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Thank you, for convening this important hearing and for inviting me to testify on a very deadly disease, malaria.

Malaria affects the health and wealth of nations and individuals alike around the world. It is not only a disease of poverty but also a disease that causes poverty and is a major constraint to economic development.

As a public health physician who has worked internationally and domestically for more than 20 years, I am very pleased at the growing interest and response to the challenge malaria poses. The international community has mobilized funding and action recently to develop and implement sustainable actions against malaria. I will address the burden and suffering caused by malaria with a special focus on East Asia and outline what USAID is doing to save lives now and in the future.

Malaria

Worldwide, it is estimated that malaria kills more than one million people each year, making it the world's third deadliest infectious disease, after AIDS and tuberculosis. But malaria -- spread by mosquitoes -- is the most common of the three diseases, with more than 500 million persons experiencing acute malaria illness annually, compared with 5.3 million for AIDS and 8.8 million for TB. Each year there are about 3.6 million confirmed malaria cases and 6,000 malaria deaths in Asia and the Near East. However, there are probably many more unreported cases and deaths given that malaria occurs mostly in rural areas where health services and surveillance are weak. Malaria also accounts for a loss of approximately $12 billion a year in gross domestic product in Africa alone.

Eighty-five percent of malaria deaths occur in Africa, while about eleven percent of the deaths occur in Asia and the Near East. In Africa, malaria's greatest impact is felt by very young children and pregnant women because of their reduced immunity to the malaria parasite. As many as a quarter of childhood deaths in endemic areas of Africa are attributable to malaria. But infection of African women during pregnancy also takes a huge toll, both on the health of the mother as well as on the development of her unborn child. Placental infection in Africa is a significant contributor to low birthweight and subsequent neonatal death. In areas of unstable or epidemic malaria such as Asia, all persons are also at risk of serious illness and death. The drain on the physical and

financial resources of households and communities of the disease, as well as the often ineffective attempts to respond to it, is well documented.

Scope of USAID role in battling Malaria

The United States is and has been a leading force worldwide in the battle against malaria. USAID has directed and supported critical research that forms the backbone of some of the most effective interventions, including insecticide-treated mosquito nets (ITNs), rapid diagnostics, and drugs. It is also studying ways to identify and deal with increasing drug resistance. Our technical and financial resources are being brought to bear around the world and leveraged to increase global commitments to reduce illness and death. This year USAID committed over $80 million for malaria programs - a nearly four-fold increase since 1998 when USAID's Infectious Disease Initiative was launched. These new and expanded resources have allowed for a significant scaling-up of malaria activities to have national level impact and have led to increased coverage with interventions, better policies and visibly stronger programs. Many countries in Asia are also receiving support for malaria from the Global Fund to Fight AIDS, TB, and Malaria. I will say more about the Global Fund later.

Seven countries in Asia receive USAID support for malaria, with a major focus on limiting the emergence and spread of drug-resistant forms of malaria in the Mekong sub-region of Southeast Asia. These include Afghanistan, Cambodia, India, Indonesia, Philippines, Nepal and Thailand. Activities supported are determined by local priorities, resource availability, and complementary activities by other donors and multinational institutions.

The international efforts to fight malaria are largely coordinated by a global partnership that includes leaders from across Asia, local health institutions, the World Health Organization (WHO), UNICEF, World Bank, UNDP, multilateral agencies, the Department of Health and Human Services (HHS), specifically the Centers for Disease Control and Prevention (CDC), international, national and local NGOs, and the private sector. USAID is a key partner in the Roll Back Malaria Partnership.

Integrated Flexible Program Approach Saves Most Lives

International experts have identified three priority interventions to reduce deaths and illness from malaria, each of which is backed by solid evidence of their effectiveness. These three interventions are consistent with USAID's priority areas for investment in malaria. They are:

1. Provision of prompt and effective treatment with an antimalarial drug within 24 hours of onset of fever;
2. Prevention of malaria primarily through the use of insecticide-treated mosquito nets (ITNs) by young children, pregnant women, and other high-risk populations; and

3. Provision of intermittent preventive treatment (IPT) for pregnant women as a part of the standard antenatal services--proper use of which can reduce overall child deaths by up to 30% and significantly reduce sickness in children and pregnant women. [this one is not really a focus in Asia since little has been documented on malaria in pregnancy]

Other parts of an integrated program—based on appropriate epidemiology and mosquito characteristics--are:

a. Indoor Residual Spraying and use of insecticides
b. Environmental Clean-up to remove mosquito breeding sites

The three interventions to reduce deaths and illness from malaria are internationally agreed upon and can be adapted to the local context depending on the needs and priorities.

