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

September 17, 2024

Dear Director Young:

As members of the Global Health Technologies Coalition (GHTC)—a group of 50 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools to 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 in the fiscal year 2026 (FY26) budget request.

In addition to building the ecosystem that helps to ensure Americans' health and security, investing in global health innovation also yields significant domestic economic benefits, including remarkable job creation, economic advantages, and a flourishing technology sector propelled by US dollars and expertise. After analyzing the data, GHTC and our partners at Policy Cures Research released a report quantifying the return on investment (ROI) of US funding for global health R&D over the past 16-plus years. Highlights of this ROI analysis include:

- More than **600,000** new jobs in the United States.
- A direct influx of more than **$104 billion** into the economy.
- A separate and additional **$102 billion** into the economy from basic-science-related global health research.
- And finally, an estimated **$251 billion** that will be infused into the economy from future innovations underpinned by the past 16 years of investment and invention.

Broadly, the US government agency network that supports global health R&D and the above ROI includes **the Department of State; the US Agency for International Development (USAID); the Department of Health and Human Services, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Advanced Research Projects Agency for Health, and the Biomedical Advanced Research and Development Authority (BARDA); and the Department of Defense (DoD).**

In this letter, we aim to provide an overview of the global health R&D ecosystem within the US government, detailing how this crucial work is accomplished and highlighting the unique roles of each component in the global health R&D chain. Thanks to these distinctions and effective interagency collaboration, the United States remains the world leader in global health R&D, a position we can maintain by sustaining and building on our investments during an era marked by pandemics and competing geopolitical models for development support.

The US global health R&D apparatus

Our historical investments and enduring legacy as a champion of global health diplomacy underscore the essential nature of US funding for the development and deployment of new vaccines, drugs, devices, diagnostics, and other health technologies. This support is crucial for addressing the world's greatest health challenges—achieving an AIDS-free generation; ending malaria, tuberculosis, neglected tropical

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diseases, and preventable maternal and child deaths; making progress against antimicrobial resistance (AMR); and preventing future outbreaks of emerging infectious diseases.

Agency	Number of Approved Technologies Supported	Number of Technologies Supported Currently In Late-Stage Development
USAID	20	40
NIH	46	217
CDC	17	19
DoD	19	64
BARDA	7*	14

Figure 1. Includes only technologies for neglected diseases and emerging infectious diseases except COVID-19. Also excludes products for sexual & reproductive health.

**If COVID-19 technologies were included, BARDA would have an additional 45 in the "Number of Approved Technologies Supported" column.*

As outlined in our ROI report, since 1999, US support has led to the development of 67 approved global health technologies (excluding COVID-19-related technologies), representing just over a quarter of all approved global health technologies created worldwide during this period. Figure 1 highlights how these technologies have received support from multiple corners of the US government to reach approval, a notoriously difficult task. Looking ahead, there are 579 technologies in late-stage development worldwide, with the US government supporting 261 (45 percent) of them through US interagency collaborations, as shown in Figure 1.

The United States' track record of successfully developing lifesaving drugs, vaccines, microbicides, diagnostics, and vector control products is a testament to the efficacy and collaboration of the US government's network of global health R&D agencies. In the Appendix of this letter, we will delve into each agency's contribution to global health R&D, providing detailed examples and descriptions. Here is a quick guide:

- **USAID** supports the development, introduction, and scale-up of urgently needed drugs, vaccines, diagnostics, and other technologies to address the unmet health needs of people in the world's poorest places. The agency specializes in late-stage clinical research and implementation research and is the only US agency with a mandate to focus on global health *and* development.
- **NIH** advances basic, applied, and clinical research across a range of global health areas and products. NIH excels at basic and early-stage biomedical research, unlocking scientific discoveries that can later be translated into lifesaving global health technologies by the private sector, nonprofits, and other US agencies.
- **CDC** focuses on the R&D of new diagnostic, prevention, and surveillance technologies for global health security at home and abroad. CDC also evaluates the effectiveness of tools, especially diagnostics, that are already in use to determine future R&D needs.
- **DoD** supports R&D for infectious diseases, AMR, and other health conditions that pose a risk to US national security and service members stationed abroad. Additionally, because DoD focuses on producing health tools for austere settings like the battlefield, the tools it advances are often well-suited for use in low-resource communities worldwide.
- **BARDA** works with industry and other partners to bridge the "valley of death" between basic research and product development, where R&D efforts without a market most often fail. BARDA's mandate is to protect Americans against threats to public health, including emerging infectious

diseases, pandemic influenza, and AMR—though the technologies it supports often have wider global health applicability.

This network is especially critical when considering the inevitability of future pandemics. In the recent past, the successful R&D of medical countermeasures to fight novel pathogens and outbreaks was built on preexisting research and technological advancements supported by past investments in global health R&D at USAID, NIH, CDC, DoD, and BARDA. This has been true for every new strain of influenza; coronaviruses like SARS, MERS, and the virus that causes COVID-19; and deadly hemorrhagic fevers like Ebola and Marburg. Without investment today, we will be ill-prepared for tomorrow.

