

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

October 6, 2020

Dear Director Vought:

As members of the Global Health Technologies Coalition (GHTC)—a group of 30 organizations advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools for neglected diseases; emerging infectious diseases, such as COVID-19; and other 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 most pressing, ending the COVID-19 pandemic and preventing future outbreaks of emerging infectious diseases. The COVID-19 pandemic has demonstrated that R&D must be the tip of the spear of our response to, and prevention of, global health emergencies: our lack of tools to prevent and treat this disease has wreaked havoc on the global economy and strained vulnerable health systems to their breaking point.

Beyond the clear and pressing need for R&D for COVID-19, federal funding for global health R&D has been shown to yield a significant return on investment for the United States: creating jobs, growing the economy, expanding US R&D capacity, leveraging private-sector and other funding, and promoting cost-savings in health treatment and services—significant benefits in addition to its impact protecting American health and security.

- Development of a safe and effective SARS-CoV-2 vaccine on a dramatically compacted timeline is conceivable only because of **past US government investments in global health R&D** which have fueled new biotechnologies, manufacturing platforms, and clinical trial methods. In fact, nearly every advanced COVID-19 vaccine candidate in development supported by the US government is built on previous vaccine research for other global health threats, including Zika, Ebola, SARS, MERS, HIV/AIDS, malaria, tuberculosis (TB), and pandemic influenza.
- **US government funding for COVID-19 R&D has enabled progress towards at least 70 health innovations** including diagnostics, therapeutics, vaccines, and medical devices—a testament to how quickly science can progress with focused investment.
- US investment in global health R&D between 2007 and 2015 supported the development of an impressive **array of life-saving health technologies**, including at least 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 in that period was **invested within the United States**.

- Between 2007 and 2018, **US government investment in global health R&D injected \$14.5 billion into the American economy.** This investment is estimated to have **created 240,000 new jobs and generated an additional \$40 billion in economic output.**
- According to a nationwide survey conducted by Research!America in 2018, prior to the COVID-19 pandemic, **80 percent of respondents said Americans should be concerned with global health and 65 percent said the US government should be responsible for funding global health research**—numbers expected to rise as the pandemic continues to demonstrate that diseases do not respect borders and that the health of Americans is intimately linked to that of our global neighbors.

As you develop the fiscal year 2022 (FY22) budget, we urge you to 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). At this time of crisis, the Administration must make forward-thinking choices to respond to the emergency before us and draw on the painful lessons emerging from it to ensure that we are primed and ready for the next health threat—while also committing to continue progress against the full range of global health challenges. **Global health R&D, which improves the lives of people around the world while creating jobs, spurring economic growth, and supporting US interests and health security, is a win-win investment from a strategic and humanitarian perspective.**

As COVID-19 infections rise in low- and middle-income countries (LMICs), the global health community is assessing urgent needs for funding increases to many core global health programs in FY22—both to protect progress made to date against these enduring threats and assess where assets can be leveraged directly to treat and prevent COVID-19. In light of these considerations, GHTC’s minimum and recommended funding levels for FY22 are as follows:

| <i>In millions</i> | FY22 Minimum Funding Level <i>(Highest of FY20 enacted or House proposed FY21)</i> | FY22 Recommended Funding Level |
|---------------------------------|--|---------------------------------------|
| State Department | | |
| PEPFAR | \$4,370 | \$5,500 |
| Global Fund | \$1,560 | \$1,560 |
| | | |
| USAID | | |
| HIV/AIDS | \$330 | \$350 |
| Malaria | \$770 | \$770 |
| Maternal and Child Health | \$851 | \$900 |
| Neglected Tropical Diseases | \$102.5 | \$125 |
| Nutrition | \$150 | \$250 |
| Tuberculosis | \$310 | \$600 |
| Global Health Security | \$125 | \$172.5 |
| Family Planning in all accounts | \$750 | \$1,660 |

| | | |
|---|--|--|
| CDC | | |
| Center for Emerging Zoonotic and Infectious Diseases | \$646 | \$735 |
| Center for Global Health | \$572.8 | \$670 |
| <i>of which Global Public Health Protection</i> | \$183.2 | \$208.2 |
| Global Tuberculosis | \$9.2 | \$21 |
| | | |
| NIH | | |
| National Institute of Allergy and Infectious Diseases | \$6,013.1 | \$6,356 |
| Office of AIDS Research | \$3,107 | \$3,845 |
| Fogarty International Center | \$86.5 | \$91 |
| | | |
| BARDA | \$561.7 | \$750 |
| | | |
| 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, vaccines and treatments for Ebola, game-changing short-course preventative therapies for TB, improved diagnostics for infectious diseases, new maternal health technologies, and a vaccine to combat malaria. It is critical that we sustain and continue to build on this leadership.

