States’ role in developing new global health tools to save lives and ensure US leadership in today’s global society. We stand ready to work with you on these important issues that are essential to achieving our country’s global health goals. Please do not hesitate to contact Kaitlin Christenson, Coalition Director, at [kchristenson@ghtcoalition.org](mailto:kchristenson@ghtcoalition.org) or (202) 822-0033, if you have questions or need any additional information.

Sincerely,



Aeras



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