Improving Treatment with Effective Drugs

Historically, national malaria control programs have relied primarily on monotherapy with drugs, such as chloroquine, amodiaquine, or sulfadoxine-pyrimethamine SP (Fansidar®). These are the first-line treatment for *Plasmodium falciparum* infections, which are responsible for the vast majority of deaths due to malaria. However, many of these drugs are no longer useful in Southeast Asia as well in other parts of the world including Africa because of widespread drug resistance among *P. falciparum* parasites. Malaria programs in many of the Mekong countries now use a combination therapy which includes one of the newer artemisinin-based drugs. In Cambodia, Indonesia, and Thailand, USAID has been supporting efforts to improve rapid diagnosis and treatment of malaria, particularly in poor, underserved populations or where the disease is re-emerging. Although prohibited from providing assistance to Burma, USAID is providing support to nongovernmental organizations (NGOs) in western Thailand to address malaria and other priority infectious diseases among Burmese migrants.

USAID Instrumental In Tracking Spread Of Resistance -- Documenting Need For Better Drugs

Like many infectious diseases such as TB, gonorrhea, and pneumonia, resistance to antimalarial drugs can develop and spread in areas where these medicines are not used properly or where their quality is poor. In Southeast Asia, strains of *P. falciparum* have developed resistance over the past 20 years to multiple antimalarial agents and very few drugs remain effective.

Because of the cross-border nature of the drug-resistant malaria problem and the need for improved surveillance and disease-control capacity in Southeast Asia, USAID has been supporting since 1999 a coordinated, regional approach led by the World Health Organization to monitor drug-resistant malaria in East Asia and, more recently, in South Asia and limit its spread. The U.S. Centers for Disease Control and Prevention have also been involved in these efforts. As a result of drug-resistance data collected with the

assistance of USAID and other donors and partners, malaria treatment policies have recently been updated in a number of East Asian countries including Cambodia and Thailand.

At the country level, USAID is working with national malaria programs to: improve the diagnosis of *P. falciparum*; providing effective combination therapies to vulnerable populations; expanding the use of insecticide-impregnated mosquito nets to limit transmission of malaria and the need for antimalarial drugs; and monitoring drug resistance, drug-use practices, and drug quality.

Drug Resistant Strains Present Additional Challenges

East Asia and the Pacific include Burma, Cambodia, China, East Timor, Indonesia, Laos, Mongolia, Philippines, Thailand and Vietnam. Populations at risk for severe disease and death in East Asia include children, pregnant women, people routinely in contact with forested areas where malaria-transmitting mosquitoes live, and rural and mobile populations with limited access to health services. While improved access to prompt diagnosis and effective treatment has contributed to a decrease in the number of malaria deaths here over the past decades, the recent emergence and spread of multi-drug-resistant (MDR) malaria threatens to reverse these gains as treatments become more complicated and costly.

USAID has been instrumental in documenting the extent of the drug-resistance problem as well as studying the factors--such as poor drug use and poor drug quality--that are contributing to the emergence and spread or resistance. This information is critical for focusing interventions on priority areas in order to preserve the effectiveness of current antimalarial drugs that are safe and affordable. Only a limited number of alternative drugs are available if the current therapies fail and there is little economic incentive for new drug discovery and development, given its high cost and the fact that malaria predominantly affects the world's poorest nations. Newer drugs are also likely to be significantly more expensive which can limit people's access to them, especially in poor, rural communities. If steps are not taken immediately to address the root causes of drug resistance, these drug combinations will also lose their effectiveness in the near future.

Identifying Factors Contributing to Drug Resistance

There are two main factors that are driving the emergence of drug-resistant malaria in East Asia and elsewhere. They are: poor use of antimalarial drugs; and use of poor-quality antimalarial drugs. Both result in under-dosing which can allow malaria parasites to survive and adapt while exposed to sub-lethal amounts of the medicines. On the issue of poor drug use, health care providers and drug sellers can contribute to the problem in several ways, including: prescribing/dispensing the wrong drug when a patient has malaria; and prescribing/dispensing the proper drug, but in an incorrect dosage. Patients can assist the development of drug resistance by failing to complete the full drug course when they are ill. This may occur because they only had enough money to buy a partial treatment or because they stopped treatment once they started feeling better. Self

diagnosis and medication can also lead to the wrong drug being used and/or the wrong dose. This occurs frequently as people go to traditional healers and drug sellers first before visiting trained health providers, especially if the official sources are not always stocked with the first-line therapy. Since prescriptions are rarely required for obtaining antimalarial drugs in the private and informal sector, patients have easy access to medicines. This may be especially common in international border areas where patients are poor and they may be avoiding the public health care system because they are in the country illegally or they do not speak the local language.

