

**Written Testimony Submitted for the Record to the
Senate Defense Appropriations Subcommittee
Regarding FY 2012 Funding for Malaria and Tropical Disease Related Programs**

**On behalf of the
American Society of Tropical Medicine and Hygiene
Karen A. Goraleski, Executive Director
111 Deer Lake Road, Suite 100, Deerfield, IL 60015
kgoraleski@astmh.org | 847-480-9592 x222**

Executive Summary

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 Senate Defense Appropriations Subcommittee.

The central public policy priority of ASTMH is reducing the burden of infectious disease in the developing world. To that end, we advocate implementation and funding of federal programs that address the research, prevention, and control of infectious diseases that are leading causes of death and disability in the developing world, and which pose threats to U.S. citizens. Many of our current priorities overlap with the excellent and long-standing tropical medicine and neglected disease research work being done within the Department of Defense, including malaria and other vector-borne diseases; tropical diseases such as dengue fever and leishmaniasis; and enteric diseases.

Because U.S. servicemen and women are often deployed to tropical regions endemic to tropical diseases, reducing the risk that these diseases present to servicemen and women is often critical to mission success. Our military has long taken a primary role in the development of treatments for tropical diseases, such as anti-malarial drugs. As a result of this investment and the innovation employed by these military scientists, they have developed many of the most effective and widely-used treatments for these diseases.

For this reason, we respectfully request that the Subcommittee expand funding for the Department of Defense's longstanding and successful efforts to develop new drugs, vaccines, and diagnostics designed to protect service members from malaria and tropical diseases. Specifically, ASTMH requests that increased funding be allocated to the Army Medical Research Institute for Infectious Diseases (USAMRIID), the Walter Reed Army Institute of Research (WRAIR), and the U.S. Naval Medical Research Center (UNMC), who work closely together to maximize and ensure the most efficient research portfolios.

United States Army Medical Research Institute for Infectious Diseases

USAMRIID's mission includes advancing research to develop medical solutions—vaccines, drugs, diagnostics, and information—to protect our military service members from biological threats. USAMRIID has Biosafety Level 3 and Level 4 laboratories and world-class expertise in the generation of countermeasures for biological threats playing a critical role in the status of our country's preparedness for biological terrorism and biological warfare. While their primary mission is to protect the service members, like each of the research facilities, their important work benefits civilians as well.

Walter Reed Army Institute of Research

A large part of DOD investments in infectious disease research and development are facilitated through WRAIR, which since FY 2007 has performed more than \$250 million in DOD research. Through critical public private partnerships with companies such as GSK and Sanofi, as well as non-profits such as the Gates Foundation and Medicines for Malaria Venture, 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. While each of these investments is crucial to the protection of U.S. troops abroad, WRAIR is also a partner to the global health community in saving the lives of some of the world's poorest people suffering from some of the most neglected diseases.

WRAIR 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 Global Emerging Infectious Surveillance in Kenya; military entomology network field sites in Thailand, the Philippines, Nepal, Cambodia, Korea, Kenya, Ethiopia, Egypt, Libya, Ghana, Liberia and Peru; as well as several other coordination efforts with national health ministries and defense units. This diversity in research capacity puts WRAIR in the unique position to be a leader in research and development for tropical diseases—research that will aid our military men and women as well as people living in these disease-endemic countries.

United States Naval Medical Research Center

NMRC is a premier medical and health research organization whose focus includes tropical medicine and infectious disease. The Infectious Disease Directorate (IDD) 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. Their current research efforts are focused on malaria, bacterial causes of traveler's diarrhea, dengue fever, and scrub typhus with particular emphasis on vaccine discovery and testing. The research is enhanced by IDD's close working relationship with the Navy's three overseas medical research laboratories located in Peru, Egypt, and Indonesia. These laboratories also afford diplomatic advancement through the close working relationships they have developed with governments and citizens of those countries.

