

**Written Testimony Submitted for the Record (May 21, 2012) to the  
Senate Defense Appropriations Subcommittee  
Regarding FY 2013 Funding for Infectious Disease Research and Development**

**On behalf of the American Society of Tropical Medicine and Hygiene  
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The American Society of Tropical Medicine and Hygiene (ASTMH)—the principal professional membership organization representing, educating, and supporting scientists, physicians, clinicians, researchers, epidemiologists, and other health professionals dedicated to the prevention and control of tropical diseases—appreciates the opportunity to submit written testimony to the Senate Defense Appropriations Subcommittee.

**ASTMH respectfully requests that the Subcommittee expand funding for the Department of Defense's (DoD) longstanding efforts to develop new and more effective drugs, vaccines, and diagnostics designed to protect service members from infectious diseases including funding for the important research efforts at the Walter Reed Army Institute of Research (WRAIR) and the U.S. Naval Medical Research Center (NMRC)**

**DoD Research Protects the U.S. Military and Civilians and Contributes to Global Health**

A core component of ASTMH membership supports the work of the DoD, and we understand first-hand the important role that research and development play in protecting our servicemen and women deployed abroad from the threat of infectious disease, as well as contributing significantly to civilian medical applications. Specifically, DoD infectious disease research contributes to the protection of

- U.S. troops that are currently deployed or likely to be deployed in many tropical areas;
- The safety of U.S. citizens, working, traveling, participating in volunteer work, and vacationing overseas who are impacted by these same tropical diseases;
- Our country from agents responsible for these diseases, which could be introduced and become established in the U.S. (as was the case with West Nile virus), or might even be weaponized; and
- Citizens around the world who suffer disability and death from many of these same tropical diseases.

**Walter Reed Army Institute of Research**

A large part of DoD investments in infectious disease research and development are facilitated through WRAIR. Between 2007 and 2010, WRAIR's Center for Infectious Disease Research performed more than \$260 million of research for the DoD and had an additional \$140 million in collaborative research work with external partner organizations. WRAIR has advanced their work through critical public-private partnerships and collaborative efforts with entities such as

GlaxoSmithKline and Sanofi;

- Non-profit organizations such as the Bill & Melinda Gates Foundation, Medicines for Malaria Venture, and PATH, and
- Other U.S. agencies including CDC, USAID, and NIH.

WRAIR invests in

- malaria vaccine and drug development;
- drug development for leishmaniasis;
- enteric disease research;
- vector control for malaria and other vector-borne infections; and
- HIV/AIDS research and treatment.

One example of WRAIR's successful work and collaboration includes the development of several significant and promising vaccine candidates, including RTS,S, developed with PATH Malaria Vaccine Initiative and GlaxoSmithKline, which recently underwent the first ever large-scale Phase 3 trial for a malaria vaccine. In trials last year, the vaccine candidate decreases clinical episodes of malaria in children in Africa by approximately 50 percent. While we celebrate this news and the promise that it brings for children living in malaria-endemic countries, RTS,S is not suitable as a vaccine for adults who have never experienced malaria during childhood, such as our military personnel. As a result, there remains a significant need for continued research funding in order to achieve more robust results.

WRAIR is headquartered in Silver Spring, Maryland, and has research laboratories around the globe including

- a public health reference laboratory in The Republic of Georgia;
- dengue fever clinical trials in the Philippines;
- malaria clinical studies and surveillance in Kenya;
- military entomology network field sites in Thailand, the Philippines, Nepal, Cambodia, Korea, Kenya, Ethiopia, Egypt, Libya, Ghana, Liberia, and Peru; and
- several other coordination efforts with national health ministries and defense units.

This diversity in research capacity puts WRAIR in a unique leadership position in research and development for tropical diseases—research that aids our military men and women as well as people living in disease-endemic countries.

### **United States Naval Medical Research Center**

NMRC and its affiliated labs conduct basic and applied research in infectious disease. The Infectious Disease Directorate of NMRC focuses on malaria, enteric diseases, and viral rickettsial diseases. IDD has an annual budget exceeding \$10 million and conducts research on infectious diseases that are considered to be a significant threat to our deployed sailors, marines, soldiers, and airmen.

The primary objective of the Navy Malaria Program is to develop a vaccine that kills the parasite during the first few days of development in the liver, before it breaks into the blood. The program is also investigating vaccines that would target blood-stage infection to limit the severity of symptoms associated with this stage. Both of these vaccines could alleviate much of the suffering caused by this parasite in tropical areas.

The research is enhanced by IDD's close working relationship with the Navy's three overseas medical research laboratories located in Peru, Egypt, and Cambodia. These laboratories, like those of WRAIR, afford diplomatic advancement through the close working relationships they have developed with governments and citizens of those countries. ASTMH has heard first-hand accounts of the successful diplomatic impact that both the WRAIR and NMRC overseas labs have on the communities where they are guests. Many of the researchers and staff who work in the labs are local to the area and speak highly of the role of the U.S. military labs.

### **Tropical Medicine and U.S. Military Operations**

The term "tropical medicine" refers to the wide-ranging clinical, research, and educational efforts of physicians, scientists, and public health officials with a focus on the diagnosis, mitigation, prevention, and treatment of diseases prevalent in the areas of the world with a tropical climate. Most tropical diseases are located in sub-Saharan Africa, parts of Asia (including the Indian subcontinent), Central and South America, and parts of the Middle East. These are the same areas military troops are often deployed. Since many of the world's developing nations and economies are located in these areas, tropical medicine tends to focus on diseases that impact the world's most impoverished individuals.