In addition, as our world becomes more interconnected and the global impact of COVID-19 continues to unfold, 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. As evidenced by the COVID-19 pandemic and the preceding Zika and Ebola epidemics, health crises overseas can quickly become health crises at home. 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 health in low- and middle-income countries and 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 lower health treatment costs in low- and middle-income countries. Through partnerships with nonprofit and private-sector organizations, USAID has contributed to impressive health breakthroughs.

- The USAID Center for Innovation and Impact (CII) applies business-minded approaches to accelerate the research, development, and scale-up of health innovations, leveraging funding from the private sector and other sources. USAID CII has led multiple Grand Challenges for Development, utilizing this open innovation model to mobilize governments, companies, and foundations around important issues, source new solutions, test new ideas, and scale what works. USAID CII is a core partner of the Saving Lives at Birth Grand Challenge program which identifies and accelerates **innovations to protect mothers and newborns in low-resource settings**. Over 120 promising innovations have been advanced through this program, including the Bubble CPAP kit, a simple and affordable innovation that helps preterm newborns breathe by blending oxygen with air from the room at the right balance, all without electricity or compressed air—an innovation that, with some adaptations, may prove invaluable in freeing up ventilators desperately needed for COVID-19 patients. Through Saving Lives at Birth, USAID has leveraged a \$20 million US government investment to attract more than \$150 million in additional funding.
- The Grand Challenge model has also been deployed to great effect to advance innovations for global health emergencies. In 2014, as the largest Ebola epidemic in history unfolded in West Africa, USAID and partners launched the Fighting Ebola Grand Challenge, which attracted 1,500 submissions of potential **innovations to combat Ebola**. International experts reviewed more than 1,500 ideas and rapidly selected 14 promising innovations to support. These included a low-cost battery-powered infusion monitor to deliver IV fluids in settings without reliable electricity and the STAMPS Sensor, a disposable, Bluetooth-enabled, band-aid-like sensor that remotely measures key vital signs—including heart rate, respiratory rate, temperature, and oxygen saturation—of Ebola patients in Ebola Treatment Units.
- In 2016, faced with the growing threat of Zika virus across Latin America, USAID launched the Combating Zika and Future Threats Grand Challenge to crowdsource and advance **innovative approaches to fight Zika and prevent future infectious disease threats**, including a multiplex point-of-care diagnostic test that uses Blu-ray technology to diagnose Zika and dengue from a single drop of blood.
- In response to the growing global reach of the COVID-19 pandemic, USAID issued a Request for Information on March 30 seeking proposals for low-cost, scalable innovations that could support the international COVID-19 response, including new products, service delivery approaches, and information channels. In just 9 days, the agency received 230 responses with proposals for **innovations to combat COVID-19 in low-resource settings**, but funding is urgently needed to invest in these proposals and ensure the pandemic is contained globally.
- In addition to contributing to previous global health emergencies, USAID is also a key partner on R&D for enduring global health threats, such as multidrug-resistant (MDR) TB. USAID has been a critical funder of the STREAM Trial, 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. STREAM Trial Stage 2 is serving as the phase 3 trial for several potential shorter treatment regimens against MDR-TB and is expected to conclude in late 2021. One form of MDR-TB, extensively drug-resistant TB (XDR-TB), has historically had a survival rate below 40 percent, worse than some strains of Ebola. USAID supported Nix-TB, a clinical trial for a new drug, pretomanid, that was approved by the US Food and Drug Administration in 2019 for use as part of a **combination therapy for highly drug-resistant forms of TB**. In clinical trials, the new therapy had a success rate of nearly 90 percent for treating highly drug-resistant TB, offering hope for patients with XDR-TB in the United States and around the world.