Tropical Medicine and Tropical Diseases

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 vector borne diseases prevalent in the areas of the world with a tropical climate. Most tropical diseases are located in either sub-Saharan Africa, parts of Asia (including the Indian subcontinent), or Central and South America. Many of the world’s developing nations are located in these areas; thus tropical medicine tends to focus on diseases that impact the world’s most impoverished individuals.

U.S. troops are currently deployed or likely to be deployed in many of these same tropical areas. U.S. citizens, working, traveling and vacationing overseas are similarly impacted by these same tropical diseases, many of which have been ignored and neglected for decades. Furthermore, some of the agents responsible for these diseases could be introduced and become established in the U.S. (as was the case with West Nile virus), or might even be weaponized.

The U.S. has a long history of leading the fight against tropical diseases which cause human suffering and pose a great financial burden that can negatively impact a country’s economic and political stability. The benefits of U.S. investment in tropical diseases extend beyond economics and humanitarianism and into diplomacy as well.

Malaria – A Formidable Foe for U.S. Military Operations

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. Malaria has long been a threat to US military deployment success. In fact, more person-days were lost among U.S. military personnel due to malaria than to bullets during every military campaign fought in malaria-endemic regions during the 20th century. For this reason, the U.S. military has long 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 have saved countless lives 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. However, 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 regions endemic to the disease. 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 malaria parasite demonstrates a notorious and consistent ability to quickly develop resistance to new drugs. The latest generation of medicines is increasingly facing drug-resistance. Malaria parasites in Southeast Asia have already shown resistance to mefloquine; resistant strains of the parasite have also been identified in West Africa and South America. There are early indications that parasite populations in Southeast Asia may already be developing limited resistance to artemisinin, currently the most powerful anti-malarial available. Further, 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.”

Resistance is not yet universal among the global *Plasmodium falciparum* population, with parasites in a given geographic area having developed resistance to some drugs and not others. However, the sheer speed with which the parasite is developing resistance to mefloquine and artemisinin – drugs developed in the 1970s – bodes of a crisis of such significance that military malaria researchers cannot afford to rest on their laurels.

WRAIR, in concert with multiple organizations including the CDC and vaccine manufacturers, has developed several exciting vaccine candidates, including one that recently began the first ever large-scale Phase 3 trial for a malaria vaccine, (RTS,S). In earlier trials, the vaccine has been shown to decrease clinical episodes of malaria by over 50% in children in Africa. Despite these advances, the vaccine might be unsuitable for deploying personnel and travelers, because of its efficacy level. As a result, there is still a significant need for continued funding for ongoing research.

Developing new antimalarials as quickly as the parasite becomes resistant to existing ones is an extraordinary challenge, and one that requires significant resources, especially as U.S. military operations in malaria-endemic countries increase. Without new anti-malarials to replace existing drugs as they become obsolete, military operations could be halted in their tracks by malaria. The recent malaria outbreak affecting 80 of 220 Marines in Liberia in 2003 serves as 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.

Tropical Disease Impact on Military Operations

Few other U.S. government agencies devote as much time, funding, manpower, and direct research to tackling these devastating diseases as the DOD. The work ultimately goes beyond protecting soldiers and benefits the people living in the countries where these diseases cause the most harm. The recent success of the RTS, S malaria vaccine and its advancement to Phase 3 trials is just one success story from this program. DOD also does great research for other tropical diseases including leishmaniasis and dengue fever, two potentially deadly diseases of great risk to our troops and even greater risk to the citizens of these disease endemic regions.

Leishmaniasis is a vector borne disease that is caused by the parasite leishmania. It is transmitted through the bite of the female phlebotomine sandfly. Leishmaniasis 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. Coinfection 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, the 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 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 the at risk populations world wide that are living in leishmaniasis endemic countries.

Dengue 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 is possible and last year we saw a few cases pop up in the US. 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 department of defense 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. The drugs and prophylaxis used to keep our men and women safe from malaria and tropical diseases during previous conflicts in tropical regions are no longer reliable. 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 malaria and tropical disease prevention, treatment, and control.

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 matters.

Thank you for your attention to this matter.