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**STATEMENT BY**

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**BEFORE THE**
**HOUSE SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION**

**UNITED STATES**

**HOUSE OF REPRESENTATIVES**

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**2:00 p.m.**

Summary: The PATH Malaria Vaccine Initiative (MVI) would like to recommend that the House Subcommittee on Labor, Health and Human Services, and Education, increase funding for the National Institutes of Health (NIH) to increase its support for malaria vaccine research. NIH plays a critical role in seeking strategies to combat malaria by performing everything from basic malaria research to vaccine and drug research and development. The National Institute of Allergy and Infectious Diseases (NIAID), in particular, is responsible for much of the U.S. government's malaria research. NIAID performs and oversees groundbreaking research that is vital to malaria vaccine development and to the entire field of vaccinology. Without adequate resources applied at NIAID, malaria's death toll could continue to climb, as progress toward new tools to defeat the disease is stalled. Impressive progress is being made and in order to make more and faster progress, increased NIH funding is essential.

Mr. Chairman and other distinguished members of the subcommittee, I sincerely appreciate the opportunity to testify in support of increased funding for the National Institutes of Health (NIH). I specifically request that the committee recommend increased funding for NIH to increase its support of malaria vaccine research.

I am Dr. Filip Dubovsky, scientific director of the PATH Malaria Vaccine Initiative (MVI). MVI works to accelerate the development of promising malaria vaccine candidates and to ensure that once a vaccine is licensed, it will be made available to children in the developing world. This is an incredibly exciting time in malaria vaccine research. NIH, MVI, and others are poised to significantly advance the science of malaria vaccine development.

## Malaria Matters

Malaria is a parasitic infection transmitted by mosquitoes. The resulting disease can be devastating to anyone, but pregnant women and young children are especially vulnerable to the disease. Creating a vaccine against malaria has been difficult, because the malaria parasite is complex and can hide from the body's defense mechanisms.

NIH plays a critical role in seeking strategies to combat malaria—performing everything from basic malaria research to vaccine and drug R&D.

Why is increased funding for malaria vaccine R&D so urgently needed? Let me give you just one example.

About 70 kilometers north of Dar es Salaam, Tanzania, rests the village of Bagamoyo. Nestled within this historic village is a hospital whose doctors treat children suffering from malaria. From the waiting area—a cemented surface outdoors in stifling heat, with no chairs, and no water—you can hear the cries of children and see the desperation in the faces of parents who hope for restoration of their child's health. Unfortunately, these children have limited access to effective malaria-control measures. And unlike us, these parents face the reality that theirs could be one of the 2,000 or more children in Africa who die each day from malaria. Adding a vaccine to the malaria control arsenal could help prevent these deaths.

Most of the more than one million people who die from malaria every year are sub-Saharan African children. Those who are not killed by the disease often suffer its long-lasting, debilitating effects. Malaria wreaks havoc on societies and economies.

But malaria is both preventable and treatable. New and better tools are needed to end the deaths from the disease, and NIH is helping to create them.

Due to the notable progress made on several fronts in recent years, many in the public health community believe malaria can be defeated. Examples of this progress include the implementation of programs to scale up malaria-control interventions to the national level, the introduction of long-lasting, insecticide-treated nets in several endemic countries, and the success of a pediatric malaria vaccine in clinical trials supported by MVI in Mozambique.

The Mozambique results prove that it is absolutely possible to make a malaria vaccine that can have significant public health impact. If the appropriate forces are marshaled, progress against malaria can be accelerated over the next several years.

## NIH plays a leading role in the global quest for a malaria vaccine

NIH is one of the largest public-sector investors in malaria R&D. The Malaria R&D Alliance, which is a coalition of organizations working to find new and improved ways to defeat malaria, published a report last year entitled, "Malaria Research & Development: An Assessment of Global Investment." This study revealed that while only $323 million was invested in malaria R&D worldwide in 2004, NIH stood out as the largest investor and the only one to invest in the full spectrum of malaria R&D—from basic research to vaccine development to implementation research. Much of the success we are currently witnessing in the malaria field is based on work supported initially by NIH.

The National Institute of Allergy and Infectious Diseases (NIAID), in particular, is responsible for much of the U.S. government's malaria research. NIAID performs and oversees groundbreaking research that is vital to malaria vaccine development and, for reasons I will discuss later, the entire field of vaccinology. Without adequate resources applied at NIAID, malaria's death toll could continue to climb as progress toward new tools to defeat it is stalled.