Why these investments matter

Our recent experience with COVID-19 has underscored two central truths for future global health R&D investments. First, R&D must account for the needs of all settings, including those with inconsistent or limited access to electricity, sanitation, health care expertise and workforce, and refrigeration. The inequitable distribution of tools designed for diverse settings to prevent and treat COVID-19 has inflicted deep cuts in the global economy and health systems. Second, the unprecedented pace of scientific progress for COVID-19 R&D demonstrates how quickly science can advance toward eradicating poverty-related and neglected diseases with greater and more focused investment. In the United States, focused investment enabled progress toward at least 98 health innovations, including diagnostics, therapeutics, vaccines, and medical devices.

COVID-19 showed us that protecting the well-being of Americans requires a globally focused, whole-of-government approach. Purposeful and coordinated investment in global health R&D is critical to both combating health threats abroad and promoting global health equity and security. Health crises abroad often quickly escalate into health crises at home, as evidenced by the rise and spread of dengue cases in the Americas (3,290 cases this year in the United States), the global mpox outbreak, the proliferation of H5N1 across US dairy farms, drug-resistant infections in conflict zones, and the still-recent Zika and Ebola epidemics. Furthermore, as the planet warms and climate change restructures habitable environments for disease vectors like mosquitoes—as seen through last year's locally transmitted cases of malaria in Maryland, Florida, and Texas—global health threats are spreading.

The global health community is urging funding increases for core global health programs in FY26—both to protect progress made against historic public health challenges worldwide and to treat and mitigate emerging health threats. **So much has been done globally to achieve our ambitious goals for disease eradication, but new geopolitical and environmental challenges have also emerged, and the disease landscape has changed. With that in mind, the United States must double down on its global**

health investments and maintain its international leadership as a bastion for global health innovation. GHTC's minimum and recommended funding levels for FY26 are as follows:

(IN MILLIONS)	FY24 Omnibus	FY25 President's Budget Request	House FY25	Senate FY25	FY25 RECOMMENDED	**FY26 RECOMMENDED**
USAID						
NEW: GLOBAL HEALTH R&D FUND (SIGHT FUND)	N/A	N/A	N/A	N/A	N/A	**$250**
HIV/AIDS	$330	$330	$330	$330	$350	**$350**
MALARIA	$795	$795	$800	$795	$925	**$925**
MATERNAL AND CHILD HEALTH	$915	$940	$915	$940	$1,150	**$1,180**
NEGLECTED TROPICAL DISEASES	$114.5	$114.5	$114.5	$114.5	$125	**$125**
NUTRITION	$165	$160	$172.5	$165	$300	**$300**
TUBERCULOSIS	$394.5	$394.5	$394.5	$394.5	$1,000	**$1,000**
GLOBAL HEALTH SECURITY	$700	$900	???	$730	$1,000	**$900**
STATE DEPT.						
PEPFAR	$4,395	$4,395	$4,395	$4,395	$5,140	**$5,145**
GLOBAL FUND	$1,650	$1,190	$1,250	$1,200	$2,000	**asking the U.S. to contribute the full 1/3 of the next replenishment**
CDC						
CENTER FOR EMERGING AND ZOONOTIC INFECTIOUS DISEASES	$760.27	$780.77	$780.77	$805	$900	**$900**
GLOBAL HEALTH CENTER	$692.8	$692.8	$563.9	$697.6	$1,002.3	**$1002.3**
OF WHICH GLOBAL PUBLIC HEALTH PROTECTION	$293.2	$293.2	$293.2	$296.7	$456.4	**$456.4**

	FY24 Omnibus	FY25 President's Budget Request	House FY25	Senate FY25	FY25 RECOMMENDED	**FY26 RECOMMENDED**
OF WHICH GLOBAL TUBERCULOSIS	$11.7	$11.7	$11.7	$11.7	$21	**$21**
*OF WHICH PARASITIC DISEASES AND MALARIA	$29	$29	$29	$30	$40	**$40**
NIH						
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$6,562.28	$6,581	**$6,631	$6,692.3	$7,840.25	**$7,840.25**
OFFICE OF AIDS RESEARCH	-	-	-	-	$3,953	**$3,953**
FOGARTY INTERNATIONAL CENTER	$95.16	$95.16	$95.16	$95.16	$116.1	**$116.1**
BARDA	$1,015	$970	$1,100	$1,070	-	**-**
NEW: EMERGING INFECT. DISEASES LINE	$10	-		$10	$775	**$775**
AMR IN ALL ACCOUNTS	-	-			$500	**$500**
ARPA-H	$1,500	$1,500	$500	$1,500	Robust funding for global health R&D	**Robust funding for global health R&D**
DOD	-	-			Robust agency-wide funding for global health R&D	**Robust agency-wide funding for global health R&D**

Notes:

*CDC's Division of Parasitic Diseases and Malaria has shifted under the National Center for Emerging and Zoonotic Infectious Diseases from Global Health Center, but the budget line has not yet changed.

