### Written Testimony Submitted by PATH to the United States Senate Defense Appropriations Subcommittee Regarding FY 2011 Funding for DOD Research and Development June 9, 2010

PATH appreciates the opportunity to submit written testimony regarding Fiscal Year (FY) 2011 funding for global health research and development to the Senate Defense Appropriations Subcommittee. PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, we help provide appropriate health technologies and vital strategies that change the way people think and act.

We wish to take this opportunity to recognize the specific and unique areas of expertise that the Department of Defense (DOD) brings to bear in advancing innovation that ensures that people in low-resource settings have access to life-saving interventions and technologies. Through DOD, the US Government is able to apply this core capacity to improving health throughout the world.

The global health research efforts of DOD respond to diseases many Americans may never see up close, but which military personnel stationed in the developing world experience alongside local communities. Medicines, vaccines, and diagnostics for health threats that disproportionately affect the developing world are critical for their protection. Health is also an important factor in global stability and security. The heavy burden of disease in the developing world hinders economic and social development, which in turn perpetuates conditions that breed political instability. DOD health research therefore benefits not only the US military but also has the potential to reduce this health burden, and by doing so, reduce the likelihood of physical conflict.

PATH requests that in FY 2011, the Subcommittee provide robust support for DOD research and development programs aimed at addressing these health challenges, particularly two important programs. First, we request that the Subcommittee provide increased support for military malaria vaccine development efforts. Second, we request that the Subcommittee support research at the Defense Advanced Research and Projects Agency (DARPA) aimed at delivering health care to military personnel and civilians in remote, resource-poor, and unstable locations. PATH also requests that no funding cuts be made to DOD research and development.

#### **Malaria and Vaccines**

Malaria is a parasitic infection transmitted by mosquitoes. More than one-third of the world's population is at risk of malaria, with approximately 250 million cases occurring every year. Most of the nearly one million annual deaths from malaria are among children in Africa under the age of five. A malaria vaccine is desperately needed to help prevent these deaths. While consistent use of effective insecticides, insecticide-treated nets, and malaria medicines saves lives, eradicating or even significantly reducing the impact of malaria will require additional interventions, including vaccines. Immunization is one of the most effective health interventions available. Just as it was necessary to use vaccines to control polio and measles in the United States, vaccines are needed as part of an effective control strategy for malaria. Furthermore, vaccines are typically the most efficient means of protecting military personnel from disease threats. When troops are deployed, and particularly under combat conditions, compliance with drug regimens or other disease-protection protocols can be difficult, if not impossible. Vaccination, in contrast, can be performed prior to deployment, and allows deployed personnel

to remain focused on mission success, rather than chemoprophylaxis, bed nets, or insecticide application.

# Malaria and the US Military

A 2006 Institute of Medicine (IOM) report<sup>\*</sup> found that "malaria has affected almost all military deployments since the American Civil War and remains a severe and ongoing threat." For this reason, the military has historically taken an active and leading role in the development of health technologies to protect military personnel from malaria, or to treat them if they become infected with the disease. This work includes a robust, cutting-edge program aimed at developing a highly-efficacious malaria vaccine, suitable for use by military personnel. The aforementioned IOM study noted "the fact that a vaccine would be the best method of averting the threat of malaria given the likely increasing number of deployments to high-risk areas." An effective vaccine would provide unparalleled protection to servicemen and women serving in malaria-endemic countries and regions, and would significantly reduce the impact of noncompliance, drug resistance, and other significant obstacles that currently limit the military's ability to provide protection from malaria. Military researchers within the Military Infectious Disease Research Program, including the US Army Medical Research Institute of Infectious Diseases, US Naval Medical Research Center, and the Walter Reed Army Institute of Research (WRAIR), are at the forefront of efforts to develop a malaria vaccine.

