

March 18, 2020

The Honorable Richard Shelby Chairman Senate Appropriations Committee Chairman Senate Appropriations Subcommittee on Defense 304 Russell Senate Office Building Washington, DC 20510 The Honorable Patrick Leahy Vice Chairman Senate Appropriations Committee 437 Russell Senate Office Building Washington, DC 20510

The Honorable Richard Durbin Ranking Member Senate Appropriations Subcommittee on Defense 711 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 30 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people—we write to highlight the critical role of US programs that support global health research and development (R&D) and 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, neglected tropical diseases, and emerging infectious diseases, such as Coronavirus Disease 2019 (COVID-19). This reality is aptly reflected in the motto of the Walter Reed Army Institute of Research, "Soldier Health, World Health." For fiscal year 2021 (FY21), 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, 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.

The 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 continues: the Walter Reed Army Institute of Research together with the National Institute of Allergy and Infectious Diseases conducted

Phase 1 clinical testing of the rVSV-ZEBOV Ebola vaccine candidate deployed to help counter the recent Ebola outbreak in the Democratic Republic of the Congo, underscoring the additional public health benefits of DoD's infectious disease research. ERVEBO was used to vaccinate more than 250,000 at-risk individuals. With a 97.5% efficacy rate against the Ebola Zaire virus, this vaccine is highly protective and is now a vital tool for this and future Ebola outbreaks. In the first week of March 2020, the last known Ebola patient in DRC was discharged from a treatment facility, and while the country is in a waiting period before the outbreak can be officially declared over, it is clear that the new tools developed with US government support were vital to the containment of this deadly outbreak.

Not only are DoD's research and development 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, tuberculosis, 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 particular, malaria, which threatens the lives of nearly 3.2 billion people in tropical and poor regions of the world, is a significant threat to the operational readiness of the US military. In fact, more persondays 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.

The study of infectious diseases, including malaria, tuberculosis, dengue fever, leishmaniasis, and smallpox, has historically been an important component of the 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. **The DoD continues to conduct research aimed at developing solutions to global health challenges. For example:**

- The Congressionally Directed Medical Research Program (CDMRP)'s Peer Reviewed Medical Research Program included tuberculosis (TB) as a priority research area from FY16 to FY19, but TB remains a concern for the DoD. Our military's global footprint means servicemembers are posted in regions that experience high rates of TB. For instance, in Europe, where 80,000 troops and dependents are stationed, there were 323,000 cases of TB and 74,000 cases of MDR-TB in 2015. In the Western Pacific region, 74,000 troops and dependents live amidst 1.6 million cases of TB and 100,000 cases of MDR-TB. We are at an unprecedented point in TB research with positive advancements in drugs, diagnostics, and vaccines in development. New technologies are the only way we will successfully eliminate TB, and DoD funding is core to this effort. We respectfully request that Congress return tuberculosis to the list of eligible diseases under the Peer-Reviewed Medical Research Program in FY21.
- Malaria has also previously been included as an eligible disease under CDMRP's Peer-Reviewed Medical Research Program in FY04 and from FY12 to FY18. Malaria is considered a "significant disease of concern" by the US Africa Command Surgeon, and the US military has continued to increase its presence in Africa and Asia, which are primary locations for malaria transmission.

Because servicemembers deployed by the US military comprise most of the healthy adults traveling each year to malarial regions on behalf of the US government, DoD should continue to have a primary role in the development of antimalarial drugs and vaccines. In order to continue protecting our military from its longest-running and deadliest infectious disease foe, we respectfully request that Congress return malaria to the list of eligible diseases under the Peer-Reviewed Medical Research Program in FY21.

- The US Military Malaria Vaccine Program (USMMVP), made up of the Naval Medical Research Center Malaria Department and Walter Reed Army Institute of Research 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. The Walter Reed Army Institute for Research 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 the US Food and Drug Administration (FDA) and, to date, is the only vaccine to show a protective effect against malaria among young children in Phase 3 clinical trials. Pilot introduction of the vaccine in select countries African countries is now underway.
- The Walter Reed Army Institute of Research 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 over 60 years.
- 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 and is 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.
- 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 Advance Research Program 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 salt water 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 is conducting groundbreaking work on vaccine and

chemical reagent thermo-stabilization 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.

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 the Walter Reed Army Institute of Research and the Naval Medical Research Center, including their work on chemoprophylaxis, novel vaccines for threats like malaria, disease surveillance technologies, and other countermeasures for diseases of military and global health importance. We request that you return tuberculosis and malaria to the list of eligible diseases under the CDMRP's Peer-Reviewed Medical Research Program. We also urge you to consider increased support for DoD infectious disease research programs as part of the Administration's proposal to increase DoD funding in FY21. Finally, 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.

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 Director Jamie Bay Nishi at jnishi@ghtcoalition.org or (202) 822-0033 if you have questions or need any additional information.

Sincerely,



American Society of Tropical Medicine and Hygiene



Elizabeth Glaser Pediatric AIDS Foundation Until no child has AIDS.

Elizabeth Glaser Pediatric AIDS Foundation



AVAC



FIND



Global Health Council



International AIDS Vaccine Initiative



Innovative Vector Control Consortium



PATH



Sabin Vaccine Institute



TB Alliance



HarvestPlus



Infectious Diseases Society of America



Medicines for Malaria Venture



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Treatment Action Group

