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Multi-drug Resistant Tuberculosis: Assessing the U.S. Response to an Emerging Global Threat

**Before the Subcommittee on Africa and Global Health
Committee on Foreign Affairs
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Chairman Payne, Representative Smith, distinguished members, thank you for convening this important hearing and for inviting me to testify. Thank you for putting the spotlight on multi-drug resistant (MDR) tuberculosis (TB). The timing of this hearing is particularly relevant since the Fourth Global Drug-resistance Report was released today and less than a month from now, the U.S. Agency for International Development (USAID) will join its partners in commemorating World TB Day. The World TB Day theme of "I am stopping TB" reminds us that we all have a role to play in controlling TB.

The U.S. is on the frontlines of the battle against TB. USAID, the Centers for Disease Control and Prevention (CDC), the Office of the Global AIDS Coordinator, and the National Institutes of Health (NIH) have been working closely together over many years on combating TB and have extraordinarily good working relationships that take advantage of our respective strengths and ensure that USG resources for TB and for TB/HIV are used in the most effective and efficient manner possible. We all work closely with our international and in-country partners, and the USG is recognized not only as the leading bilateral donor for TB, but also for our technical leadership and very supportive engagement. USAID and CDC represent the U.S. Government on the international Stop TB Partnership Coordinating Board, and a USAID staff member is currently serving as Chair of the Coordinating Board.

I will speak briefly about the problem and challenges of TB, particularly as related to MDR TB and extensively drug resistant (XDR) TB. I will also outline USAID's efforts to battle the disease, particularly MDR and XDR TB, and to build local capacity to control TB and deal with the threat of MDR TB; and describe our plan to accelerate programs with the additional funds in FY 2008. I will also talk about why I believe there is reason to be optimistic about the future.

Challenges of Tuberculosis

In six years as an Assistant Administrator with USAID, first in the Europe and Eurasia Bureau and now in Global Health, I have visited hospitals, TB clinics and prison infirmaries in Russia, Moldova and other countries. I have seen the personal toll TB takes. TB kills about 1.6 million people each year, and each year, nine million people develop TB. With HIV/AIDS claiming over 2 million lives each year, and malaria killing more than 1 million, TB is one of the three leading causes of deaths worldwide due to infectious diseases. About 10 percent of TB patients are also co-infected with HIV, and TB is the leading cause of death for AIDS patients.

TB not only takes an enormous personal toll, it also places a tremendous economic burden on families, communities, and countries. While TB treatment is often free, diagnosis, laboratory charges, transport, food, and other costs can account for 8-20% of annual household income for TB patients, according to a study recently released by the World Bank.

Dr. Raviglione's testimony describes one of the more significant challenges we face - that of MDR TB and XDR TB. The occurrence of MDR and XDR TB is a growing problem. In every country that has conducted a survey for anti-TB drug-resistance, drug resistance has been found. The challenge we face is that in many countries, we do not know if we have a problem, especially in Africa where surveillance capacity is particularly weak. Many of the countries most affected by drug-resistant TB are the least able to confront the problem of drug resistance. Health system infrastructure and laboratory capacity are often inadequate. Anti-TB drugs are sold over-the-counter in many countries and untrained providers fail to follow appropriate standards for TB treatment. Crowded health facilities and

the mixing of HIV-positive persons with persons with active TB disease put both patients and health workers at risk of contracting the disease.

The 2008 Global MDR TB and XDR TB Report is the fourth in a series. As Dr. Raviglione noted, it gives us the most data we have to date on the status of MDR and XDR TB. Since USAID began working on TB in 1998, we have supported country-level drug-resistance surveys and this biannual Global Report on TB drug-resistance. We are very proud that we have helped make this vital data available, and we will continue to support this important work. We must know where the problem is to address it, and these data provide us with critically important information for targeting our collective response.