- USAID is an important partner in the development of **microbicides** and supported clinical trials for the **monthly dapivirine microbicide ring** for HIV prevention, which was just approved by the European Medicines Agency in July 2020 and is estimated to lower the risk of HIV infection for women by at least one-third.
- USAID supported the development of **child friendly TB medicines** that have been scaled up quickly to address the global burden of pediatric TB, which still takes the lives of 500 children every day. One million treatment courses have already been ordered, and 116 countries and counting—which collectively account for 75 percent of the global pediatric TB burden—have adopted the improved medicines.
- 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®, over 390 million pediatric treatments have been distributed in over 50 endemic countries. This is estimated to have saved the lives of nearly one million children. USAID also continues to invest in the development of safe and effective vaccines and vector control tools to combat the malaria parasite and mosquito vector.
- USAID supported the development of MenAfriVac®, a low-cost **meningitis A vaccine**. Since its introduction in 2010, the vaccine has been introduced in 24 countries in the African meningitis belt, virtually eliminating meningitis A epidemics wherever it has been used. To date, more than 325 million people have been vaccinated with MenAfriVac®, protecting them from devastating disease.
- 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 **m 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.
- In addition to sustaining and growing funding for all USAID Global Health accounts that support R&D, we support an additional \$200 million for USAID to lead the US government’s participation in the Coalition for Epidemic Preparedness Innovations (CEPI). Every other G7 country is currently funding CEPI’s work to develop and manufacture COVID-19 vaccines to ensure fair allocation to countries around the world, and the US will not be fully protected from COVID-19 until the entire world is protected. CEPI’s work to develop and make available these vaccines is critical to helping the world recover from this pandemic and be better prepared for the next global health emergency.

USAID supports work in other critical 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 children.

If funding cuts to USAID’s global health R&D activities on the magnitude proposed in the President’s FY21 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 just approved by the European Medicines Agency in July 2020. 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 urgently needed HIV prevention tools, including promising late-stage HIV vaccine trials as well as cutting-edge research to develop—and make globally available—broadly neutralizing antibodies to protect against HIV infection. Sustainable funding for global health R&D partners such as IAVI has proven to support scientific advances with wide-ranging impact: in response to COVID-19, IAVI is leveraging technology initially developed for an HIV vaccine candidate with funding from the President’s Emergency Plan for AIDS Relief (PEPFAR) to develop a COVID-19 vaccine and therapeutic antibodies, with a particular focus on accessibility in LMICs.
- 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. In 2018 there were 10 million new TB cases, 1.2 million TB deaths among HIV-negative people, and an additional 251,000 deaths among HIV-positive people. An estimated 484,000 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 ZeNix and BEAT-TB trials, and could delay access to new, simpler, and less-expensive options for treating 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 global malaria control and 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, limit the development of next generation bed nets to fight insecticide resistance, slow the development of malaria vaccines, and reverse 15 years of historic progress in the fight against malaria.
- The USAID NTD program has had remarkable success, having delivered 2.6 billion treatments to 1.3 billion people by leveraging \$22 billion in drug donations at a remarkable value to the American taxpayer, with every \$1 in USAID funding leveraging \$26 in drug donations from the private sector. To continue achieving these results and delivering drugs to the populations in need the most effective way, USAID also supports the development of new tool to diagnose, treat, and prevent NTDs. Cuts to the NTD Program would scale back progress towards new tools that could more efficiently leverage US dollars to achieve disease elimination targets.

It is also critical to recognize that, in addition to hobbling global health R&D, cuts to USAID global health accounts would threaten progress in saving lives and supporting healthy populations around the world. Cuts of the magnitude proposed in the President’s FY21 budget proposal could result in some of the following backslides:

- More than 144,000 additional new HIV infections and 419,000 additional HIV-related deaths each year.

- 120,000 additional preventable maternal, newborn, and child deaths.
- Over 20 million bed nets not being distributed, which would mean an additional 40 million people could be at risk of malaria.

We strongly recommend that you fund the Global Health Programs account at the minimum funding levels recommended above and urge USAID 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 the development of new tools and technologies critical to global health—such as diagnostics to identify global threats like COVID-19, 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. Funding for Global Health Security at CDC has also supported the development of National Public Health Institutes in more than 25 countries over the past decade to help streamline public health activities and enable improved disease detection and outbreak response. In many countries, these CDC-supported entities are now leading their country’s COVID-19 preparedness and response activities. The thread connecting all of CDC’s international activities is the agency’s scientific and technical leadership, which makes CDC 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, which has the potential to confirm active measles and rubella infections in the field to stop outbreaks faster.

