

March 18, 2020

The Honorable Richard Shelby
Chairman
Senate Appropriations Committee
304 Russell Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
Vice Chairman
Senate Appropriations Committee
Ranking Member
Senate Appropriations Subcommittee on State,
Foreign Operations, and Related Programs
437 Russell Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Chairman
Senate Appropriations Subcommittee on State,
Foreign Operations, and Related Programs
290 Russell Senate Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

As members of the Global Health Technologies Coalition (GHTC)—a group of 30 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other 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 Committee'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 2021 (FY21).

To this end, for FY21 we strongly urge the Committee to sustain and protect funding for research to develop new global health products and innovations through the Global Health Programs account under the State Department and the US Agency for International Development (USAID). This means rejecting cuts to global health programs called for by the Administration for FY21 and supporting at minimum sustained funding at FY20 levels for each disease or population-specific program under State and USAID global health accounts. To ensure R&D is appropriately prioritized, we also urge you to instruct USAID to prioritize R&D within each of the disease and condition areas under USAID's Global Health Programs account. We also urge you to direct USAID to expand the annual report on its health-related research and development strategy and publicly release the annual report required by the Global Health Innovation Act (P.L. 115-411), which details the development and use of global

health innovations by the programs, projects, and activities of USAID, as these reports are vital for transparency and oversight.

The United States has long played a leading role in research and innovation for new technologies to combat global health challenges. Global health research through USAID and the State Department has supported such breakthroughs as new treatments for malaria, innovative microbicides to prevent transmission of HIV in low-resource settings, and interventions to help women and infants in childbirth. 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 investments in global health R&D are investments in global health security. Evidenced by the 2014 Ebola epidemic in West Africa and today by the growing outbreak of Novel Coronavirus Disease 2019 (COVID-19), health crises abroad can quickly become health crises at home and protecting the well-being of Americans requires a globally focused approach. The impact of the rVSV-ZEBOV (ERVEBO) Ebola vaccine—which was developed with funding in part from the US government—on the ongoing epidemic in the Democratic Republic of the Congo demonstrates the power of having the right tool at the right time to respond to a health emergency. ERVEBO has been used to vaccinate more than 250,000 at-risk individuals. With a 97.5% efficacy rate against the Ebola Zaire virus, this vaccine is highly protective and is now a vital tool for this and future Ebola outbreaks. In the first week of March 2020, the last known Ebola patient in DRC was discharged from a treatment facility, and while the country is in a waiting period before the outbreak can be officially declared over, it is clear that the new tools developed with US government support were vital to the containment of this deadly outbreak.

As humans continue to live closer to wildlife, the threat of emerging infectious disease outbreaks will intensify. The recent COVID-19 has demonstrated once again that we do not readily have all the tools needed to prevent, diagnose, and treat many neglected and emerging infectious diseases—a reality that was brought into sharp focus during the Zika epidemic and West African Ebola epidemic just a few years ago. Today's investments in global health innovations to prevent and treat neglected and emerging diseases in the developing world—such as extensively drug-resistant tuberculosis, malaria, and NTDs—will save millions of lives in the future from perpetual and emerging health challenges.

With less than one-half of one percent of the federal budget, USAID works around the world to support US goals in global health and development and strengthen relationships with key US partners. 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 developing countries. In this work, USAID harnesses its comparative advantage of strong on-the-ground presence in low- and middle-income countries to support end-to-end product development, including through clinical trials, of global health technologies appropriate for the low-resource settings where they will be used. **We applaud the efforts that USAID has made in fostering innovation in health technologies, including:**

- Partnering across government agencies and among private-sector partners to identify breakthrough innovations to combat infectious disease epidemics in response to recent outbreaks of Ebola and Zika. USAID's Fighting Ebola Grand Challenge identified 1,500

innovative technologies to advance the fight against Ebola and is funding further refinement of 14, including novel personal protective equipment. The Combating Zika and Future Threats Grand Challenge received over 900 crowdsourced technology proposals and selected 26 projects to fund, which cut across vector control, vector and disease surveillance, diagnostics, and other interventions.