Globally, we have a strategy to fight TB and a clear plan for what is to be done. That plan, articulated in the Stop TB Partnership's Global Plan to Stop TB, 2006-2015 clearly identifies actions that need to be taken to reduce the burden of TB. It also includes clear benchmarks for the critically needed new tools and weapons in the fight against TB. We must have new and more effective diagnostics, drugs, and vaccines. The most commonly used diagnostic - a microscope for detecting TB through a sputum smear -- is over 100 years old. Today's treatment consists of a four-drug cocktail that is more than 40 years old, and to ensure cure, these drugs must be taken for six to nine months.

USAID's support for TB

The core of USAID's work on TB is focused on developing the capacity of countries affected by TB to put in place effective programs to combat and control TB. As part of that work, USAID has been working closely with in-country partners, WHO, CDC, PEPFAR, and others to implement the priorities identified by the Global MDR and XDR TB Response Plan issued by WHO. Like the global response plan, USAID's first priority is building strong TB programs to prevent future MDR cases - the most important action to stop the spread of MDR and XDR.

USAID programs support the priorities of the national TB control programs and are coordinated with resources from other international donors including the Global Fund to Fight HIV/AIDS, TB and Malaria and the World Bank. CDC and PEPFAR are core partners for USAID, and we are working closely together in many countries.

Between 2000 and 2007, USAID provided nearly \$600 million for TB programs worldwide, including about \$166 million directed specifically for Africa. This is in addition to funding for TB/HIV provided under PEPFAR. USAID supports TB programs in 37 countries, focusing particularly on 19 of these countries, which are primarily high burden TB countries, or high priorities for MDR TB or TB/HIV. Our programs support the expansion and strengthening of basic TB programs or DOTS (Directly Observed Therapy, Short Course) as the key intervention for preventing the emergence of drug-resistant TB.

USAID also supports high priority late stage research, currently focusing on evaluating promising new TB drugs and testing new diagnostics in high burden countries. Our investments in research are coordinated closely and complement those of the NIH and CDC.

USAID also supports the scale up of MDR treatment, procurement of laboratory equipment and supplies, quality assurance for laboratories, community-based DOTS, and information and communication activities to raise awareness of TB and to stimulate demand for services. USAID-assisted programs in countries such as India, the Philippines, and Afghanistan are leaders in engaging private providers and NGOs to provide DOTS services. To help ensure synergies between USG investments in TB and HIV/AIDS, many of our TB focus countries overlap with focus countries of the President's Emergency Plan for AIDS Relief (PEPFAR). These countries are Ethiopia, Kenya, Mozambique, Namibia, Nigeria, South Africa, Tanzania, Uganda, and Zambia. In these countries, USAID resources strengthen TB control services for the general population whereas PEPFAR resources generally focus on TB-HIV/AIDS collaborative activities targeting persons co-infected with both TB and HIV.

Despite the magnitude of the problem, we are making progress in controlling the epidemic. In 2005, the World Health Organization (WHO) reported that the rate of new TB cases - or the TB incidence rate -- leveled off for the first time since the WHO began collecting data about the disease. The rate at which TB cases were detected has doubled since 2000. Globally the target of successfully treating 85% of TB cases has nearly been met, and we continue to make steady progress toward the target of 70% case detection. Our efforts are having an impact and this is good news.

USAID's MDR/XDR Response

Specifically with regard to MDR/XDR TB, USAID is deeply concerned about the magnitude of the drug-resistance

problem and we are committed to addressing it. In addition to our work to help countries strengthen their basic TB programs, USAID has also been a global leader in addressing MDR TB. In the last year and a half, we have moved quickly to help countries and our international partners respond to the latest data on MDR and XDR TB. This has included support for drug-resistance surveys and the building of laboratory capacity to detect resistant strains, expanding country level programs to treat MDR TB patients, and support for the Green Light Committee, which helps ensure that countries have effective programs to manage MDR TB patients and second line anti-TB drugs.