The **Center for Global Health** (CGH) 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 (FETP), marking its fortieth anniversary in 2020, has trained more than 18,000 disease detectives in 80 countries on how to detect and rapidly respond to infectious disease outbreaks. Since 2005, FETP graduates have participated in 4,000 outbreak investigations and public health emergencies around the world. In recent years, FETP graduates have helped Nigeria contain the 2014 Ebola outbreak, bolstered Uganda’s public health defenses against the recently defeated Ebola epidemic in the neighboring Democratic Republic of the Congo (DRC), and today, 85 percent of FETP programs have trainees supporting their country’s COVID-19 response efforts. CGH also provides critical scientific and technical support to other agencies and interagency global health initiatives such as PEPFAR, the President’s Malaria Initiative, and USAID’s NTD Program. CGH also develops and validates innovative tools for use by US bilateral and multilateral

global health programs and leads laboratory efforts to monitor and combat drug and insecticide resistance—functions essential to ensuring that global health programs are responsive, efficient, and tailored for maximum impact.

In tandem, the **National Center for Emerging Zoonotic and Infectious Diseases** (NCEZID) provides advanced laboratory services, including biosafety labs which enable CDC to study hazardous pathogens, and advanced molecular detection techniques that allow CDC to identify infectious diseases of unknown origin. These capabilities are today being leveraged for the COVID-19 response: NCEZID was instrumental in the development of the first COVID-19 diagnostic used in the US, and their Office of Advanced Molecular Detection is leading the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES) initiative, a new national genomics consortium to coordinate SARS-CoV-2 sequencing across the country that is providing crucial information to track the spread of the virus and identify diagnostic and therapeutic product targets. The center also plays a leading role in the National Strategy for Combating Antibiotic-Resistant Bacteria to prevent, detect, and control outbreaks of antibiotic-resistant pathogens, such as drug-resistant TB, which pose a growing threat to public health. NCEZID also leads important research and development of rapid diagnostic tests for known diseases such as the bubonic plague, rabies, Zika, Ebola, Lyme disease, and parasites; supports early-stage research and development of vaccines for infectious diseases such as Nipah virus and dengue, Lassa, and Rift Valley fevers; and serves as an international reference hub for vector-borne viral and bacterial diseases. As one example of NCEZID's unique global health impact, early in the 2016 Zika outbreak, NCEZID scientists developed a new diagnostic called the Trioplex that detects Zika virus, dengue, and chikungunya in a single test.

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, such as through the development of a low-burden 12-week antibiotic course (3HP) that prevents latent TB infections from becoming active TB infections. Controlling the spread of TB, an airborne disease spread through respiration, bears many similarities to controlling the spread of COVID-19, so the Division of Tuberculosis Elimination has been a critical reservoir of expertise for combatting COVID-19 in recent months. Disruptions due to COVID-19 have made TBTC research significantly more expensive, as trial participants must be exempted from local travel restrictions and delays are experienced in everything from enrollment to supply chains.

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 FY21 budget proposal could result in some of the following backslides:

- Cuts to CDC's TB program will hobble its ability to support primary programs while simultaneously responding to COVID-19. R&D activities under threat include the evaluation of novel diagnostics to detect latent TB infection (LTBI) and clinical research on a CDC-developed LTBI treatment that could 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.
- Proposed cuts of more than 20 percent to CDC’s global HIV/AIDS programming would 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.
- Funding for the Division of Parasitic Disease and Malaria has remained virtually 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. The cut of more than five percent proposed for FY21 would further constrain the Division’s work to ensure that global health programs are responsive, efficient, and tailored for maximum impact through the development and validation of tools for these enduring infectious disease threats.

It is important to stress that cuts to CDC global health accounts in general will have a significant impact on global health security. As COVID-19 stretches health systems around the world to their limit, years of hard-won progress against persistent global health threats like HIV/AIDS, malaria, TB, and NTDs are at risk. Robust funding for all of CDC’s global health functions is essential to mitigate this damage and ultimately ensure that Americans are protected from a range of enduring and emerging health threats. These investments are all interrelated and complementary: CDC’s investments in global health security have laid the foundation for the agency’s global response to COVID-19, and these investments were built on decades of sustained efforts to combat HIV, malaria, and TB; eradicate polio; and prepare for and detect influenza and other pandemic threats. The entire ecosystem of CDC’s global health work requires robust funding if our efforts to defeat COVID-19, prepare for the next pandemic, and protect global health security are to be successful.

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.