** This is the sum allocation for the proposed National Institute of Infectious Diseases and National Institute on

the Immune System and Arthritis. These are the two institutes that House Republicans proposed creating by splitting NIAID.
Fiscal year 2024 (FY24)
Fiscal year 2025 (FY25)
Fiscal year 2026 (FY26)
President's Emergency Plan for AIDS Relief (PEPFAR)
The Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)
Supporting Innovative Global Health Technologies (SIGHT)
Centers for Disease Control and Prevention (CDC)
Biomedical Advanced Research and Development Authority (BARDA)
Advanced Research Projects for Health (ARPA-H)
Research and development (R&D)
Department of Defense (DOD)

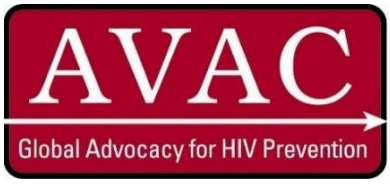
Beyond the legacy funding lines GHTC advocates for across the US government, we have been fierce advocates for a new global health R&D budget line and program area at USAID that would act as a disease-agnostic, flexible, and catalytic fund to infuse new funding into R&D efforts to close the biggest gaps in our global health toolkit and save more lives more quickly. A bipartisan bill known as the Supporting Innovative Global Health Technologies (SIGHT) Act, which would lay the foundation for the creation of such a fund, was introduced in the House of Representatives in November 2023. The SIGHT Fund idea has also received support from the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies through its recent fiscal year 2025 bill report that would require USAID to submit a feasibility report to Congress on implementation of the SIGHT Fund.

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. The administration must make forward-thinking choices to respond to the current health threat landscape and draw on the painful lessons learned from past emergencies to ensure that we are primed and ready for the next outbreak—while also committing to continue progress against the full range of global health challenges.

Signed,

AMERICAN SOCIETY FOR MICROBIOLOGY

ASTMH
AMERICAN SOCIETY OF TROPICAL MEDICINE & HYGIENE
ADVANCING GLOBAL HEALTH SINCE 1903


AVAC
Global Advocacy for HIV Prevention


BU
Institute for Health System Innovation & Policy


bugworks


CEPI


CHReaD
Fast-tracking health R&D, innovation, and access.


DNDi
Drugs for Neglected Diseases initiative


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


FIND
Diagnosis for all


GARD P


Georgia
Global Health
Alliance


Global Health Council


Global Health
Investment
Corporation


IVCC


INTERNATIONAL
VACCINE INSTITUTE


MMV
Medicines for Malaria Venture


PATH


POLICY CURES RESEARCH.


POPULATION
COUNCIL
Ideas. Evidence. Impact.


PHAU
Public Health Ambassadors Uganda
Prevent • Promote • Protect


results


SABIN
VACCINE INSTITUTE


SAHTAC


SpeakUpAfrica.


TAG
Treatment Action Group


TB Alliance


1DAY
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APPENDIX

USAID

For decades, the 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 fostered impressive innovations for critical health technologies. As seen in the budget chart, the Global Health Technology Coalition's (GHTC's) global health research and development (R&D) advocacy for USAID touches on each of their core Global Health Bureau (GHB) accounts. Below are some examples of how each account has contributed to the global health toolbox:

HIV/AIDS: Supporting research to develop safe, effective, accessible, and acceptable tools for use in low-resource settings, including investigational HIV vaccines and microbicides and a microbicide vaginal ring to prevent HIV infection in women.

Malaria: Supporting the development of vaccines, antimalarials, insecticides, and novel vector control tools, including a promising single-dose drug for preventing relapse of *Plasmodium vivax* malaria, which today includes a crucially important pediatric formulation, and the child-friendly malaria drug Coartem® Dispersible. Since 2009, more than 475 million courses of this medicine have been distributed in more than 50 countries, saving an estimated one million child lives.

Maternal and child health: Developing interventions to help women and children during childbirth in low-resource settings that may not have consistent access to electricity, refrigeration, trained health care workers, or other resources, such as oxygen therapies.

Neglected tropical diseases (NTDs): Supporting the development of drugs and diagnostics, including point-of-care diagnostic tests for schistosomiasis, improved drugs for treating onchocerciasis (or river blindness), and tools to fight dengue and other mosquito-borne diseases that have been deployed from Indonesia to the Florida Keys with promising results.

Nutrition: Innovating solutions to tackle malnutrition—which contributes to more than 40 percent of preventable childhood deaths and a myriad of other health effects—through evidence-based food technology solutions such as micronutrient supplements; fortified foods; and biofortified, nutrient-rich staple food crops.

