

April 28, 2022

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

The Honorable Richard Shelby
Vice Chair
Senate Appropriations Committee
Ranking Member
Senate Appropriations Subcommittee on Defense
304 Russell Senate Office Building
Washington, DC 20510

The Honorable Jon Tester
Chair
Senate Appropriations Subcommittee on Defense
311 Hart Senate Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

As members of the Global Health Technologies Coalition (GHTC)—a group of 40 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people—we write to highlight the critical role of US programs that support global health research and development (R&D) and thank you for your support of important R&D at the US Department of Defense (DoD) for tools to protect the warfighter which also have applicability in the broader global health context.

We write to emphasize the importance of DoD's infectious disease research not only in promoting the safety of our servicemembers abroad, but also in supporting US global health efforts to address HIV/AIDS, malaria, tuberculosis (TB), neglected tropical diseases, antimicrobial resistance, and emerging infectious diseases, including COVID-19. This reality is aptly reflected in the motto of the Walter Reed Army Institute of Research (WRAIR), "Soldier Health, World Health." **For fiscal year 2023 (FY23), we respectfully urge the Subcommittee to sustain and protect funding for research to develop new global health technologies at DoD both within the Defense Health Program and the Congressionally Directed Medical Research Program (CDMRP), and where possible target new funds from proposed increases in Defense spending to important infectious disease research that benefits both our servicemembers and vulnerable populations overseas.**

DoD plays a unique role in the advancement of new vaccines, drugs, and health technologies that prevent and treat infectious diseases that many Americans never see up close but that our servicemembers stationed overseas experience alongside local communities. We saw this most recently with DoD's response to the 2014 Ebola outbreak in West Africa. DoD's quick work to advance the development of Ebola vaccines and treatments during troop deployment to West Africa underscores the importance of DoD research for countermeasures to address the many disease threats that may undermine operational effectiveness. The effects of this commitment continue. WRAIR, together with the National Institute of Allergy and Infectious Diseases, conducted phase 1 clinical testing of the rVSV-ZEBOV Ebola vaccine candidate, which was vital to containing the 2018-2020 Ebola outbreak in the Democratic Republic of the Congo (DRC), the second deadliest in history, underscoring the additional

public health benefits of DoD's infectious disease research. It is clear that the new tools developed with US government support will be vital to containing and preventing future outbreaks.

Not only are DoD's R&D efforts for infectious diseases critical to protecting our troops overseas, but they are also important for promoting global health and global health security. Diseases like HIV/AIDS, TB, malaria, and neglected tropical diseases devastate hundreds of millions of people around the world, pose public health threats in the United States, and inhibit the economic growth of our global trading partners. In our increasingly interconnected world, infectious diseases are a plane ride—or mission deployment—away, and research at DoD yields tremendous dividends for saving lives around the world, promoting global growth and development, and ensuring global health security.

In a 2017 analysis, the US Army was identified as a top contributor to the development of FDA-approved vaccines. At the time of analysis, the US Army had contributed to the development of at least 16 different vaccines, second among all organizations only to Merck, which had contributed to 18. This impressive record did not include recent successes, including RTS,S, the world's first malaria vaccine to receive approval from a regulatory authority, and vaccines for COVID-19.

With DOD's historic success in developing vaccines, it was well-prepared to support the race for COVID-19 vaccines. DOD's most influential role was supporting cross-government efforts such as Operation Warp Speed (now the Countermeasures Acceleration Group), which relied heavily on DoD for logistics and contracting support. DoD also worked independently to develop vaccines with specific product profiles. In 2020, DoD sponsored Inovio to develop a DNA-based vaccine that could be delivered through the skin via a needleless device. If the vaccine had been successful, it would have had the advantage of both being stable at room temperature and eliminating the need for syringes and needles, which would have made it highly effective in low-resource settings which lack consistent access to refrigerated storage and health care workers. At WRAIR, DoD has been developing the Spike-Ferritin Nanoparticle (SpFN) vaccine, which may provide broad protection against a range of SARS-CoV-2 variants. A critical component of the SpFN vaccine formulation is an adjuvant called ALFQ, which is an ancestor of malaria vaccine research at WRAIR.

DoD's vaccine development efforts have had high impact against infectious diseases, and the agency has also driven R&D more broadly to advance basic science and the development of other tools such as drugs and diagnostics relevant to global health.

Support for DoD health research is needed for emerging and enduring health threats. Malaria, which threatens the lives of nearly 3.2 billion people in tropical regions around the world, is a significant threat to the operational readiness of the US military. In fact, more person-days were lost among US military personnel due to malaria than to bullets during every military campaign fought in malaria-endemic regions during the 20th century. Thanks to ongoing research at DoD, nearly all the most effective and widely used antimalarials were developed in part by US military researchers. Many antimalarials, however, are at risk of becoming less effective because of growing antimicrobial resistance.