USAID has been instrumental in documenting the extent of the drug-resistance problem in the Mekong region, as well as studying the factors--such as poor drug use and poor drug quality--that are contributing to the emergence and spread or resistance. This three pronged approach in the Mekong is unique in allowing decision-makers to more broadly understand factors that affect community behaviors and to monitor their impact on drug resistance. Documentation of changes in drug resistance, quality and use will enhance the ability of countries to evaluate their national malaria drug policy and to introduce changes from a more informed perspective. This information is critical for focusing interventions on priority areas in order to preserve the effectiveness of current antimalarial drugs that are safe and affordable. A recent study of antimalarial drug use in western Cambodia revealed that only 11percent of people who had malaria were using the recommended first-line therapy of artesunate+mefloquine, despite efforts by health officials to make the drug combination widely available through both the public and private sector. Moreover, 41 percent of people receiving treatment for malaria did not take the full course of the medicine. And 50 percent of people were self-prescribing with medications obtained in the private market.

Even if everyone in East Asia uses antimalarial drugs properly, malaria parasites can still be exposed to sub-lethal doses of antimalarial medicines if poor quality drug formulations are used to treat the disease. Unlike in developed countries, poor-quality medicines—either produced intentionally as counterfeits or accidentally because of poor quality control-- are readily available on the open market and often visually indistinguishable from the genuine products. In one study in East Asia, 38% of "artesunate" samples from drug shops in Burma, Cambodia, Laos, Thailand, and Vietnam contained insufficient or no active ingredient. Other studies have detected other poor-quality antimalarial drugs, including chloroquine, mefloquine and quinine. Besides contributing to drug resistance, poor drug quality has real health implications for the individual patient. In 1999, at least 30 people in Cambodia died after taking SP (an older, less effective antimalarial drug) which was sold to them as artesunate. Poor-quality drugs can also contain toxic products which can be lethal if ingested.

Ensuring Drug Quality and Appropriate Drug Use

USAID is strengthening national drug regulatory authorities. The aim is to improve the manufacturing of pharmaceuticals through good manufacturing practices, including drug quality control in national malaria programs. At 17 sentinel surveillance sites in six countries in Southeast Asia and Africa, the United States Pharmacopeia Program (USP

DQI) has trained staff of national malaria programs to collect and test drugs for quality, using low technology screening methods. Sentinel surveillance sites, national malarial control programs and drug regulatory authorities will be linked to create regional warning systems for poor quality drugs found in the market. USP DQI has also provided technical assistance in good manufacturing practices to selected producers of malaria drugs in Cambodia, Laos, and Vietnam. At the same time, USAID is also working with the Management Sciences for Health (MSH) Rational Pharmaceutical Management (RPM) Plus program to identify household and provider drug management and use problems, and to strengthen the capacity of local health officials and partners in East Asia to utilize this information to improve access to high-quality antimalarial drugs in the public and private sectors and to ensure their appropriate use. RPM Plus is also working with WHO and other partners to develop and implement a standardized methodology for monitoring the extent of ACT introduction as first line therapy in several Mekong countries.

Mainstreaming Rapid Diagnostics

New community-based approaches to diagnostics, including rapid diagnostics tests, can help overcome insufficient laboratory capacity or resources so that disease surveillance information can be rapidly used for action. USAID is working to develop diagnostics tests for both *P. falciparum* and *P. vivax* infections and assisting in mainstreaming their use around the world. In Southeast Asia, artemisinin-based combination therapies (ACTs) are routinely deployed with rapid diagnostic test kits so that these newer and more-costly therapies are used only when needed. USAID has also been supporting the development of quality assurance system to allow countries in East Asia to verify that their rapid tests are not degrading over time under normal field conditions.