Tuberculosis (TB): 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; an all-oral, six-month regimen for the treatment of drug-resistant TB; and a new, all-oral treatment regimen, studied through the Centers for Disease Control and Prevention's (CDC's) Tuberculosis Trials Consortium (TBTC) and the National Institutes of Health–sponsored AIDS Clinical Trials Group, which reduces the time it takes to treat drug-susceptible TB from six months to four.

Emerging infectious disease (EID) work done without sustainable funding: Sourcing and scaling up breakthrough innovations to combat EIDs, including COVID-19, Ebola, and Zika. USAID's

Fighting Ebola Grand Challenge—led by the Center for Innovation and Impact—identified 1,500 innovative technologies to advance the fight against Ebola and advanced 14. One of these technologies is a low-cost, battery-powered tool used during both the Ebola and COVID-19 responses that manages the flow rate of IV treatments with a simple gravity system, replacing the need for expensive, difficult-to-use infusion pumps.

In March 2020, USAID issued a request for information for proposals for low-cost, scalable innovations that could support the international COVID-19 response. It received hundreds of proposals, but without dedicated funding to advance and scale them, USAID made limited investments despite the enormous scale of global need. **This and other gaps in dedicated funding to combat the EIDs of yesterday, today, and tomorrow led GHTC to home in on the idea of creating a new catalytic fund at USAID for disease-agnostic global health R&D.**

Through an analysis of USAID's annual reports on health-related R&D, we found **USAID's spending on global health R&D has stagnated, shrinking as a proportion of total global health spending**. Now at less than 2 percent of overall US global health investments through USAID and the Department of State, funding used for global health R&D has been far outstripped by the need for new tools amid growing antimicrobial resistance (AMR), shifting disease burdens, and emerging disease threats. This shrinking spending is a symptom of limited resources and the disease-specific, siloed nature of funding at GHB, which requires program leads to not only decide between prioritizing immediate impact over innovation and long-term progress but also limits them from funding multipurpose products that extend across multiple disease areas or from pivoting as health emergencies arise.

For these reasons, for fiscal year 2026 (FY26), GHTC proposes the creation of a new USAID Supporting Innovative Global Health Technologies (SIGHT) Fund with an initial appropriation of $250 million. The SIGHT Fund would be a new and complementary source of flexible funding for global health R&D that would:

- Increase the net proportion of spending on R&D within the GHB without siphoning off funds from disease-specific program offices.
- Provide more flexibility and predictability for USAID program managers who make R&D investment decisions and shift the risk burden of these investments away from programs already stretched thin, allowing them to make bolder, more forward-thinking R&D investment decisions.
- Enable greater investments in cross-disease health tools, which currently struggle to find support in the disease-specific funding structure of GHB, as well as innovations to address other challenges, such as AMR, which lack a dedicated program office.
- Institutionalize innovation as a core USAID global health priority by creating healthy competition for R&D funding, prompting disease-specific program offices to more frequently and critically reflect on gaps and the innovations needed to fill those gaps to achieve US global health goals.

In parallel, the bipartisan SIGHT Act (H.R.6424) has been introduced in the House of Representatives and exploratory SIGHT Fund language has been introduced into the Senate's fiscal year 2025 Labor, Health and Human Services, Education, and Related Agencies appropriations bill, which indicates that authorizers and appropriators alike are interested in the role that the SIGHT Fund could play in changing the global health technologies landscape.

In addition to standing up this new R&D funding mechanism and maintaining support for existing bilateral health programs advancing health innovations, in FY26, USAID should continue to partner with global institutions supporting health innovation for pandemic preparedness such as the Coalition for Epidemic Preparedness Innovations and the World Bank's Pandemic Fund.

As USAID works to implement its global health R&D strategy, it should continue to delineate bilateral investments in global health R&D and investments through outside partners. Furthermore, to improve transparency, the congressionally directed annual reports on this strategy should continue to include specific funding amounts dedicated to research and product development by each program; specific information about health product development goals and timelines; details about USAID's 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 providing insight and transparency into how USAID thinks strategically about R&D investments. In recent years, however, these reports have not consistently been made public—a trend that should be corrected to enable transparency and foster open collaborations among global health R&D stakeholders.

To be clear, a core tenet of this proposal is that the SIGHT Fund supplements, rather than supplants, existing funding and partnership models for global health innovation across GHB. As health challenges persist in multiple arenas, **GHTC strongly recommends funding the Global Health Programs account at or above the minimum funding levels noted in the table above, urging USAID to invest in R&D for new global health innovations in each of the disease and condition areas within the account and support the creation of a new SIGHT Fund to center innovation as a core global health priority and enable progress toward desperately needed global health tools.**

HHS

Institutions within the Department of Health and Human Services (HHS)—including **CDC, the National Institutes of Health (NIH),** and **the Biomedical Advanced Research and Development Authority (BARDA)**—make major contributions to the development of new global health technologies.