Strong, steady growth in NIH’s budget has enabled the agency to develop new technologies to combat COVID-19 at unprecedented speed. There are only two other known coronaviruses that can cause fatal diseases: SARS-CoV, which appeared in 2002, and MERS-CoV, which appeared in 2012. NIH funded and conducted extensive research on both, developing animal models, treatments, and vaccines. These past investments enabled NIH scientists to quickly understand and immediately respond to COVID-19 with focused research and accelerated development of diagnostics, therapeutics, and vaccine candidates. Because of this base of research on coronaviruses, fueled by robust funding, NIH scientists were able to, within two weeks of discovering COVID-19, determine how the virus enters cells; within two months, develop the world’s first COVID-19 vaccine to enter human trials; and within five months, devise a comprehensive strategic research plan and distribute more than 310 research grants averaging \$1.5 million each.

Supported by strong base appropriations and more than \$3.5 billion in emergency supplemental funding (as of July 2020), NIH is leading two public-private partnerships to create new diagnostics and therapeutics for COVID-19:

- The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, which has convened 6 US agencies, 20 private companies, 4 nonprofit organizations, and the European Medicines Agency. To date, this program has been driven by the agency's discretionary funding, an example of how growing base funding for NIH allows for rapid reallocation of resources as health needs emerge and shift.
- The Rapid Acceleration of Diagnostics (RADx) initiative, a program to accelerate development and scale-up diagnostic tests for the United States, which is being run in close coordination with other US government agencies. One part of RADx, RADx-tech, is a national call for innovators to propose ideas for point-of-care COVID-19 diagnostics that are scalable, easy to use, and fast to produce, with the aim of finding innovations that could enable 6 million tests per day in the United States (approximately 2 percent of the US population) by the end of 2020. If successful, many of these innovations could benefit global response efforts. As of mid-July 2020, RADx-tech has received 600 applications and advanced 27 projects to phase 1 clinical trials and one project to phase 2.

While the agency's contributions to COVID-19 are top of mind, NIH has been a leader on R&D for a range of enduring health threats for decades. For example, NIH-funded research has led the development of new and improved 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.

Several institutes and centers serve as hubs for global health R&D at NIH. 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. NIAID scientists, in partnership with Moderna, developed the first COVID-19 vaccine, mRNA-1273, and moved the vaccine to human clinical trials just 65 days after the genome of the virus was shared—a record far shorter than any previous vaccine development timeline.

Beyond COVID-19, NIAID has contributed to several game-changing global health innovations. 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. At the 2018 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 clinical research demonstrating that a combination of two newer drugs, bedaquiline and delamanid, could be safely taken together to treat drug-resistant TB in HIV-positive and HIV-negative individuals. NIAID also 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 carried out by the Institute amid the recent outbreak in eastern DRC. The technology underpinning this treatment is also being used to develop new potential therapeutics for COVID-19. NIAID also supported the development and testing of investigational Ebola vaccines used to stem the eastern DRC 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.

The **Fogarty International Center (FIC)** serves as a critical link between researchers in the United States and researchers in more than 100 countries. FIC strengthens international research and laboratory capacity, facilitates global research partnerships, improves surveillance of emerging infectious diseases, and trains scientists who make critical contributions to long-standing global public health challenges such as HIV/AIDS and emerging threats like antimicrobial resistance, Zika, Ebola, and COVID-19. FIC is facilitating critical international clinical trials for many NIH COVID-19 initiatives, such as RADx and ACTIV. FIC-trained scientists embedded in scientific research agencies and ministries of health around the world are now on the frontlines of the COVID-19 response. With less than one-quarter of one percent of the total NIH budget, FIC delivers significant returns for American and global health. Progressively increasing FIC’s base budget would allow them to pursue a wider range of research priorities with extramural partners. To better support the full range of NIH institutes and centers critical to COVID-19 and other global threats, GHTC joins other advocacy organizations in calling for an additional \$10 million to be appropriated to FIC in each of the next five fiscal years, which would support sustainable growth and long-term planning in pursuit of its mission of building research capacity in partner 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 FY21 budget proposal could result in some of the following backslides:

- Proposed cuts of more than 7 percent to NIAID will threaten progress in basic research for neglected and infectious diseases; limit pioneering research on vector-borne diseases that is pivotal to developing a Zika vaccine and innovative antimalarials; would limit research needed to develop new HIV/AIDS vaccine technologies aimed at stopping the virus before it can enter human cells; and would affect progress in developing new tools against new and emerging infectious disease threats beyond COVID-19.
- A proposed cut of nearly 9 percent to FIC will affect critical research partnerships overseas that have been vital to addressing COVID-19, mitigating other global health security threats such as 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 FIC.