Impressive progress is being made. The core strength of NIH is in its support of basic science and translational research—the clinical application of scientific medical research from the lab to the bedside—in malaria. The unflagging support of the world's best scientists over the past four decades has generated the scientific foundation that assures us a malaria vaccine is not only feasible but likely. However, there has been a gap in manufacturing and testing these potential malaria vaccines because the private sector lacks the incentive to invest in the development of products whose market is primarily poor countries. NIAID has developed a two-pronged approach to tackling this problem.

- The Malaria Vaccine Development Unit at NIAID/NIH is a special unit that develops, manufactures, and tests new malaria vaccines. A number of its products have been made and have entered clinical trials in the U.S. The most promising of these vaccines are being tested in Mali, Africa even as we speak. NIH also provides critical training to scientists in malaria-endemic countries to enhance the ability to control malaria. In addition, NIH is developing clinical trial sites in Africa to prepare for the increasing number of vaccine candidates moving into clinical testing.
- The Division of Microbiology & Infectious Diseases at NIAID/NIH has a vaccine manufacturing and testing contract that taps into our country's thriving biotechnology sector and brings together the best ideas, technology, and know-how. Through this approach, malaria vaccines are being manufactured and prepared for clinical evaluation. Simultaneously, vaccine trial centers in the U.S. and abroad are being supported to demonstrate the utility of these products.

Both these mechanisms have been key to bridging the manufacturing gap. More NIH support would enable even more and faster progress.

In addition to funding scientists, NIH is also setting up processes that will allow the entire malaria vaccine R&D field to leap forward. This includes MR4, the repository for reagents used by the global malaria vaccine community; the development of standardized assays; the transfer of specific technologies and breakthroughs from the NIH labs to scientists and developers throughout the world; and coordination of malaria vaccine development at a global level (with MVI, the US Agency for International Development, the World Health Organization, the

European Union, and the European Malaria Vaccine Initiative). NIH is truly a global partner and leader in the malaria vaccine field.

NIH's malaria vaccine program is critical not only to the malaria vaccine field and those in the United States and worldwide who will someday benefit from highly effective malaria vaccines, but also to the field of vaccinology. The unfortunately high prevalence of the disease makes malaria vaccines an ideal platform for assessing new vaccine technologies that are directly applicable to emerging diseases and biodefense. In fact, almost every innovation in vaccine development has been assessed in malaria vaccines. This includes DNA platforms and novel adjuvants that enhance the potency of vaccines.

NIH has also been highly successful in turning antigens into viable candidates and manufacturing them for clinical trials. This has led to a critical mass of malaria vaccine candidates in or nearing clinical trials. Results from some of these trials are expected later this year.

## What more funding can do

Additional funding to NIH would allow that institution the flexibility to increase its support of malaria vaccine R&D. This increased support would lead to more and better vaccine candidates in the pipeline, the ability to streamline approval processes (thereby speeding up development), and faster development of clinical trial sites to accommodate the growing number of candidates ready for evaluation. These are just three examples.

The current major roadblock common across vaccines is formulation—how to put the various vaccine components together in a bottle, making a product that can be assessed in people. More funding will enable increased effort in this area, which will then lead to more candidates ready for clinical trials, sooner. Even a few million dollars applied to this effort can make a big difference in lives saved.

The paradox is that clinical testing is more expensive than earlier stages of development—and it gets more expensive as the product progresses toward evaluation in field trials. As they achieve success, NIH needs additional funding to avoid bottlenecks.

We applaud the U.S. government for its current support for the work being done at NIH. We believe that our charge now lies in ensuring that U.S. government spending on malaria increases in order to make the maximum possible impact on this disease now and into the future. Now that we have come so far, we must not lose focus. Additional resources should be applied to capitalize on the many advances in the field.

## More funding is needed to leverage success

The message that I want to leave with you today is clear: NIH has been a good steward of its currently available malaria resources and could do even more with increased support. I urge the committee to stand in support of increased malaria funding for NIH. Public dollars invested in malaria vaccine development are paying off—yielding concrete results that are making a difference as we try to tackle this devastating problem.

NIH research dollars are being used and leveraged wisely. However, at a time when we are poised for even more success, funding is not keeping pace with developments. It is critical that we continue to boost spending in light of recent successes.

Evidence proves that a malaria vaccine is possible. The vaccine pipelines are filling, which is good—more candidates mean more likelihood of success, especially if what is learned from them is applied across the field. The paradox is that as we are successful and move vaccines to later stages of development, the work becomes more expensive. Today, it is truly money more than science that limits the creation of a new tool that could save millions of young lives.

I urge the committee to increase funding for NIH to allow that agency more flexibility to increase its support of malaria vaccine research.

Thank you for your consideration.