

April 25, 2022

The Honorable Patrick Leahy
Chairman
Senate Appropriations Committee
437 Russell Senate Office Building
Washington, DC 20510

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

The Honorable Christopher Coons
Chairman
Subcommittee on State, Foreign
Operations, and Related Programs
218 Russell Senate Office Building
Washington, DC 20510

The Honorable Lindsey Graham
Ranking Member
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 40 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), addressing antimicrobial resistance, and ending preventable child deaths. Over the past two years, the importance of strong investment in global health R&D has become clearer than ever before as scientists raced to develop the tools desperately needed to diagnose, treat, and prevent COVID-19. We have watched with awe as scientists have shattered speed records for vaccine development, forged unique collaborations to advance science across borders, and deployed an unprecedented amount of energy and resources from a range of health areas to tackle this global foe—upending assumptions about how science works, and how fast.

Today, we have a robust set of tools to counter COVID-19 in high-income countries, but still lack critical tools designed to meet the unique needs of patients and health workers in low-resource settings, where basic resources like electricity, laboratory capacity, and reliable cold chain storage cannot be taken for granted. These inequities in infrastructure account for some of the glaring disparities in COVID-19 vaccine coverage between high-income regions and low- and middle-income regions of the globe—as of writing, nearly 80% of the population of North America has received at least one vaccine dose, compared to less than 20% of sub-Saharan Africa. The next phase of our global response to COVID-19 must include a focus on ensuring that we have COVID-19 tools designed to be effective in every corner of the globe, a fundamental building block of equitable global health security.

We are grateful for the Committee's ongoing support for global health R&D and recognize that you face many difficult decisions in balancing many important priorities for annual appropriations and the

allocation and use of emergency appropriations for unprecedented R&D and public health needs over the past two years. However, we believe the case has never been stronger to further bolster US support of global health innovation.

To this end, in fiscal year 2023 (FY23), we strongly urge the Committee to sustain and grow funding for research to develop new global health products and innovations through the Global Health Programs account under the State Department and US Agency for International Development (USAID). This means supporting at minimum sustained funding at FY22 enacted levels for each disease or population-specific program under State and USAID global health accounts, and supporting funding increases where possible, including those outlined in the President’s FY23 discretionary budget request.

However, beyond the need to just sustain funding for existing accounts critical to global health R&D, several worrisome trends have converged in the past several years which necessitate a new, reinvigorated approach to funding global health innovation at USAID. Below we outline these trends and a proposed solution: **the creation of a new Supporting Innovative Global Health Technologies (SIGHT) Fund, a new and additive source of flexible, catalytic funding for the research, development, and deployment of new global health products, created through a new appropriation to the USAID Global Health Bureau. Together with the partners listed on a companion letter, we call for the creation of the SIGHT Fund in FY23 with an initial appropriation of \$250 million in addition to robust funding for existing lines under the Global Health Programs account.**

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 and long-acting pre-exposure prophylaxis to prevent transmission of HIV in low-resource settings, and interventions to help women and infants in childbirth. Notably, decades of research, including on HIV/AIDS, severe acute respiratory syndrome, and other diseases, laid the groundwork for understanding the molecular biology and immunology of COVID-19, and many of the leading COVID-19 vaccine candidates were built using platforms originally developed for other global health challenges. Our investments in global health R&D made a decade ago laid the foundation on which COVID-19 tools were rapidly developed and deployed; our investments in R&D today will directly influence the extent of our preparedness for health threats facing us a decade from now.

Evidenced not only by COVID-19 but also recently by the 2014 Ebola epidemic in West Africa and 2016 Zika emergency, 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—demonstrates the power of having the right tool at the right time to respond to a health emergency. The vaccine helped contain the 2018-2020 Ebola outbreak in the Democratic Republic of the Congo (DRC), the second-deadliest Ebola outbreak in history.