Combination Therapy Recommended by WHO, Roll Back Malaria and USAID

We know from many infectious diseases that simultaneous use of multiple drugs instead of a single regimen slows development of resistance. The World Health Organization (WHO) and the Roll Back Malaria partnership (including USAID as one of the partners) now recommend that all countries experiencing resistance to their current first-line, single-drug therapy should change to a combination therapy, ideally including an artemisinin drug. The rationale for using combination therapy for malaria is similar to that for the treatment of tuberculosis, cancer, and HIV infections. When used alone, antimalarial drugs are more likely to select resistant parasites. The addition of a rapidly-acting and highly effective second drug, such as artemisinin or one of its derivatives, greatly reduces the probability of selecting parasites that are resistant to both drugs. This should prolong their useful therapeutic lifetimes. The WHO and Roll Back Malaria (RBM) recommend several ACT options: artemether/lumefantrine (Coartem®) or artesunate plus either amodiaquine, sulfadoxine-pyrimethamine, or mefloquine. USAID has supported the development and critical research for ACTs.

Over the past year the RBM partnership has developed a comprehensive “roadmap” on how best to ensure access to and effective use of ACTs. The roadmap highlights major milestones and potential barriers towards achieving full access to and appropriate use of

ACTs – and more importantly, establishes a framework for prioritizing the actions of the RBM partnership.

USAID and our global partners have worked with endemic countries over the past several months to assess their treatment needs. We are working with pharmaceutical producers to gauge their interest, willingness, and ability to scale-up production of ACT as well as with financial institutions to determine their ability to mobilize sufficient support for the financing of ACTs. We are also seeking help from development and technical support agencies to ensure in-country support for effective application of these resources.

We have identified four potential "bottlenecks" or barriers that hinder access to and effective use of ACTs

- The capacity of agricultural producers to increase their yields of the plant *Artemisia annua*, the source of artemisinin
- The number and capacity of pharmaceutical industry to produce high quality ACTs
- The availability of resources to finance their procurement
- The availability of training and capacity to build support in country for widespread and appropriate use.

The identification of these potential bottlenecks in turn has led to an agreement within the RBM partnership of the key actions needed for their resolution.

Enhancing Production Quality and Capacity

Ensuring high quality and low cost ACTs requires an adequate pool of qualified ACT producers. Currently, there is only one pharmaceutical company which has been "prequalified" by WHO as a manufacturer of quality ACTs. USAID in 2004 and 2005 will continue to work with WHO to maximize the number of "prequalified" companies. USAID's support will target both upgrading the production capacity of pharmaceutical companies to meet WHO's standards for prequalification and will assist the WHO in expediting the evaluation process. USAID and its partners in Roll Back Malaria are currently working with legitimate local producers in Asia to assist them in incorporating Good Manufacturing Practices into their drug production facilities. This will help reduce the number of poor-quality antimalarial drugs available on the market, improve cure rates, and slow the emergence of drug resistance.

Financing ACTs

USAID and RBM partnership is taking a two-pronged strategy: (1) to identify financing over the next 18-24 months for country procurement of ACTs; and (2) to address the longer-term financing of ACTs. To meet the long-term demand, USAID has commissioned the Institute of Medicine to convene an expert panel to study options for funding ACTs from 2007 and beyond. This study has just been released and provides a clear and practical "roadmap" for the long-term financing of ACTs.

While recent public discussions of malaria treatment have largely focused on which drugs to use, the real challenge to providing effective treatment is in the "nuts and bolts" of delivering these drugs to those in need: enabling policies must be in place; logistic and management capabilities need to be upgraded; health workers need to be appropriately trained and supported; and communities and households need to be knowledgeable and cognizant of appropriate services. USAID is working with partners in the public and private sector in all of these areas to ensure that effective, affordable, and safe antimalarial drugs get to the patients who need them.

With these and other similar challenges in mind, USAID is bringing the full weight of its technical and programmatic resources in support of those countries that have made changes in their policies to ACTs to ensure that they have adequate support in procurement and management of ACTs, training of health workers in diagnosis and use of ACTs for treatment of malaria, and mobilizing communities and households. USAID is also presently working with 25 Global Fund recipient countries -- 11 in East Asia have received GFATM awards for malaria-- in preparing detailed plans for the introduction of ACT over the next year.

Prevention of Malaria

For those individuals at risk from malaria, insecticide treated nets (ITNs) are the most practical and effective means for protecting the largest percentage of populations. Consistent use of an ITN has been shown to decrease severe malaria by 45%, reduce premature births by 42% and cut all-cause child mortality by 17%–63 %. In most settings, ITNs are unquestionably the most effective way that families can protect themselves from malaria.