CDC

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 Ebola and even the bubonic plague. 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. Recently, the CDC released its Global Health Strategic Framework (GHSF), which provides the public and appropriators with better insight into how CDC "builds, executes, and evaluates its work at the country level and through global programs that the agency implements across countries and regions." CDC sees the framework as the new standard for how it carries out global health security by aligning country needs to one of the CDC's "core capabilities," which include data and surveillance; laboratory; workforce and institutions; prevention and response; innovation and research; and policy, communications and diplomacy.

GHTC's advocacy focuses on CDC's **Global Health Center (GHC) and National Center for Emerging and Zoonotic Infectious Diseases (NCEZID).** GHC provides expertise on immunizations, disease eradication,

and public health capacity-building around the globe through its Divisions of Global HIV & TB, Global Public Health Protection, and Global Immunization. Among the far-reaching and high-impact work of GHC, one main priority is to "research, develop, and evaluate new tools and approaches to combat global health threats." As a global hub for infectious disease research, GHC is uniquely equipped to develop and validate tools for disease surveillance and diagnosis. For example, CDC has developed an HIV rapid test that can diagnose HIV in minutes and distinguish recent from long-standing HIV infections. This test, now commercialized by two manufacturers, is being integrated into routine HIV testing services in 17 US President's Emergency Plan for AIDS Relief (PEPFAR)-supported countries to establish a real-time HIV surveillance and response system. To that point, GHC operates in some countries where USAID does not have a presence, extending the reach of US global health programming and providing critical scientific and technical support to other agencies and interagency global health initiatives, such as PEPFAR and USAID's NTD Program.

Funded under GHC but sitting in NCEZID, the **Division of Parasitic Diseases and Malaria (DPDM)** works to protect Americans and those living abroad from malaria and other parasitic diseases that can cause blindness, malnutrition, and disfigurement. DPDM provides parasitic lab capabilities and scientific expertise for the United States and the world. DPDM laboratories have led to the development and implementation of a multiplex-based serologic test that allows for the detection of antibodies and numerous antigens from a single fingerstick blood sample. This multiplex serological assay facilitates integrated surveillance for parasitic and other infectious diseases and can also be used to evaluate vaccine coverage in a population. Additional funding requested in FY26 for DPDM is essential for course-correcting a long-stagnated budget and resourcing the division to manage a growing domestic and global workload supporting innovation. Not to mention, due to last year's domestic malaria outbreak and other parasitic disease outbreaks in the United States, there has been a necessary focus on laboratory readiness and integrating genome sequencing techniques to support case investigations. This focus requires increased operational costs that must be covered in future appropriations.

Beyond DPDM, **NCEZID** provides advanced laboratory services and molecular detection techniques that enable researchers to understand and monitor infectious diseases, identify new infectious diseases of unknown origin, and develop new diagnostic tests and other tools to combat global health challenges. For example, NCEZID developed Trioplex, a diagnostic that can differentiate between Zika, dengue, and chikungunya viruses, and supports early-stage R&D of vaccines for infectious diseases such as Nipah, dengue, Lassa fever, and Rift Valley fever, as well as CDC's development of a new, rapid, and cost-effective test to detect the invasive malaria vector *Anopheles stephensi*.

Additionally, the NCEZID Office of Advanced Molecular Detection uses DNA sequencing and advanced computing technologies to study infectious diseases, revealing insights about their basic biology that are critical to developing diagnostics, drugs, and vaccines. The office plays a leading role in the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria to prevent, detect, and control outbreaks of antibiotic-resistant pathogens—including drug-resistant TB—that pose a growing threat to public health.

Lastly, **TBTC,** a collaboration between CDC and international partners, conducts research to improve TB diagnosis, management, and prevention. Even though TBTC is operated by the Division of Tuberculosis Elimination within the National Center for HIV, Viral Hepatitis, STD, and TB Prevention, a domestic CDC office, it relies on CDC's global activities and international presence to be successful. Over 20 years, TBTC trials with more than 16,000 participants have led to new TB technologies and improved treatment guidelines, halving the duration of prevention and treatment regimens. Ongoing and planned TBTC studies will further optimize TB prevention regimens, extend their benefits to children, and help

accelerate the development of the next generation of TB drugs and even shorter treatment regimens for TB. Funding for TB R&D in CDC's domestic and global accounts and at other US agencies, including NIH, USAID, BARDA, and the Advanced Research Projects Agency for Health (ARPA-H), should be increased to reach the United States' fair share funding target as identified at the 2023 United Nations High-Level Meeting on TB, which would amount to just 0.15 percent of US gross domestic expenditure on R&D.

Investments in CDC's global activities have a direct impact on American global health security. As health systems around the world are stretched 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.

NIH

NIH excels at basic and early-stage biomedical research, unlocking scientific discoveries that can later be translated into lifesaving global health technologies by the private sector, nonprofits, and other US agencies. While NIH primarily facilitates basic research on global health challenges through intramural programs and external grants to universities, nonprofits, and other organizations across the United States, its ongoing investments in clinical trials for HIV/AIDS—and, increasingly, trials for malaria and TB products—also makes it one of the biggest global funders of clinical development in each of these disease areas. Maintaining the integrity of NIH's 27 institutes and centers is crucial to retaining talent, increasing momentum and trust with trial sites, and ensuring the success of ongoing, lifesaving research.

