STATEMENT OF
THE TB COALITION

submitted to

THE SENATE STATE, FOREIGN OPERATIONS AND RELATED AGENCIES APPROPRIATIONS SUBCOMMITTEE

on the

FISCAL YEAR 2010, STATE, FOREIGN OPERATIONS AND RELATED AGENCIES APPROPRIATIONS BILL

May 25, 2009

On behalf of the undersigned organizations:
American Thoracic Society

Department of State
Summary of Programs

U.S. Agency for International Development
Tuberculosis Program
FY2010 Funding Recommendation: $650 million

Introduction

Tuberculosis (TB) is the second-leading infectious disease killer in the world, taking 1.8 million lives per year. Currently, about a third of the world's population is infected with the TB bacterium. The disease is predicted to kill millions more people in the next decade. TB is a leading global killer of women of reproductive age and the leading cause of death among people with HIV/AIDS. **We recommend that the FY10 State-Foreign Operations Appropriations bill provide $650 million for USAID's global tuberculosis program, to begin a five-year scale up to the global TB funding authorized under the Lantos-Hyde Act.**

The rise in HIV infection levels and the neglect of TB control programs have caused a global resurgence of TB. Drug-resistant strains of TB, including multi-drug resistant (MDR) TB and extensively drug-resistant, (XDR) TB are spreading. While most TB prevalent today is a preventable and curable disease when international prevention and treatment guidelines are used, many parts of the world -- such as Africa -- are struggling to implement them, giving rise to more drug resistant TB and increasingly XDR-TB.

Drug Resistant TB as a Global Health Crisis

MDR-TB is TB that is resistant to at least two of the best anti-TB drugs, isoniazid and rifampicin. These drugs are considered first-line drugs. MDR-TB has been identified in all regions of the world, including the U.S. XDR-TB is resistant to two main first-line drugs and to at least two of the six classes of second-line drugs. This makes the strain very difficult and costly to treat. Because it is resistant to many of the drugs used to treat TB, XDR-TB has an extremely high fatality rate. In an outbreak in South Africa that lasted from late 2005 through early 2006, XDR TB killed 53 out of 54 infected patients. All of those who were tested were co-infected with HIV. The convergence of several factors threatens to result in XDR-TB occurring on a much broader scale. The major factors include inadequate attention to and funding for basic TB control measures in high TB burdened countries, resource-limited settings, which also have high HIV prevalence; and the lack of investment in new drugs, diagnostics and vaccines for TB.

Resources Needed to Address TB

Currently, the extent of the global drug resistant TB burden remains unknown. A global supranational laboratory capacity must be built to enable drug susceptibility testing in all parts of the world. Immediate interventions require outbreak and cluster investigations to identify and interrupt the chains of transmission, and implementation of infection control precautions to protect healthcare workers, other patients, and their families. New rapid diagnostic tests must be deployed and promising new drugs against TB must be promptly evaluated for efficacy and safety, especially in populations with virtually untreatable forms of XDR TB. Further investment must be made in developing new TB vaccines that will protect against all strains of TB, including those that are MDR and XDR. Drug resistant TB develops as a result of poor basic TB control. Thus one of the best ways to prevent outbreaks of drug resistant strains is to reinvest in basic TB control programs.

The following specific resources are required to address the current unmet domestic and global needs:

1) Build supranational TB reference laboratory capacity for rapid surveys to evaluate susceptibility to first- and second-line anti-TB drugs and genotype isolates to guide planning for the global response.

2) Improve the domestic and global preparedness and outbreak response capacity, and options for effective treatment of affected persons. This includes providing travel and technical support for subject-matter experts to identify and investigate outbreaks; building capacity to institute infection control measures in affected areas -- with emphasis on healthcare settings where vulnerable HIV-infected persons congregate; and improving the use of anti-TB drugs and adherence to measures that prevent the development of drug resistance.

3) Accelerate field-testing of new methods to screen for drug resistance and for real-time culture and drug-susceptibility testing of clinical isolates from TB patients.

4) Consistent with its mission of supporting health-related research in developing countries, USAID funding is needed to improve the capacity to conduct clinical research to evaluate the efficacy and safety of new promising compounds against drug-resistant forms of tuberculosis; to

develop new drugs to target resistant microbes that can be safely used in conjunction with antiretroviral therapy; and to accelerate clinical trials to develop new vaccines and diagnostics.