Free Nets To Those Most In Need

USAID promotes targeting free or heavily subsidized ITNs to the most vulnerable (pregnant women and children under five years) and poorest populations – thus ensuring economics is not a barrier to net ownership. For example, USAID support in Indonesia helped the Ministry of Health to respond to malaria outbreaks and distribute 95,000 long-lasting insecticide treated bed nets which provided protection for approximately 500,000 people in high-risk malaria areas of Central Java, and in Bali, Aceh and Lombok.

New technologies now provide long-lasting nets and treatments that remove the necessity for retreatment. These technical developments, the product of committed commercial sector engagement with Roll Back Malaria partners, render ITNs even more affordable, more easily used, and more effective. ITNs also have an additional advantage. Studies show some protection of children who live nearby a net, as opposed to IRS where there is no added protection.

DDT

Contrary to popular belief, USAID does support use of DDT in its malaria control programs. We are supportive of careful use of DDT for malaria control through the spraying of interior house walls - Indoor Residual Spraying, or (IRS). DDT is only used for malaria control through this spraying method. The spraying of pesticides which may include DDT does have a potential role in malaria prevention in some countries under certain circumstances. A number of other insecticides can also be used for IRS, and are in many countries when those alternative insecticides are safer and equally effective. IRS, when efficiently conducted in appropriate settings, is considered to be as efficacious as ITNs in controlling malaria.

From a purely technical point of view in terms of effective methods of addressing malaria, USAID and others have not seen IRS as the highest priority component of malaria programs for many reasons. In many cases, indoor residual spraying of DDT, or any other insecticide, is not practical, cost-effective and is very difficult to maintain. IRS requires major infrastructure, including a high level of organization, geographic coverage, application personnel and financial resources, regardless of what insecticide is used. To be effective, IRS needs 80 percent community compliance. It is also more expensive in rural or peri-urban than in urban areas.

In most countries in Africa where USAID provides support to malaria control programs, it has been judged more cost-effective and appropriate to put U.S. government funds into other malaria control activities than IRS. However, in countries in which circumstances support the use of IRS (including DDT) USAID has funded and supported such malaria control programs.

USAID regulations (22 CFR 216) require an assessment of potential environmental impacts of supporting either the procurement or use of pesticides in any USAID assisted project, but if the evidence assembled in preparing such an environmental review indicates that DDT is the only effective alternative and it could be used safely (such as in interior wall spraying undertaken with WHO application protocols), then that option would be considered. The U.S government is signatory to the Stockholm Convention on Persistent Organic Pollutants (the POPs treaty), which specifically allows an exemption for countries to use DDT for public health use in vector control programs, as long as WHO guidelines are followed and until a safer and equally effective alternative is found.

The United States voted in favor of this exemption. For example, this exemption was used to spray DDT and other insecticides in South Africa when certain mosquitoes developed resistance to the major alternative class of insecticides, the synthetic pyrethroids. Such situations are relatively rare, however, and demonstrate the value of the provisions of the POPs Treaty, which restrict and document use of DDT, but provide for its use when appropriate.

Prevention of Malaria in Pregnancy

While preventing malaria in pregnancy is not a major focus of work in Asia, it is in Africa. Each year, more than 30 million African women become pregnant in malaria-endemic areas and are at risk for *Plasmodium falciparum* malaria infection during pregnancy. Most women live in areas with relatively stable malaria transmission, where the major impact of infection during pregnancy is related to anemia in the mother and the presence of parasites in the placenta. The resulting impairment of fetal nutrition contributing to low birth weight (LBW) is a leading cause of poor infant survival and development in Africa. HIV infection diminishes even more a pregnant woman's ability to control *P. falciparum* infections. The prevalence and intensity of malaria infection during pregnancy is higher in women who are HIV-infected. Women with HIV infection are more likely to have symptomatic infections and to have an increased risk for malaria-associated adverse birth outcomes.

WHO has recommended intermittent preventive treatment (IPT) using the antimalarial drug, sulfadoxine-pyrimethamine (SP), as the preferred approach to reduce the adverse consequences of malaria during pregnancy in areas with stable transmission. Since more than 70% of pregnant women in Africa attend antenatal clinics, IPT provides a highly effective base for programmes through use of safe and effective antimalarial drugs in treatment doses which can be linked to antenatal clinic visits. The potential of IPT to attain high levels of program coverage and its benefit in reducing maternal anemia and LBW makes it a preferred strategy in sub-Saharan Africa. In HIV-negative pregnant women, two doses of IPT provide adequate protection, but a minimum of three doses appears to be necessary in HIV positive women. Outside of areas with stable transmission in Africa and in other regions of the world, while malaria in pregnancy is a risk for both the mother and fetus, there is no evidence that IPT is worthwhile.