Current and past NIH investments allow for nimble responses. Previous research on SARS-CoV-2 and MERS-CoV, funded by NIH, provided a foundation for quickly addressing COVID-19. Within two weeks of identifying the virus, NIH scientists understood how it enters cells; within two months, NIH developed the first COVID-19 vaccine for human trials; and within five months, the agency created a research plan and distributed more than 310 grants averaging $1.5 million each. NIH also launched two public-private partnerships—the ACTIV and Rapid Acceleration of Diagnostics initiatives—to advance COVID-19 therapeutics and diagnostics, initially funded by discretionary resources and later supported by COVID-19 relief bills. However, these emergency packages of funding hamper NIH's capacity to continue research on the virus that causes COVID-19 and other viruses with pandemic potential. Preparation for health threats on the horizon begins with sustained funding for the health threats of today.

For decades, NIH has been a driver of innovation for a range of enduring global health threats, with several institutes and centers serving as hubs for different elements of R&D.

The **Fogarty International Center (FIC)** plays an important role in accelerating science, partnerships, and technical assistance to advance new technologies for some of the world's most pressing health challenges. With less than one-fifth of one percent of the total NIH budget, the center delivers significant scientific returns for global and American health, forging international partnerships to facilitate truly global research. Many FIC-trained scientists now hold high-ranking academic and government positions around the world and have made critical contributions to long-standing global public health challenges, such as HIV/AIDS and emerging threats like COVID-19, Zika, and Ebola.

Ultimately, FIC investments abroad improve public health in the United States. FIC's investments in scientific capacity globally improve our ability to detect emerging and novel disease threats sooner. The center also creates a platform for partnerships between scientists in the United States and around the world. When FIC investments lead to new tools or interventions designed for low-resource settings,

these innovations can be deployed back in the United States, where they can drive down costs and improve access to health care in rural settings—an exchange known as reciprocal innovation. Progressively increasing FIC's base budget would allow it to pursue a wider range of research priorities with extramural partners. GHTC calls for an additional $20 million to be appropriated to support sustainable growth and long-term planning in pursuit of FIC's mission of building research capacity in partner countries.

For over six decades, most NIH funding for neglected disease R&D has flowed through the **National Institute of Allergy and Infectious Diseases (NIAID)**, which conducts research across a range of global infectious disease threats, including HIV/AIDS, malaria, TB, NTDs, influenza, Zika, Ebola, and COVID-19. NIAID scientists, in partnership with Moderna, developed the first COVID-19 vaccine, mRNA-1273, and advanced the vaccine to human clinical trials just 65 days after the genome of the virus was shared—far quicker than any previous vaccine development timeline.

Beyond COVID-19, NIAID has recently contributed to several major global health innovations:

- NIAID supported, through a public-private partnership, 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 two hours. In comparison, older diagnostic methods can take several weeks.
- 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 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 developed an Ebola treatment, mAb114, which was found to dramatically improve the survival rate of infected patients in a clinical trial carried out amid a recent outbreak in the Democratic Republic of the Congo. The technology underpinning this treatment has also been used in research on therapeutics for COVID-19—illustrating how continued investment in a range of global health challenges helps prime our research infrastructure and scientific knowledge base for emerging threats.
- NIAID established the Antiviral Drug Discovery Centers for Pathogens of Pandemic Concern as part of the Antiviral Program for Pandemics. These centers will work with industry to study viral families with high pandemic potential, develop new drugs that target those viral families, and prepare them for use during future pandemics.
- NIAID and the National Institute of Child Health and Human Development have demonstrated scientific leadership to accelerate the research, development, and implementation of multipurpose prevention technologies for sexual health that are effective, affordable, acceptable, and easy to deliver.

The **Office of AIDS Research (OAR)** has led NIH's groundbreaking work in HIV/AIDS R&D since 1988. 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 estimated that 14.4 million life-years have been gained since 1995 through the use of HIV/AIDS therapies developed through NIH-funded research. Furthermore, the HIV Prevention Trials Network, a worldwide collaborative clinical trials network funded by NIH, is dedicated to the discovery and development of game-changing breakthroughs, including recently FDA-approved long-acting injectable

cabotegravir. Today, as we seek to accelerate progress toward the end of HIV/AIDS in the United States in this decade and stem the tide of HIV/AIDS globally, continued investment in NIH's HIV research will pay dividends by increasing the effectiveness of our prevention and treatment tools—the need for which has increased exponentially as COVID-19 has derailed global goals to end the HIV epidemic. This request is based upon the most recent analysis of need as part of OAR's congressionally mandated fiscal year 2025 Professional Judgment Budget.