HIV/AIDS-TB Integration

TB is a major killer of people with HIV globally and the leading cause of death for people with HIV in Africa. Because of the rapid fatality rates associated with TB in people with HIV/AIDS, it is critically important to increase efforts to detect and treat TB among this population. Yet, World Health Organization data indicates that only about one percent of people living with HIV/AIDS are screened for TB. If active TB is left untreated, a TB-HIV co-infected person can die within a matter of weeks even if (s)he is on anti-retrovirals for HIV. It is critical that national TB programs work closely with national AIDS programs to ensure HIV services are implementing the "Three I's" (1: Isoniazid preventive therapy; 2: Intensified case finding; 3: Infection control) which can greatly reduce transmission of TB and overall burden of TB among people with HIV.

Need for New TB Tools

Although drugs, diagnostics, and vaccines for TB exist, these technologies are antiquated and are increasingly inadequate for controlling the global epidemic. The most commonly used TB diagnostic in the world, sputum microscopy, is more than 100 years old and lacks sensitivity to detect TB in most HIV/AIDS patients and in children. Current diagnostic tests to detect drug resistance take at least one month to complete. Faster drug susceptibility tests must be developed to stop the spread of drug resistant TB. The TB vaccine, BCG, provides some protection to children, but it has little or no efficacy in preventing pulmonary TB in adults.

There is an urgent need for new anti-TB treatments, and particularly for a shorter drug regimen. Currently, the drug regime for TB treatment is 6-9 months. A shorter drug regimen with new classes of drugs active against susceptible and drug-resistant strains would increase compliance, prevent development of more extensive drug resistance, and save program costs by reducing the time required to directly observe therapy for patients. There is also a critical need for drugs that can safely be taken concurrently with antiretroviral therapy for HIV. The good news is that new drugs in development hold the promise of shortening treatment from 6-9 months to 2-4 months.

The Comprehensive TB Elimination Act, enacted into law in October 2008, provided authorization language to spur the development of new TB diagnostic, treatment and prevention tools through the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). Provision of the coalition's recommendation level of $210 million in FY2010 for CDC's Division of TB Elimination would accelerate early-stage research and epidemiology studies that are critical to the development of these new tools. In addition, USAID plays a vital role in supporting research into diseases that affect the developing world, including tuberculosis, and appropriate funding for USAID's TB research program will provide a strong U.S. reinvestment into new TB tools to help ease the global disease burden.

Congressional Response

President Bush signed the Lantos-Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis and Malaria into law in July 2008. This historic legislation reauthorized the President's Emergency Plan for HIV/AIDS Relief and enacted legislation to implement the

global Stop Tuberculosis (TB) Strategy through the U.S. Agency for International Development's (USAID) global TB program.

The Stop TB Strategy expands efforts to detect and treat all forms of TB, including TB in people with HIV/AIDS. The Lantos-Hyde Act authorized the resources and tools to speed the integration of HIV/TB programs. The Act also authorized support for the development of urgently needed new TB diagnostic, treatment and prevention tools, including vaccines.

Recommendations

The Lantos-Hyde Act authorized $4 billion over five years for global TB programs through USAID. We recommend that the FY10 State-Foreign Operations Appropriations bill provide $650 million for USAID's global tuberculosis program, to begin a five-year scale up to the global TB funding authorized under the Lantos-Hyde Act. The appropriation of an additional $70 million for CDC's global TB activities through the FY10 Labor-HHS Appropriations legislation will provide the coordinated global TB investment envisioned under the Lantos-Hyde Act.

Over two-thirds of international funding for global TB control is provided through the Global Fund to Fight AIDS, Tuberculosis and Malaria, so it is critical that the U.S. provide an appropriate investment, particularly at this time when the Fund is projecting a significantly increased need to combat these diseases of poverty. We recommend that FY10 State-Foreign Operations Appropriations bill provide $2.7 billion in FY2010 for the Global Fund to Fight AIDS, TB and Malaria.

We appreciate the opportunity to submit this statement for the record. Please contact Nuala Moore, with the American Thoracic Society, at 202.296.9770 or via e-mail at Nmoore@thoracic.org.