USAID played a key role in supporting the original studies in Africa that documented the efficacy of IPT in preventing the impact of malaria on both HIV positive and HIV negative pregnant women and their offspring. Many countries have already changed their malaria in pregnancy policies. Currently, through a coalition of partners, USAID is assisting ministries of health in about 10 African countries to implement IPT and distribute ITNs as part of a package of health interventions at the antenatal clinic level. Over the last year this technical assistance has contributed significantly to revision of outdated policies in Senegal, Ghana, Rwanda, and Zambia and to increased implementation of revised policies in DRC, Tanzania, and Kenya. Among women attending antenatal services in Tanzania, delivery of intermittent preventive therapy has increased from below 30 percent to over 60 percent.

Expanding Global Network

Multilaterals, bilaterals … no one agency can do it all. Roll Back Malaria partners--leaders from across Asia, health institutions, WHO, UNICEF, World Bank, bi-lateral agencies, international, national and local NGOs, and the private sector are engaged to in the fight against malaria. One "home-grown" partnership in East Asia is the Asian Collaborative Training Network for Malaria which focuses on training and information

sharing. This organization was created by countries to deal with common issues related to malaria control. Both USAID and HHS have participated in the development of training strategies and curriculum development.

Global Fund

Through the Global Fund to Fight AIDS, Tuberculosis, and Malaria, USAID, HHS and international partners have come together to combine financial, technical, management, and other expertise to reduce the public health impact of malaria. Over the past three years, the U.S. government has contributed $623 million to the Global Fund, and has appropriated for a FY 2004 contribution of up to $547 million this year. USAID and HHS are presently working with 25 Global Fund recipient countries -- 11 in East Asia have received GFATM awards for malaria—some proposals specifically focus on drug resistant malaria and include efforts to address drug quality and drug management.

We have some of the best malaria experts in the world who have been requested to be on technical review panels for the Global Fund for malaria and USAID provides in country technical assistance to assist in the development of Global Fund proposals. Strategically, there is a rapidly evolving partnership between the Global Fund and USAID's malaria program. With USAID providing critical technical "know how" and the Global Fund providing the resources for the procurement of key commodities for the prevention and control of malaria there is a growing optimism that malaria endemic countries can soon begin turning the tide against malaria.

Partnerships

These actors are playing unique roles – roles only they can perform due to their expertise, positions and responsibilities.

Research institutions and pharmaceutical companies can develop improved treatments and interventions to help protect us against malaria and its impacts. USAID works closely with the HHS, which, with USAID support, provides technical assistance to the World Health Organization and ministries of health in a variety of areas related to malaria diagnosis and treatment, prevention of malaria in pregnancy, use of insecticide-treated mosquito nets (ITNs), indoor residual spraying (IRS), and monitoring and evaluation of malaria programs. USAID also provides funding to NIH for work on a malaria vaccine.

Community- and faith-based organizations and other NGOs extend deeply into many of the most rural areas, reaching societies and cultures to ensure health care services and malaria treatments and interventions get to hard-to-reach populations.

National governments have especially important roles to play with specific, attainable steps to reducing the impacts of malaria – steps that only they can take. The international donor community, in partnership with developing country partners, can ensure that technical and financial resources are allocated where they will be most effective.

USAID is committed to working with these important partners to turn the tide against malaria and other infectious diseases.

And with so many new partners, the coordination of our efforts becomes even more critical. This is as true among the U.S. government agencies as it is among our international partners, including the new Global Fund. Coordination efforts must occur at two levels: at headquarters and in the countries we are assisting.

Research

USAID has also targeted the creation of a vaccine for malaria. A vaccine candidate against malaria is currently being tested in Kenya and Mali where the disease disables or kills hundreds of thousands of people each year.

After initial safety trials in the United States, clinical trials jointly supported by the Gates Foundation, the Malaria Vaccine Initiative began last year in Kenya with a safety study on some 50 adults.

The tests showed that the vaccine was safe in adults in Kenya, so this year testing was extended to about 50 children aged 1 to 4 years. The National Institute of Allergy and Infectious Diseases (NIAID), a component of the National Institutes of Health (NIH), is now working with USAID in testing the vaccine on some 40 adults in Mali to obtain safety data in a different epidemiological setting.

While ACTs are now effective, we know that won't last. Research on new and better drugs is absolutely critical and another important part of USAID's strategy. We are supporting Medicines for Malaria Venture (MMV) and WHO in new drug development.