GHTC supports strong, steady increases to NIH funding to enable continued progress toward vital R&D targets and vigilance in the global fights against TB, malaria, HIV, and NTDs. From any increase in overall NIH funding, there should be proportionate increases for FIC, NIAID, and OAR.

ARPA-H

ARPA-H is designed to stimulate groundbreaking advancements in biomedical research and health care. Modeled after the Defense Advanced Research Projects Agency, ARPA-H aims to fund high-risk, high-reward projects that could lead to transformative innovations in treating diseases such as cancer, infectious diseases, and neurological disorders. By promoting collaboration across different fields and supporting innovative approaches, ARPA-H intends to speed up the development of new treatments, diagnostics, and technologies. The ultimate objective is to bridge the gap between scientific discoveries and practical applications, thereby improving health outcomes and advancing medical science.

GHTC supports robust appropriations for ARPA-H given the agency's potential to reduce health disparities and inequities in the United States and around the world—as referenced in HHS's announcement of the establishment of the ARPA-H Health Equity, Dissemination, and Implementation Office. We encourage the administration to ensure that ARPA-H programs have global relevance, especially in areas most likely to be neglected by the market, and produce technologies that can operate in many settings, especially settings with limited resources. We also encourage ARPA-H to ensure that researchers from around the globe are able to compete for research projects to ensure that the best ideas are funded, regardless of where they originate.

BARDA

BARDA, within the Office of the Assistant Secretary for Preparedness and Response in HHS, supports the advanced development of vaccines, drugs, and other medical countermeasures (MCMs) to protect Americans against threats to public health, including EIDs, AMR, and pandemic influenza. BARDA works with industry to bridge the "valley of death" between basic research and product development—so-called because many potential medical innovations stall after public funding for basic research drops off but before other public, private, or nonprofit R&D funders pick up later-stage product development efforts. Through unique contracting and incentive mechanisms, BARDA's partnerships ensure promising research is translated into urgently needed medical products by creating commercial incentives for private-sector partners to invest in R&D.

GHTC's advocacy for BARDA revolves around two key priorities: to bolster EID and AMR R&D. Over the past decade—and to an unprecedented extent since the emergence of COVID-19—BARDA has played a critical role in advancing the development of MCMs for a range of health threats, including EIDs, but **funding for the agency through base appropriations has not reflected this growing mandate**. The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 specifically authorized BARDA to implement "strategic initiatives" to develop MCMs against EIDs, pandemic influenza, and AMR. BARDA, however, was established in response to the anthrax attacks, and this historical legacy has

bent the agency toward developing MCMs for man-made threats over naturally occurring and infectious disease threats.

EIDs: Through emergency supplemental appropriations, BARDA has made a significant impact during global health emergencies. 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, with 11 FDA-approved products for filoviruses like Ebola and Zika. 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 was tested in clinical trials against COVID-19. In response to COVID-19, BARDA has supported at least 127 products, including vaccines, diagnostics, therapeutics, and devices, and devices through $25 billion in emergency supplemental funding appropriated through COVID-19 relief bills, which is more than 43 times its base fiscal year 2020 appropriation.

As we have all now seen firsthand, the delay between the emergence of a health threat and the development of appropriate tools to combat it costs lives and disrupts the most fundamental functioning of our global society. We cannot let this cycle repeat itself. To fully engage BARDA's capacity to develop tools for naturally occurring EIDs—including Disease X, pandemic influenza, pan-coronaviruses, and antimicrobial-resistant pathogens—the agency needs significant increases to its base funding for these critical challenges. The administration should propose to Congress a new annual appropriation of $775 million to grow and sustain BARDA's work on EIDs. Creating a robust, protected funding line for this work would bolster BARDA's capacity to support the development of MCMs for the full range of priority infectious disease threats identified by health experts as most likely to cause the next pandemic or have an impact on US health security.

AMR: BARDA should also prioritize funding for tools to combat AMR. Research published in *The Lancet* in January 2022 estimated that in 2019, more than 1.27 million deaths could be attributed to AMR. This number is only expected to grow without greater investment in R&D and prevention. BARDA has already made significant contributions to the global effort to curb AMR, including through the founding of the Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), as directed by the U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria. Since 2017, CARB-X has supported 93 R&D projects in 12 countries. Of these, 18 projects have already advanced into or completed clinical trials; 12 remain active in clinical development, including late-stage clinical trials; and two diagnostic products have reached the market. Indeed, BARDA is a leader across three critical stages of R&D to combat AMR spread across three programs: preclinical research supported by CARB-X, clinical research funded through the Broad Spectrum Antimicrobials Program, and post-approval funding from the Project BioShield Special Reserve Fund.