The study of infectious diseases, including malaria, serious bacterial infections, TB, dengue fever, leishmaniasis, and smallpox, has historically been an important component of DoD's medical research programs worldwide. 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, as well as training programs that benefit countries with few resources for health care. **DoD continues to conduct research aimed at developing solutions to global health challenges. For example:**

- The US Military Malaria Vaccine Program (USMMVP), made up of the Naval Medical Research Center Malaria Department and WRAIR Malaria Vaccine Branch, is the world's largest translational research enterprise dedicated to developing a malaria vaccine. USMMVP has led the development of vaccine candidates offering high-level and partial protection against malaria, as well as the discovery of novel protective malaria antigens and new ways to test vaccines prior to going into humans. WRAIR led early clinical development of the RTS,S vaccine in the 1990s and has been involved in the most recent clinical trials of alternative RTS,S regimens. The RTS,S malaria vaccine is the only malaria vaccine approved by a regulatory authority and, to date, is the only vaccine to show a protective effect against malaria for young children. The vaccine is being provided to young children through national immunization programs in Ghana, Kenya, and Malawi as part of a pilot introduction that began in 2019.
- WRAIR first synthesized the antimalarial drug candidate tafenoquine, which received FDA approval in 2018 as a single-dose treatment for the radical cure (prevention of relapse) of *P. vivax* malaria, the first new treatment developed for the strain in more than 60 years. A pediatric, water dispersible version of this treatment, has also recently been approved, further expanding its potential impact.
- The US Military HIV Research Program (MHRP) continues its efforts to develop a safe and effective HIV vaccine. MHRP's partners in Thailand and Uganda are currently involved in a trial to test a promising "mosaic" HIV vaccine designed to address several HIV strains at once, one of two HIV vaccine candidates now in late-stage clinical trials in sub-Saharan Africa.
- DoD programs in leishmaniasis and dengue fever research have led to breakthroughs in treatment for these diseases and vaccines for dengue.
- The Army and Navy overseas medical research laboratories are part of the vital global health research network, and the staff of the infectious disease programs have years of hands-on experience with some of the deadliest global diseases.
- The Defense Advanced Research Projects Agency (DARPA) pioneered technology that has led to electrochemical generators of chlorine that may be able to fulfill a community's needs for effective disinfectants for water or surfaces by using just saltwater and a simple battery source, such as a car or motorcycle battery—an intervention that could have profound health implications for populations in low-resource settings.
- DARPA is working on developing an antibody-based technology that could provide temporary protection against COVID-19. Though not a vaccine, this tool could be a critical transition technology that provides at-risk individuals with protection against the virus for several months while a vaccine is being developed.
- The Defense Threat Reduction Agency (DTRA) is conducting groundbreaking work on vaccine and chemical reagent thermostabilization as well as point-of-care diagnostic tests for infectious diseases, with positive implications for both global health and US military health in low-resource settings.

- DTRA and the Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response are collaborating with external partners to develop a novel antibiotic to treat infections caused by bacteria resistant to currently available tools. DoD is an important partner in the development of new tools to combat antimicrobial resistance, which threatens troop readiness and global health.

The advancement of global health through new innovations is bolstered by DoD's research and support of product development. Only by sustaining commitment to medical R&D will we protect servicemen and women from endemic and emerging global diseases and maintain recent gains in global health.

We urge you to work with DoD to prioritize research and product development for diseases relevant to both troop health and global health within its budget and programming plans, fund infectious disease R&D accounts as robustly as possible, and protect department-wide funding for global health R&D. Specifically, it is critical to support infectious disease research at WRAIR and the Naval Medical Research Center, including their work on chemoprophylaxis, novel vaccines for threats like malaria, disease surveillance technologies, antibiotic development, and other countermeasures for diseases of military and global health importance. We urge you to provide continued oversight to ensure that these vital infectious disease research capabilities that directly support warfighter protection are protected and sustained and consider including language in the Defense bill report directing DoD to sustain investment at no less than FY18 levels in research for chemoprophylaxis, surveillance, vaccine development, and other countermeasures for malaria at WRAIR and the Navy Medical Research and Development Center.

We understand the unique pressures you face in setting priorities for our nation and our military. Infectious disease research protects the lives of our soldiers and millions of people around the world, fosters goodwill that enhances our national security, and creates jobs and economic growth at home. These benefits are unquestionably among the nation's highest priorities.

We stand ready to work with you on these important issues that are essential to achieving our nation's global health and security goals. Please do not hesitate to contact GHTC Executive Director Jamie Bay Nishi at jnishi@ghtcoalition.org if you have questions or need any additional information.

Sincerely,



American Society of Tropical Medicine and Hygiene



AVAC



Boston University Social Innovation on Drug Resistance Program



Coalition for Epidemic Preparedness Innovations



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Pediatric AIDS Foundation**
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Elizabeth Glaser Pediatric AIDS Foundation



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Medicines for Malaria Venture

Medicines for Malaria Venture



PATH



Sabin Vaccine Institute



TB Alliance



Treatment Action Group

Treatment Action Group



Washington Global Health Alliance