Tuberculosis (TB) Background

Tuberculosis (TB) is an ancient disease. While a cure has been available for over fifty years, TB still kills more than two million people every year. Each day, nearly 25,000 people develop active TB and 5,000 die from their disease. Approximately one-third of the world's population or two billion people are infected with TB. According to the 2004 WHO Global Report on TB, in 2002 there were an estimated 8.8 million new cases of TB, of which 3.9 million were sputum smear positive (Sputum smear positive TB cases affect the lungs, are the most infectious and therefore the most responsible for transmission of the disease (SS+) or "infectious" TB). In 2002, the global incidence rate (per capita) of TB was growing at a rate of 1.1% per year, and the number of cases was growing at 2.4%. Asia leads the world in terms of burden of TB – of the 22 high burden countries in the world today (accounting for 80% of the world TB cases), 11 are in Asia, including 4 out of the top 5, (India, China, Indonesia, and Bangladesh).

The global resurgence of TB has been fueled by increasing HIV/AIDS prevalence, inadequate public health systems, and emerging resistance to anti-TB drugs. Persistent

poverty, crowded living conditions, and delayed diagnosis and treatment contribute to transmission of the disease.

TB threatens the poorest and most marginalized groups, disrupts the social fabric of society, and slows or undermines gains in economic development. An overwhelming 98% of the two million annual TB deaths - and 95% of the new TB cases each year - occur in developing countries. On average, TB causes three to four months of lost work time and lost earnings of 20 – 30 percent of household income. For families of persons who die from the disease, the impact of TB is even greater as about 15 years of income is lost due to premature death. In developing countries, the impact of TB on the family is even more important as TB generally afflicts the most economically active segment of the population between the ages of 15 and 54.

Treating TB through the Directly Observed Treatment, Short-Course (DOTS)

Much progress has been made since The Stop TB Partnership (of which USAID is a member) was launched in 1998. The Amsterdam Ministerial Conference on Tuberculosis and Sustainable Development held in March 2000 established global targets of 70% TB case detection and 85% treatment success rates in SS+ pulmonary TB cases to be achieved by the year 2005 in the 22 High Burden Countries (HBCs). These countries together account for 80% of the world's estimated cases, and served to catalyze governments and donors to address TB.

The Stop TB partners and countries have endorsed The Directly Observed Treatment, Short-Course strategy as the most effective strategy available for the treatment and control of TB. The DOTS Strategy has five components: political commitment; passive case detection among patients seeking care at health facilities and diagnosis using sputum smear microscopy; standardized short-course treatment with direct observation of therapy at least in the initial phase; assurance of an uninterrupted supply of high quality drugs.

The number of countries implementing DOTS increased from 112 in 1998 to 180 in 2002 and one high burden country (Peru) reduced TB incidence sufficiently to graduate from the list of 22 HBCs. The Partnership has grown to include over 200 donors, non-governmental organizations (NGOs) and other institutions, which demonstrates the strong global commitment to combat TB and to collaboration in that effort.

However, recent analysis of global TB trends and progress in DOTS implementation indicates that without an acceleration of DOTS expansion and program strengthening, these global targets will not be achieved for many years to come. Reported global DOTS coverage of 69% masks the reality that many people, even in areas where DOTS is reportedly available, lack true access to DOTS. While the overall treatment success in DOTS areas is 82% (2001 cohort) about 31% of the world’s population resides in non-DOTS areas where treatment success averages just 40%.

USAID's Response

USAID currently supports programs to expand and strengthen DOTS in 34 countries worldwide, including eight in Asia – Afghanistan, Bangladesh, Cambodia, Egypt, India, Indonesia, Pakistan and the Philippines. Illustrative activities supported in these countries include training of health personnel, strengthening of laboratory services and provision of laboratory equipment, development of guidelines and training materials, and technical assistance to strengthen program planning, monitoring, evaluation, and supervision.

For example, in India, USAID has been a major supporter of the very successful national TB program – where DOTS coverage reached 71 percent of the population by the end of September 2003 – 774 million people. The death rate among TB patients nationally has dropped to less than 5 percent. In Indonesia, which is another of USAID's major TB programs, USAID has provided critical support to the expansion of DOTS in two major provinces, and provided the technical support for the national TB program's implementation of a Global Fund grant for TB. In the Philippines, USAID is not only providing critical support to the national public sector TB program, contributing to a 10% increase in coverage but has pioneered an innovative private sector program. This program is designed to ensure that private sector services follow appropriate regimens and are coordinated with the public sector. This is critically important in a place like the Philippines, where people with TB symptoms are more likely to seek treatment from private providers than from the public sector.