Our efforts have particularly focused on countries that have the greatest burden of MDR TB, including Russia, South Africa, Namibia, the Baltic States, Ukraine, India, and Indonesia. Given the deadly combination of MDR/XDR TB and HIV, we have also focused attention on other parts of Africa, where laboratory capacity is particularly weak and there is very limited data on the scale of MDR TB. Let me give you a few specific examples of the kind of work USAID has done in the last year.

In Russia, the USAID-supported Orel Center of Excellence for MDR TB was officially opened in August of 2007. The Center is conducting training of 300 technical personnel involved in the Global Fund MDR TB activities, an essential input to ensuring the success of the program. The USAID-supported MDR TB treatment program in Orel achieved a treatment success rate of 76%, compared to the national average of 59%. Of the sixteen provincial TB control programs in Russia that have been approved by the GLC - which is an indication of a strong TB and MDR TB program -- six are currently supported by USAID. Infection-control measures have been implemented in all facilities in the USAID-supported sites.

In South Africa, following the XDR outbreak reported in KwaZulu Natal, USAID stepped up technical assistance to address MDR and XDR TB. USAID provided assistance to conduct an in-depth investigation into the KwaZulu Natal outbreak. We helped enhance national surveillance of MDR and XDR TB. USAID provided assistance to improve the quality of DOTS and TB/HIV care to two of the three TB crisis provinces (in line with the national TB emergency plan). USAID also assisted the MDR-TB Units in all provinces to establish teams to trace contacts of all confirmed XDR-TB cases.

In eastern, western, and southern Africa, USAID has provided substantial support to enhance regional laboratory capacity to undertake culture and drug-sensitivity testing. USAID supported the establishment of a supranational reference lab in Benin. Strengthening of national reference laboratories in Uganda and Tanzania is underway. The goal of this assistance is to create at least one laboratory that will have adequate capacity to serve as a supranational reference laboratory for East Africa, joining the USAID-supported laboratory in Benin and a lab in South Africa, to enable quality assurance and drug sensitivity testing for the continent.

In addition, PEPFAR funds through USAID, support the Green Light Committee to provide technical assistance to Global Fund grants with MDR TB components; this assistance includes preparation of GLC country applications, strengthening national laboratory capacity, strengthening country teams to manage MDR TB programs, and monitoring of GLC-approved projects. GLC has been able to substantially increase the number of patients approved for MDR-TB treatment through Global Fund grants with this USG support, and continued support ensures that the important work will continue.

Building strong human resource capacity and detailed strategic planning are crucial components of the response to MDR and XDR TB. USAID has supported regional training courses on MDR/XDR TB management in East and West Africa, India, South East Asia, and Latin America. With USAID support, WHO has carried out technical assistance visits to southern Africa countries at high risk for MDR and XDR TB - Lesotho, Malawi, South Africa, Swaziland, and Zambia - and helped prepare plans for accelerating MDR/XDR TB control activities in each country.

Confronting the challenge of MDR TB and the looming threat of XDR TB has galvanized the global TB community. The urgent need to bring this threat under control forces renewed focus on improving the quality of basic TB-control services to prevent the emergence of drug-resistance in the first place. Along with our colleagues from CDC, USAID is an active participant on the Global XDR TB Task Force, and we supported the preparation of Global MDR TB and XDR TB Response Plan 2007-2008.

USAID TB programs have also advanced TB-HIV/AIDS collaborative activities. Working closely with PEPFAR, for example, the USAID program in Ethiopia increased HIV testing among TB patients from 30% in 2006 to 60% in 2007, and in Uganda, testing increased from 70% to 82% over the same time period.

These efforts are having an impact. The target for successfully treating TB cases of 85% of detected cases has been met or surpassed in Afghanistan, Bangladesh, Cambodia, the Democratic Republic of Congo, India, Indonesia, and Pakistan. Case detection rates are also improving, with substantial increases reported by countries such as Afghanistan, Bangladesh, Pakistan, the Russian Federation, and Ukraine. Indonesia, Kenya, Philippines, and South Africa have all surpassed the case detection target of 70% of estimated cases, and several other countries are closing in on this global target.