The Unique Role and Impact of USAID in Global Health Innovation

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 human-centered design, support for clinical trials, and introduction 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:**

- Supporting research to develop safe, effective, accessible, and acceptable tools for use in the developing world to prevent HIV, including investigational HIV vaccines; microbicides and a microbicide vaginal ring 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 TB, including the world's first child-friendly TB medicines, developed with critical seed funding from USAID and introduced in 2015, and a new six-month regimen for drug-resistant TB. USAID expertise on implementation and scale-up of these innovations is a critical piece of the product development cycle and ought to be appropriately prioritized.
- Supporting the development of vaccines, treatments, 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, including oxygen therapies.
- Supporting development of drugs and diagnostics for a select group of NTDs, including tools to fight dengue and other mosquito-borne diseases that have been deployed from Indonesia to the Florida Keys with promising results.
- Supporting the development and distribution of the child-friendly malaria drug Coartem[®] Dispersible, which has been distributed in over 50 countries and has saved an estimated 980,000 child lives since its introduction in 2009.

Ongoing investments in the development of new vaccines, drugs, microbicides, and other tools have the potential to greatly accelerate efforts to address HIV/AIDS, TB, malaria, diarrheal disease, and pneumonia, as well as improve maternal and reproductive health—but **a new approach to supercharging USAID's R&D capabilities is needed to enable the agency to fulfill its innovation mandate and deliver game-changing products.**

To Continue Innovation Progress, a New Funding Approach is Needed

Despite USAID's rich history of R&D impact detailed in the examples above, **several worrisome trends have converged in the past several years to necessitate a new, reinvigorated approach to funding global health innovation at the agency.** USAID's global health innovation mandate has been increasingly constrained by three interrelated challenges:

- 1. Funding for health-related R&D has declined as a proportion of overall global health spending.** USAID devotes a small proportion of its total global health funding to R&D. In 2006, this proportion peaked at 8 percent but has steadily declined to around 5 percent as total funding for global health has grown and funding for R&D has slightly declined in real dollars.
- 2. Innovation at USAID is siloed by health area, limiting opportunities for multipurpose products and responsive research that can be pivoted and deployed in emergencies like the COVID-19 pandemic.** Funding for innovation today is primarily drawn from disease- and population-specific appropriations accounts, limiting the ability of USAID to fund products that address

multiple health issues or explore new R&D areas.

- 3. Constrained budgets force leaders in the USAID Global Health Bureau (GHB) to prioritize immediate impact over innovation and long-term progress.** With limited resources, leaders in the GHB must find a balance between funding health programs using today's imperfect tools to drive immediate impact and supporting health innovation—developing new and improved tools to drive transformative and accelerated impact in the future. Understandably, leaders often choose to limit risk and focus on immediate results rather than make bets on R&D that could transform future global health programming, achieve greater impact, and ultimately reduce costs.

Each of these challenges came into devastatingly clear focus in March 2020, when in response to COVID-19 USAID put out a call for proposals for innovations specifically designed to mitigate the pandemic in low-resource settings. During previous health crises, including Zika and the West African Ebola outbreak, USAID pursued a similar approach through Grand Challenge programs to identify and successfully fund the development of new tools, such as a battery-powered IV infusion rate monitor for Ebola treatment centers and a low-cost diagnostic for Zika, which improved care in low-resource settings. Within weeks, the agency received several hundred proposals for technologies to aid the global response to COVID-19. Unfortunately, without dedicated funding available for the agency to invest in innovation, USAID was able to support just two promising technologies, despite the clear need for tools designed and adapted to prevent and treat COVID-19 in low-resource settings—where today, partners are struggling to deliver and effectively implement first-line tools such as multi-dose vaccines and therapeutics requiring IV infusion. **The lack of dedicated USAID funding for health innovation has had serious consequences for the global response to the COVID-19 pandemic—and many other enduring health challenges. It is clear that a new approach is needed.**