USAID's Technical Leadership

In addition to our direct support for improving TB treatment programs at the country level, USAID also provides assistance to support DOTS programs worldwide through several global mechanisms and partners such as the STOP TB Partnership and the Global TB Drug Facility (GDF). USAID is actively involved in the STOP TB Partnership – the Agency is a member of the Partnership coordinating board and USAID technical personnel are members of all STOP TB technical working groups.

The Agency provides funding and technical support to the GDF, and we are the second largest donor to the GDF. Since it was launched in 2001, the GDF has raised and committed $39 million for grants for anti-TB drugs. Through the GDF and USAID's technical assistance programs countries and NGOs also receive technical assistance and training to strengthen the management of anti-TB drugs. They can also purchase anti-TB drugs through the GDF direct procurement mechanism, and therefore take advantage of the highly competitive pricing and good quality products that are available through the GDF.

In this respect, the GDF is a perfect partner to the GFATM. Using funding provided by Global Fund grants for TB, countries and organizations can purchase TB drugs through the GDF direct procurement service.

Battling Multi-Drug Resistance

USAID is also working to address the problem of multi-drug resistant TB (MDR TB). We support country surveys to measure the magnitude of TB drug resistance as part of the on-going WHO/IUATLD Global Project on Anti-TB Drug Resistance Surveillance. To date, USAID has supported surveys in 15 countries or sites (including 3 provinces in China), with studies in 16 more countries ongoing or planned (including Indonesia and India). We also support an effective response to MDR TB by funding DOTS Plus for MDR TB pilot projects in a number of countries and settings, focusing on countries with the most serious MDR TB problem such as Russia (Orel and Ivanovo oblasts), and the Baltics (Latvia, Estonia, and Lithuania), and Kazakhstan. We provide funding to support the work of the STOP TB Green Light Committee (GLC). The GLC provides technical assistance and monitoring of DOTS Plus for MDR TB pilot projects. So far, the GLC has approved DOTS Plus pilot projects in 11 countries and another 14 applications are under review. DOTS plus projects that are approved by the GLC are eligible to purchase second-line anti-TB drugs at lower prices than on the open market. Finally, we support a network of supra-national reference laboratories that provide the necessary quality control for anti-TB drug susceptibility testing, and we are supporting training and operations research in hospital infection control to help reduce the risk of transmission of MDR TB in clinic or hospital settings.

USAID and Global Fund Support

USAID missions work closely with the Global Fund to Fight AIDS, TB and Malaria (GFATM) by leveraging mission funded programs with the substantial funding provided by the GFATM. USAID missions participate in the Country Coordinating Mechanisms, assist with grant proposal writing, and help countries prepare implementation and monitoring and evaluation plans for these grants. Through USAID technical partners such as the TBCTA and others, USAID missions provide support for technical assistance, capacity building and monitoring and evaluation to help the grant-recipient countries to effectively implement and manage GFATM grant-funded programs and activities. A total of $422 million has been awarded to 21 countries in the ANE region for TB control.

Investing in Disease Detection and Control

Drug-resistant malaria and tuberculosis are just two examples of the many public health problems that exist in East Asia. However, the basic approaches just mentioned—including capacity building, partnerships, developing new tools—also apply to other infectious diseases as well. As you know, East Asia has been in the spotlight over the past few years with outbreaks of new diseases including SARS and bird flu. While their mortality has been relatively low compared to diseases such as HIV/AIDS, TB, and malaria, these new diseases have had a major economic impact on trade, tourism, and foreign investment. First-response organizations such as the World Health Organization and the U.S. HHS have been providing key support to track these epidemics and identify ways to limit their spread and impact. In addition, USAID's Office of Foreign Disaster Assistance has provided emergency assistance to affected countries. As part of longer-

term development efforts, USAID is also working to strengthen human and institutional capacity in disease surveillance and response so that new diseases can be rapidly detected and stopped before they spread widely.

Next Steps

There is much to do. If we are to meet our goal of halving Malaria by 2010, and of achieving global program targets for TB all of us, our esteemed partners from Asian governments, health institutions and our global partners must act together through the opportunity offered by the Global Fund and through the Roll Back Malaria and Stop TB partnerships at all levels, most importantly in countries, to deliver the tools we have in hand, to develop new tools, and to fulfill the promise of coordinated and concerted support to countries.