USAID's Plan for Scaling-Up in FY 2008

The generous funding increase for USAID for TB from \$93 million in FY 2007 to \$153 million in FY 2008 demonstrates the ongoing commitment of the United States Government to do its part to stop TB. We are grateful for the confidence that the Congress has in our programs, and we believe your confidence is based on the success of our programs.

USAID's FY 2008 TB funding will be used to scale up significantly interventions to respond effectively to and prevent MDR and XDR TB. Work is already underway. USAID's response supports the Global MDR TB and XDR TB Response Plan, the targets set forth in the Stop TB Partnership's Global Plan to Stop TB 2006 - 2015 and the interventions recommended in the Stop TB Strategy.

USAID is focusing its program on scaling up interventions in priority countries that either already have or are threatened by MDR or XDR TB and in countries with weak performance in case detection and treatment outcomes. Our scale-up program will assist seventeen of the twenty-five priority countries identified in the WHO's Global MDR TB and XDR TB Response Plan. In Africa, these include: Ethiopia, Democratic Republic of Congo, Nigeria, and South Africa. In Asia, increased funding will be targeted to Bangladesh, India, Indonesia, Pakistan, Philippines, and the Central Asian Republics. Finally, in the Europe and Eurasia region, increased funding will go to Russia, Ukraine, and Azerbaijan.

USAID's technical team is working with our USAID missions to prepare plans for scaled-up country programs to support the national TB programs in our priority countries. The plans will focus on several key areas. First and foremost, country programs will improve the quality of basic DOTS services to slow the emergence of drug-resistant TB. This includes laboratory strengthening, improved management of TB programs, and involvement of private providers and communities. USAID will expand the capacity to treat MDR TB to ensure that more patients with MDR or XDR TB are put on appropriate treatment. Since surveillance information is lacking in many countries, USAID will support studies to determine the prevalence of MDR/XDR TB in all priority countries where the data is not currently available. To improve diagnostic capacity, USAID will support country-level laboratory infrastructure, including capacity for culturing samples for a definitive diagnosis of TB and drug-sensitivity testing. Working closely with PEPFAR, USAID will also support improved case management of patients co-infected with HIV and TB, particularly MDR TB. Finally, USAID will continue to support infection-control measures to protect health workers and patients from disease transmission. The county plans will include clear benchmarks and targets, and will describe how USAID's resources will be coordinated with resources available from other sources such as the Global Fund and PEPFAR.

While the majority of our effort will focus on the country level, USAID will fund critical global and regional activities. These activities include providing technical support for two or three supranational reference laboratories for MDR/XDR referral in Africa, Asia, and Eurasia where they are desperately needed. USAID will also increase our support to the Green Light Committee and for technical assistance and training related to laboratory and infection control issues. We will provide \$15 million to the Global TB Drug Facility to support grants for TB drugs to countries in need. In order to expand the supply of quality-assured second line anti-TB drugs, USAID will provide technical assistance to manufacturers of second-line anti-TB drugs in order to help them achieve Good Manufacturing Practices. We will also invest in the future. Approximately 8-10% of our funding will be used for research for evaluating promising new TB drugs and drug combination regimens that could be used for treating and preventing MDR TB. This includes an increase in our funding for the evaluation of new diagnostics, including technologies for the rapid detection of TB and MDR/XDR TB, and research into the most cost-effective approaches to infection control.

U.S. Commitment

We know what needs to be done. The Global Plan to STOP TB 2006-2015 and the Global MDR-TB and XDR-TB Response Plan 2007-2008 provide us the road map and key interventions. The challenges are enormous, but we have seen steady progress in TB control in recent years. Our strategy and approach are clear, and we are beginning to see the fruits of recent investments in research. In the coming year, we expect to see improved tools to help better diagnose patients, including patients with MDR TB. The international partnership is strong, global commitment is high, and the strong endorsement from this body reflects the unwavering commitment from the U.S. government. Your support is crucial, and I thank you very much for your strong commitment. With this engagement and political will, we can stop TB.