Research at WRAIR, for example, contributed to the development of the most promising vaccine candidate in existence today, RTS,S. Early testing of RTS,S—created by GlaxoSmithKline Biologicals (GSK Bio)—was done in collaboration with the US military. Today, thanks to an innovative partnership between GSK Bio and the PATH Malaria Vaccine Initiative (MVI)—a PATH program that works to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world—RTS,S is now in a large-scale Phase 3 trial, typically the last stage of testing prior to licensure. Although the efficacy of RTS,S is unlikely to prove adequate for military purposes—despite its potential benefit to young children in Africa—it has shown that developing a vaccine against malaria is possible and paved the way for other development efforts that could ultimately allow the military to vaccinate men and women against malaria before deploying them to endemic regions. Since its establishment in 1999, MVI has partnered with the military in a number of malaria vaccine development projects, including the preclinical development of an adenovirus-vectored malaria vaccine candidate developed by GenVec, Inc. that used a modified common cold virus to deliver multiple malaria antigens.

Unfortunately, DOD spending on malaria research has been declining for several years from levels that were already comparatively small given the historic impact of malaria on overseas deployments. PATH requests that the Subcommittee reverse this trend, and provide the resources needed to develop the necessary tools—including vaccines—to protect soldiers, sailors, airmen, and marines from this deadly and debilitating disease threat. This would make possible a continuation of the kind of collaboration—characterized by joint funding—that currently exists between MVI and the US Military Malaria Vaccine Program. In particular, PATH recommends \$31.1 million in malaria R&D funding for DOD in FY2011.

<sup>&</sup>lt;sup>\*</sup> Battling Malaria – Strengthening the U.S. Military Malaria Vaccine Program. National Academy of Sciences Press, Washington, D.C. 2006

#### **DARPA and DTRA**

The Defense Advanced Research Projects Agency (DARPA) is DOD's primary research and development component and performs work on the cutting edge of multiple scientific disciplines, providing a wide range of critical new technologies and products for use by the military. DARPA has made and could make additional contributions in one area it has identified as a priority: developing health technologies that can both help the US military, and be of use in DOD-sponsored humanitarian relief operations in regions emerging from conflict. Military personnel operating in developing countries face many of the same challenges to health care delivery as do the residents of those countries: electricity and transportation interruptions that can threaten the integrity of temperature-sensitive medicines and vaccines; lack of access to trained medical personnel and facilities; and an absence of infrastructures and technologies that allow for the rapid manufacture and delivery of medicines and vaccines for the treatment of unexpected infectious disease threats. Increased support for this research would help the United States to more effectively assist developing countries that need vaccines and other basic health technologies, while ensuring that health products are delivered as efficiently as possible.

DARPA's investments in austere healthcare delivery systems—through their focus on disaster medicine in projects such as "Real World," "Rapid Altitude Climatization," and "SAVE II Ventilators"—represent a commitment to interventions that could have positive and profound health implications for populations in low-resource settings. For example, 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.

The Smart Electrochlorinator provides a chlorine solution used to treat water from a variety of sources, bringing safe water into small-community households. The devices effectively inactivate bacteria, viruses, and some protozoa to create safe drinking water. Since the generators can be powered by solar-charged batteries, they are accessible to communities that do not have an electricity infrastructure. The only resources required are 75 g of table salt and 0.1 kWh per person per year, both potentially renewable. These costs are significantly less than required for the current large-scale communities. PATH has partnered with Cascade Designs, Inc. on a new generation of smart electrochlorinator that has the potential to expand the project initiated by DARPA to broader community reach for both military and civilian benefit.

The Defense Threat Reduction Agency (DTRA) is also doing groundbreaking work as it investigates innovations in vaccine and chemical reagent thermo-stabilization and point of care diagnostic tests for infectious diseases that has positive implications for global health and US military support in low-resource settings. Such technologies will enable rapid pathogen identification in the field and threat zone to more rapidly enlist targeted interventions. PATH requests that the Subcommittee maintain funding for the DARPA and DTRA research aimed at developing solutions to these and other health challenges.

# Conclusion

In light of the critical role that at DOD plays in global health research and development, and the fact that investments in this area have been falling, we respectfully request that the

Subcommittee provide the resources to maintain this important core capacity. We thank you for your consideration, and hope that you will consider PATH as a resource and partner on this issue.