- Supporting research to develop safe, effective, accessible, and acceptable tools for use in the developing world to prevent HIV, including investigational HIV vaccines; microbicides based on antiretroviral drugs, which have shown potential to prevent HIV infection in women; and a low-cost, rapid, disposable HIV/AIDS diagnostic test for infants supported through a Saving Lives at Birth award.
- Playing a key role in the global effort to fight TB by supporting research to develop innovative, new drug regimens and diagnostics for drug-susceptible and drug-resistant tuberculosis, including the world's first child-friendly TB medicines, developed with critical seed funding from USAID and introduced in 2015, and a new all-oral treatment regimen in late-stage clinical trials that could reduce the time it takes to treat drug-susceptible tuberculosis from 6 months to 4 months. When these products are ultimately licensed, USAID provides expertise on implementation and scale-up.
- Supporting the development of vaccines, antimalarials, insecticides, and novel vector control tools against malaria, including a promising single-dose cure.
- Developing interventions to help women and children during childbirth in low-resource settings that may not have electricity, refrigeration, or access to trained health workers.
- Supporting development of drugs and diagnostics for a select group of neglected tropical diseases (NTDs), including tools to fight dengue and other mosquito-borne diseases that have been deployed from Indonesia to the Florida Keys with promising results.
- Developing tools for low-resource settings to combat emerging infectious diseases, primarily through the Grand Challenges for Ebola and Zika programs.
- Supporting the development and distribution of more than 385 million courses of the child-friendly malaria drug Coartem[®] Dispersible in 50 countries.

Ongoing investments in the development of new vaccines, drugs, microbicides, and other tools have the potential to greatly accelerate efforts to address HIV/AIDS, tuberculosis, malaria, diarrheal disease, and pneumonia, as well as improve maternal and reproductive health.

USAID is an important partner in global health product development, and it is critical for the agency to bolster this function of its global health programming. This means that **global health programs within USAID require robust funding in order to ensure they have appropriate resources both for ongoing programs and forward-looking R&D efforts.** For the vast majority of USAID's global health programming, there are no dedicated funding streams or programs expressly supporting global health R&D. Accordingly, decisions on USAID's investments in new global health technologies are made at the program level, based on overall funding allocations for each disease or population-specific health area.

To ensure research is appropriately prioritized, global health programs need appropriate resources. Funding cuts—such as those proposed in the Administration’s FY18, FY19, FY20, and FY21 budgets—would put significant strain on USAID’s global health programs and force the agency to decide between maintaining essential health care delivery programs and making long-term investments in potentially game-changing R&D.

USAID recognizes the value of global health R&D, and how new global health tools can help finally curb infectious disease outbreaks, end preventable maternal and child deaths, and achieve an AIDS-free generation. The agency’s annual strategy report on Health-Related Research and Development is an important tool, in which USAID details its work in global health R&D and describes how these efforts advance our overarching global health goals. We urge the Committee to include report language in the FY21 State, Foreign Operations, and Related Programs bill directing USAID to include in the report specific funding amounts dedicated to research and product development by each program; specific information about health product development goals and timelines; details about USAID investments in drugs, vaccines, diagnostics, and devices; details about collaborations with other federal agencies and private-sector partners; and an assessment of any critical gaps in product development for global health and recommendations for filling such gaps. This report is critical to provide insight and transparency into how USAID thinks strategically about R&D investments.

Thanks to strong Congressional support for transparency and oversight of the agency’s work on global health research, the Global Health Innovation Act (P.L. 115-411) passed at the end of the 115th Congress authorizes another annual report which details how USAID uses global health innovations in its programs, projects, and activities and how USAID collaborates with other agencies in support of global health product development. We urge the committee to direct USAID to make this report public on the Agency’s website.

We urge the Committee to maintain strong support for the Global Health Programs account under the State Department and USAID and urge the agency to invest in research and development for new global health innovations in each of the disease and condition areas within the account. This means supporting at minimum sustained funding at FY20 levels for each disease or population-specific program and rejecting cuts to global health programs called for by the Administration in FY18, FY19, FY20, and FY21.

Continued investment to support research throughout each of USAID’s global health accounts is critical to progress in global health. Such investments can ensure that the progress made in global health over the past decade, 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: **89 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, Congress 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 investment.

Please do not hesitate to contact GHTC Director Jamie Bay Nishi at jnishi@ghtcoalition.org or (202) 540-4379 if you have questions or need any additional information.

Sincerely,



American Society of Tropical Medicine and Hygiene



AVAC



Drugs for Neglected Diseases initiative



Elizabeth Glaser
Pediatric AIDS
Foundation

*Until no
child has
AIDS.*

Elizabeth Glaser Pediatric AIDS Foundation



FIND



Global Health Council



HarvestPlus



Translating science
into global health impact

International AIDS Vaccine Initiative



Infectious Diseases Society of America



International Partnership for Microbicides



Innovative Vector Control Consortium



Medicines for Malaria Venture



PATH



RESULTS



Sabin Vaccine Institute



Treatment Action Group



TB Alliance



Washington Global Health Alliance