The Supporting Innovative Global Health Technologies (SIGHT) Fund

To solve these intersecting challenges and drive a global health innovation agenda at USAID that is more flexible, responsive, and coordinated, we need a new approach that supplements and supercharges ongoing innovation efforts at USAID. Over the past year, our coalition and leading innovation partners have developed an in-depth proposal (see [factsheet](#) and [policy brief](#)) for a new **Supporting Innovative Global Health Technologies (SIGHT) Fund: a new and additive source of flexible, catalytic funding at USAID to conduct research, development, and deployment of new global health products, created through a new appropriation to the USAID Global Health Bureau.** The SIGHT Fund would be used to advance new global health products through the research pipeline—with an emphasis on clinical development, regulatory approval, and product introduction—prioritizing support for innovators close to affected communities and the engagement of end users in the research process.

To address the challenge of proportionately declining funding for health R&D, the SIGHT Fund would be launched through an **initial appropriation of \$250 million to the USAID Global Health Bureau.** This level of dedicated innovation funding would raise total annual USAID investments in global health innovation to a healthy target of approximately 10 percent of overall GHB funding, while still representing **less than 3% of US spending on global health across USAID and the State Department.** Once launched and institutionalized at USAID, appropriating multi-year funding for the SIGHT Fund would allow the agency to progressively grow innovation investments as it creates the structure and human resources needed to deploy such resources most effectively.

To address the challenge that USAID’s approach to innovation is currently siloed by health area, the SIGHT Fund would be based within the GHB but independent of any health-area technical offices. The SIGHT Fund would be disease agnostic and could be tapped for different health challenges as R&D needs evolve and opportunities emerge. As a centralized, additive source of innovation funding, the SIGHT Fund would improve research coordination across the agency, and its independence would foster investments in multipurpose products, or products that address challenges in more than one disease or condition.

To address the challenge of leaders being forced to choose between near-term programming and long-term innovation potential, the SIGHT Fund would create an additional pot of resources dedicated only to innovation. Several GHB offices have long and rich partnerships with innovators funded directly from their appropriation lines, and the SIGHT Fund would *supplement, not supplant*, these existing programs and partnerships. By expanding the global health pie rather than slicing it further, the Fund would enable USAID to make bolder investments to develop tools that are more effective, better suited to the needs of unique populations, and essential to achieving our long-term disease elimination and mitigation goals.

We urge the Committee to maintain strong support for the Global Health Programs account under the State Department and USAID—supporting at minimum sustained funding at FY22 levels for each disease or population-specific program, and supporting increases where possible, including those outlined in the President’s FY23 discretionary budget request—and creating a new SIGHT Fund for global health innovation with a new \$250 million investment. Global health innovation and implementation must not be seen as competing priorities, but rather part and parcel of the US commitment to improving global health.

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 if you have questions or need any additional information.

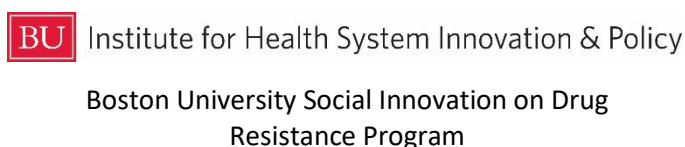
Sincerely,



American Society of Tropical Medicine and Hygiene



AVAC



Boston University Social Innovation on Drug Resistance Program



Coalition for Epidemic Preparedness Innovations



Drugs for Neglected Diseases *initiative*



Elizabeth Glaser Pediatric AIDS Foundation



FIND



Global Antibiotic Research and Development Partnership



Global Health Council



HarvestPlus



Translating science into global health impact

IAVI



Infectious Diseases Society of America



International Partnership for Microbicides



Innovative Vector Control Consortium



Medicines for Malaria Venture



PATH



RESULTS



Sabin Vaccine Institute



TB Alliance



Treatment Action Group



Washington Global Health Alliance