Biological Advanced Research and Development Authority (BARDA)

Over the past decade—and to an unprecedented extent since the emergence of COVID-19—BARDA has played a critical role in advancing global health R&D by accelerating the development of medical countermeasures (MCMs) for a range of health threats. **However, funding for the agency through base appropriations has not reflected this growing mandate.** BARDA was founded in the aftermath of the 2001 anthrax attacks and as such has had a legacy of focusing primarily on *man-made* chemical, biological, radiological, and nuclear health threats, despite the fact that its structure is also ideal for

advancing MCMs for *naturally occurring* threats such as emerging infectious diseases (EIDs), pandemic influenza, and antimicrobial resistance (AMR). In fact, to date, **most of BARDA's work on two recent naturally occurring threats, Ebola and Zika, was advanced through one-time emergency supplemental appropriations.** Increased funding for the full range of health threats—along with a specific, protected funding line for EIDs, a move advocated by GHHC during the reauthorization of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019—could have supported a larger portfolio of medical countermeasures for pandemic threats like coronaviruses.

Indeed, at the outset of the COVID-19 outbreak, as agencies like NIH announced large investments in COVID-19 research in early January, BARDA's then-director, Dr. Rick Bright, publicly stated that his agency did not have resources on hand to contribute to COVID-19 R&D. Several weeks passed before BARDA announced a Market Research Initiative to identify MCMs with the potential to help address the outbreak. The first dedicated funding to support BARDA's advancement of COVID-19 MCMs did not arrive until the Coronavirus Preparedness and Response Supplemental Appropriations Act was passed in March. Delays in utilizing the full capability of partners like BARDA because of uncertain or insufficient funding cost lives in the COVID-19 pandemic, and, if not addressed by Congress now, will cost lives in the next pandemic. Once BARDA received supplemental funding for COVID-19, it fully engaged its unique expertise in partnering with the private sector to bring medical countermeasures that lack robust commercial markets through late-stage product development. By July of 2020, BARDA had helped advance at least 46 promising innovations against COVID-19, including six of the world's most promising vaccine candidates.

COVID-19 is just the latest in a series of naturally occurring health threats BARDA has been tasked with tackling. Between 2015 and 2017, BARDA helped advance at least three Ebola vaccine candidates, at least six diagnostics for Zika, and at least five Zika vaccine candidates. 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 clinical trials conducted in the DRC. BARDA has also worked on a broad-spectrum antiviral called galidesivir, which has the potential to treat a variety of pathogens, including Ebola, Marburg, yellow fever, and Zika, and is now being tested in clinical trials against COVID-19. However, as BARDA's work on Ebola and Zika was funded through emergency appropriations, **sustainable increases in base funding for naturally occurring threats are needed to fully engage BARDA's capabilities to develop tools for emerging infectious diseases, pandemic influenza, and antimicrobial-resistant pathogens**—health threats for which little commercial incentive exists and areas where BARDA's unique end-to-end product development capabilities are sorely needed.

Among these needs for naturally occurring threats, **increased dedicated funding is also needed for AMR initiatives at BARDA**, including to support the broad spectrum antimicrobials program and the CARB-X effort to leverage public-private partnerships to develop products that directly support the government-wide National Action Plan for Combating Antibiotic-Resistant Bacteria. This effort has been successful in developing new FDA approved antibiotics and other therapeutics, diagnostics, and vaccines to prevent, diagnose and treat resistant infections.

Despite this progress, the pipeline of new products in research and development is insufficient to meet patients' needs. Increased dedicated funding for AMR initiatives is needed to prevent the collapse of the antibiotic pipeline. The ensuing rise of a post-antibiotic era would threaten global and national health security as we lose many modern medical advances that depend upon the availability of antibiotics, such as cancer chemotherapy, organ transplants, and other surgeries. TB is already the leading cause of deaths globally from AMR, and our progress against TB is at risk as drug resistance intensifies. Illness

from respiratory viruses, like COVID-19 or influenza, brings significant risk of secondary bacterial infections, particularly for patients in the ICU and those requiring ventilators. There is already early evidence of secondary bacterial infections affecting COVID-19 patients. These concerning trends evidence the need for increased dedicated funding for BARDA's AMR initiatives.