Welcoming the renewed commitment to CARB-X of up to $300 million over ten years, GHTC recommends no less than $500 million in funding for BARDA's work on AMR in FY26, including additional funding for CARB-X to ensure that it has adequate resources to launch new funding rounds and replenish a clinical pipeline that the World Health Organization (WHO) recently described as "insufficient" to tackle the challenge of the increasing emergence and spread of AMR. Strong funding should also be provided for late-stage AMR candidates. Both additional

funding to CARB-X and strong funding for late-stage AMR candidates would be in line with US support for the 2022 G7 Health Ministers' Communiqué on AMR.

Future AMR work: To continue this progress across all BARDA programs engaged in AMR, GHTC urges that BARDA's AMR work continue to support highly innovative new classes; new mechanisms of action; and nontraditional alternatives, including support for pediatric indications, multidrug-resistant sexually transmitted infections, and CDC's full list of antimicrobial-resistant threats as detailed in its *Antibiotic Resistance Threats in the United States, 2019* report. The latter includes drug-resistant TB, the leading cause of death globally from AMR. Progress against TB is at great risk as drug resistance grows, potentially faster than new treatments are developed. BARDA currently conducts no research on drug-resistant TB despite its repeated identification as a global health security threat by experts and as a "leading health security threat" to the United States in congressional testimony provided by CDC. Resourcing all these elements of AMR work is critical to preventing a post-antibiotic era that would threaten global health security and reverse antibiotic-dependent medical advances.

DoD

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 low- and middle-income countries 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 most of the healthy adults traveling each year to malaria-affected regions on behalf of the US government, the US military has historically taken the 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 malaria medicines increasingly facing drug resistance, however, there is an ongoing need for medicines to evolve and for the development of an adult vaccine and single-dose preventive therapies to adequately protect deployed service members, for whom taking prophylactic drugs at regular intervals is difficult. Not to mention the prevalence of other similar pathogens like dengue reveals the need for strong investment in multiplex diagnostics—giving our service members quick diagnoses and, thus, quicker treatments.

While focused on protecting and treating the US armed forces, the global health efforts of DoD and its partners include substantial R&D and infrastructure- and capacity-building programs that also benefit countries with limited health care 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. The world's first malaria vaccine (RTS,S/AS01), whose development traces back to the work of WRAIR and GSK in the 1980s, has now reached more than 1 million children across three pilot countries.

We strongly encourage funding for DoD's malaria drug and vaccine development programs to continue despite recent cuts at DoD to significantly reduce and eventually eliminate malaria drug and research funding—a shortsighted move that would risk the loss of world-leading infectious disease researchers, the US government's only bench-to-bedside malaria research capabilities, premier malaria research labs, and an insectary utilized by researchers worldwide. **GHTC urges the administration to make malaria**

R&D for vaccines, easier-to-administer treatments, vector control, diagnostics, and other related technologies a continued DoD priority and to ensure that WRAIR and NMRC are funded for this work at no less than fiscal year 2018 levels.

Malaria is not the only infectious disease threat our military faces. For instance, the DoD has historically funded leishmaniasis research. Leishmaniasis, like malaria, is a parasitic disease and is spread through the bites of small sandflies. DoD has also invested in another critical infectious disease with implications for both US military readiness and global health: HIV/AIDS. For decades, DoD has sponsored 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 in humans. This research holds promise for ending the HIV/AIDS epidemic at home and abroad.

DoD also supports research on global health security threats. WRAIR led the first clinical trials for a Marburg vaccine developed by NIH. Marburg—a deadly cousin of Ebola—is on WHO's list of top emerging diseases likely to cause major epidemics. Throughout the COVID-19 pandemic, as part of Operation Warp Speed (now the Countermeasures Acceleration Group), DoD's Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense and WRAIR were instrumental in advancing research on vaccine candidates. DoD's infectious disease research must be robust. If cuts to the infectious disease research programs continue, the core capabilities of DoD's infectious disease research labs will be weakened, and researchers will be lost. When COVID-19 emerged, DoD leveraged these labs and researchers to address the pandemic by developing a safe and effective vaccine. In the future, these labs will be needed as a warm base to quickly pivot to whatever new threats soldiers may face, but this adaptability requires consistent funding.

Congress should also retain tuberculosis in their list of diseases covered by the Congressionally Directed Medical Research Program's Peer Reviewed Medical Research Program. TB has resumed its status as the largest infectious disease killer globally after surpassing COVID-19 in 2023 and remains a significant concern for DoD because of its potential impact on our armed forces. Each year, more than 10 million people continue to fall ill with TB and an estimated 1.3 million died in 2022 from the infectious disease. Currently, 30 countries are classified as having a high TB burden by WHO based on the number of incident cases of TB and the severity of the disease (incident per capita). These countries include many in which the United States has a large military presence. Furthermore, an estimated 410,000 people developed multidrug-resistant TB in 2022, posing a growing risk to our current methods of treatment and containment.

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, and protect agency-wide funding for global health R&D. It is critical to support infectious disease research at WRAIR, NMRC, and the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense, including their work on chemoprophylaxis, disease surveillance technologies, novel vaccines, and other countermeasures for diseases of military and global health importance.