### **Case Studies - The Importance of DoD's Infectious Disease Research Efforts**

**Malaria** has resulted in the loss of more person-days among U.S. military personnel than to bullets during every military campaign fought in malaria-endemic regions during the 20th century.

Because service members deployed by the U.S. military comprise a majority of the healthy adults traveling each year to malarial regions on behalf of the U.S. government, the U.S. military has understandably taken a primary role in the development of anti-malarial drugs, and nearly all of the most effective and widely used anti-malarials were developed in part by U.S. military researchers. Drugs that now continue to save civilians throughout the world were originally developed by the U.S. military to protect troops serving in tropical regions during WWII, the Korean War, and the Vietnam War.

In recent years the broader international community has increased its efforts to reduce the impact of malaria in the developing world, particularly by reducing childhood malaria mortality, and the U.S. military plays an important role in this broad partnership. Nonetheless, military malaria researchers at NMRC and WRAIR are working practically alone in the area most directly related to U.S. national security: drugs and vaccines designed to protect or treat healthy adults

with no developed resistance to malaria who travel to malaria-endemic regions. NMRC and WRAIR are working on the development of a malaria vaccine and on malaria diagnostics and other drugs to treat malaria—an especially essential investment as current malaria drugs face their first signs of drug resistance.

The latest generation of malaria medicines is increasingly facing drug-resistance. The most deadly variant of malaria—*Plasmodium falciparum*—is believed by the World Health Organization to have become resistant to “nearly all anti-malarials in current use.” The malaria parasite demonstrates a notorious and consistent ability to quickly develop resistance to new drugs. Malaria parasites in Southeast Asia have already shown resistance to the most recently developed anti-malarial drug, artemisin.

Developing new antimalarials as quickly as the parasite becomes resistant to existing ones is an extraordinary challenge, and one that requires significant resources before this becomes widespread, especially as U.S. military operations in malaria-endemic countries of Africa and Asia increase. Without new anti-malarials to replace existing drugs as they become obsolete, military operations could be halted in their tracks by malaria. The 2003 malaria outbreak affecting 80 of 220 Marines in Liberia is an ominous reminder of the impact of malaria on military operations. Humanitarian missions also place Americans at risk of malaria, as evidenced by several Americans contracting malaria while supporting Haitian earthquake relief efforts.

**Leishmaniasis** is a vector-borne disease that comes in several forms, the most serious of which is visceral leishmaniasis, which affects internal organs and can be deadly if left untreated. According to the WHO, over 350 million people are at risk of leishmaniasis in 88 countries around the world. It is estimated that 12 million people are currently infected with leishmaniasis, and 2 million new infections occur annually. Co-infection of leishmaniasis and HIV is becoming increasingly common, and WHO notes that because of a weakened immune system, leishmaniasis can lead to an accelerated onset of AIDS in HIV-positive patients.

Because of leishmaniasis’ prevalence in Iraq, DoD has spent significant time and resources on the development of drugs and new tools for the treatment of leishmaniasis. As more troops return from Iraq and Afghanistan, it is likely DoD and the Department of Veterans Affairs will see an increase in leishmaniasis cases in our soldiers. WRAIR discovered and developed Sitamaquine, a drug that, once completed, will be an oral treatment for leishmaniasis. While essential for the safety of our servicemen and women abroad, these types of innovations will also be extremely beneficial to at-risk populations worldwide living in leishmaniasis- endemic countries.

**Dengue fever** (“breakbone fever”), according to the WHO, is the most common of all mosquito-borne viral infections. About 2.5 billion people live in places where dengue infection can be transmitted by mosquitoes, and last year we saw a few cases pop up in the U.S. There are four different viruses that can cause dengue infections. While infection from one of the four viruses will leave a person immune to that strain of the virus, it does not prevent them from contracting the other three, and subsequent infections can often be more serious.

The DoD has seen about 28 cases of dengue in soldiers per year. While none of these cases resulted in the death of a soldier, hospitalization time is lengthy. Currently, there are several research and development efforts under way within the DoD both for treatments and vaccines for dengue.

### **U.S. Government Action is Needed for Mission Readiness**

The role of infectious disease in the success or failure of military operations is often overlooked. Even a cursory review of U.S. and world military history, however, underscores that the need to keep military personnel safe from infectious disease is critical to mission success. Ensuring the safety of those men and women in future conflicts and deployments will require research on new tools. Additional funds and a greater commitment from the federal government are necessary to make progress in tropical disease prevention, treatment, and control.

Although several promising new infectious disease drugs are in development at WRAIR and NMRC, the U.S. government's funding level for these programs has been anemic for several years. There are indications that the current budget process may decrease or not keep up with medical research inflation, let alone an increase in real dollars, despite burgeoning evidence that many of our military's current drugs are rapidly approaching obsolescence.

Fortunately, a relatively small amount of increased funding for this program would restore the levels of research and development investment required to produce the drugs that will safeguard U.S. troops. In relation to the overall DoD budget, funding for infectious disease research programs is very small. Cutting funding for this program would deal a major blow to the military's efforts to reduce the impact of these diseases on soldiers and civilians alike, thereby undercutting both the safety of troops deployed to tropical climates and the health of civilians in those regions.

ASTMH feels strongly that increased support for efforts to reduce this threat is warranted. A more substantial investment will help to protect American soldiers and potentially save the lives of millions of individuals around the world. We appreciate the opportunity to share our views in our testimony, and please be assured that ASTMH stands ready to serve as a resource on this and any other tropical disease policy matter.