Today, as COVID-19 continues to wreak havoc on health systems and the global economy, we are at a peak of the boom-and-bust cycle of pandemic preparedness investments. BARDA has been appropriated \$6.5 billion to advance medical countermeasures for COVID-19 across the first four COVID-19 emergency supplemental funding packages—more than elevenfold its base FY20 appropriation—and one proposal under consideration for the next supplemental funding package dedicates another \$20 billion to BARDA's COVID-19 work. This emergency funding is filling a critical gap that could have been proactively addressed with more consistent and forward-thinking investment in BARDA's capabilities to advance products for EIDs and other naturally occurring threats.

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 FIC. We support the minimum funding levels recommended above for CDC: at a moment when public health is in the spotlight as never before, 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 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—is today significantly contributing to our nation's response to COVID-19, but this authority must be supported with robust base appropriations for all naturally occurring infectious disease threats, rather than a continued reliance on emergency supplemental funding packages as new threats emerge.

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 LMICs are exposed to 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 and an important role in malaria vaccine development. Nearly all the most effective and widely used antimalarials were developed in part by US military researchers, a remarkable accomplishment. With the latest generation of malaria medicines increasingly facing drug resistance, however, there is an ongoing need for medicines to evolve and for the development of an adult vaccine to adequately protect deployed servicemembers, for whom taking prophylactic drugs at regular intervals is difficult. We strongly encourage funding for 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. Development of the world's first malaria vaccine (RTS,S/AS01)—currently in pilot implementation in parts of Ghana, Kenya, and Malawi—traces back to the work of WRAIR and GSK in the 1980s. The RTS,S vaccine has now reached more than 300,000 children across the three countries.

DoD also supports research on global health security threats. For example, DoD's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND) is funding research on INOVIO Pharmaceutical's INO-4800 DNA-based COVID-19 vaccine candidate, which can be rapidly manufactured, remain effective for up to one year in room-temperature storage, and delivered with a needleless device. In addition, WRAIR is developing the Spike Ferritin Nanoparticle (SpFN) COVID-19 vaccine candidate which will begin clinical trials in September of 2020. DoD's unique capabilities in developing health tools designed for use in austere settings make it an invaluable player in the global health R&D ecosystem. Additional investment in DoD's COVID-19 R&D efforts will support the development of tools that will work everywhere in the world where the pandemic persists—even after the US has successfully contained it within our own borders.

COVID-19 is just the latest in a series of pandemic threats DoD has addressed through its R&D capabilities. WRAIR led the first clinical trials for a Marburg vaccine developed by 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.

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.

DoD's global health R&D programs often directly benefit Americans at home. DoD's COVID-19 vaccines may be deployed in the United States, and past innovations, such as thermo-stabilization technologies to improve vaccine supply chains, have improved public health and saved lives. These types of technologies increase efficiency for health systems around the world and in the United States.

As you consider 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 critical to support infectious disease research at WRAIR, NMRC, and JPEO-CBRND, 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** compared to continued spending to treat complicated, costly health conditions and emergency spending to counter global pandemics:

- **Investments in COVID-19 innovations for low-resource settings**, including diagnostics, therapeutics, and vaccines, will lead to incalculable savings if they effectively stem the pandemic and prevent future, recurring outbreaks in the United States.
- **Before COVID-19, large-scale disease pandemics were estimated to potentially cost the global economy more than \$60 billion a year**, while an investment in **R&D to prevent these pandemics was estimated to cost only \$1 billion per year**. Today, it is projected that COVID-19 is costing the global economy more than \$375 billion *per month*. We must continue to invest in innovations to recover from COVID-19 and prevent future 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 50-cent vaccine to combat Meningitis A**. By the end of 2020, the vaccine is **predicted to have saved \$9 billion** in treatment costs.

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. We stand ready to work with you to advance US leadership in global health and global health innovation, and we ask that support for global health R&D not come at the expense of other humanitarian assistance and development accounts. At this time of crisis, the Administration must make forward-thinking choices to respond to the emergency before us and draw on the painful lessons emerging from it to ensure that we are primed and ready for the next health threat—while also committing to continue progress against the full range of global health challenges.

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,



**Elizabeth Glaser
Pediatric AIDS Foundation**
Fighting for an AIDS-free generation



