STATEMENT OF
THE TB COALITION

submitted to

THE SENATE LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION APPROPRIATIONS SUBCOMMITTEE

on the

FISCAL YEAR 2010 LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION APPROPRIATIONS BILL

May 25, 2009

On behalf of the undersigned organizations:
American Thoracic Society

Department of Health and Human Services
Summary of Programs

Centers for Disease Control and Prevention
National Tuberculosis Elimination Program
Division of TB Elimination
FY2010 Funding Recommendation: $210 million

National Institutes of Health
National Institutes of Allergy and Infectious Diseases

Tuberculosis

The TB Coalition is a network of public health, research, professional and advocacy organizations working to support policies to eliminate TB in the U.S. and around the world. The TB Coalition is pleased to submit our recommendations for programs in the Labor-Health and Human and Education purview. **The TB Coalition, in collaboration with Stop TB USA, recommends a funding level of $210 million in FY 2010 for CDC's Division of TB Elimination, as authorized under the Comprehensive TB Elimination Act.**

TUBERCULOSIS

Tuberculosis (TB) is an airborne infection caused by a bacterium, ***Mycobacterium tuberculosis***. TB primarily affects the lungs but can also affect other parts of the body, such as the brain, kidneys or spine. TB is the second leading global infectious disease killer, claiming 1.8 million lives each year. Currently, about a third of the world's population is infected with the TB bacterium. It is estimated that 9-14 million Americans have latent TB. Tuberculosis is the leading cause of death for people with HIV/AIDS in the developing world. According to a 2009 World Health Organization (WHO) report on global TB control, about 5 percent of all new TB cases are drug resistant. The global TB pandemic and spread of drug resistant TB present a persistent public health threat to the U.S.

The major factors that have caused the spread of drug resistant TB -- including multi-drug resistant TB (MDR) and extensively drug resistant (XDR) TB -- are inadequate attention to and funding for basic TB control measures in high TB burden; resource-limited settings, which also have high HIV prevalence; as well as the lack of investment in new drugs, diagnostics and vaccines for TB. 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 and Eastern Europe -- are struggling to implement them, giving rise to more drug resistant TB and increasingly, XDR-TB.

XDR-TB as a Global Health Crisis

XDR-TB has been identified in all regions of the world, including the U.S. The strain is resistant to two main first-line drugs and to at least two of the six classes of second-line drugs. Because it is resistant to many of the drugs used to treat TB, XDR-TB treatment is severely limited and the strain has an extremely high fatality rate. In an outbreak in the Kwazulu-Natal province of South Africa from late 2005 through early 2006, XDR TB killed 52 out of 53 infected HIV-infected patients within just three weeks of diagnosis. According to the CDC, there have been 83 cases of XDR-TB in the U.S. between 1998 and 2008. While the treatment success rate for XDR-TB in the U.S. is about 64 percent, the extremely high costs of treating XDR-TB, coupled with high fatality rates associated with the strain make XDR-TB a significant public health concern for the U.S.

New TB Tools Needed

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. Skin tests used in the U.S. are more effective at detecting TB, but take up to 3 days to complete. 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.

TB in the U.S.

Although the numbers of TB cases in the US continue to decline, with 12,898 new cases reported in 2008, progress towards TB elimination has slowed. The average annual percentage decline in the TB rate slowed from 7.3 percent per year during 1993-2000 to 3.8percent during 2000-2008. Foreign-born and ethnic minorities bear a disproportionate burden of U.S. TB cases. The proportion of TB cases in foreign-born people has increased steadily in the last decade, from 27 percent of all cases in 1992 to 58 percent of all cases in 2008. Border states and states with high immigration levels such as California, and Texas and New York are among the highest-burdened TB states. U.S.-born blacks make up almost half (45percent) of all TB cases among U.S.-born persons.

In the 1970s and early 1980s, the U.S. began significantly reducing the TB control infrastructure. Consequently, the trend towards TB elimination was reversed and the nation experienced an unprecedented resurgence of TB, including many MDR-TB cases. There was a 20 percent increase in cases reported between 1985 and 1992. In just one city, New York City, the cost to regain control of TB was over $1 billion. The 2000 Institute of Medicine (IOM) report, *Ending Neglect: the Elimination of Tuberculosis in the United States,* found that the resurgence of TB in the U.S. between 1985 and 1992 was due in large part to funding reductions and concluded that with proper funding, organization of prevention and control activities, and research and development of new tools, TB could be eliminated as a public health problem in the U.S.

Drug-resistant TB poses a particular challenge to domestic TB control, owing to the high costs of treatment and intensive health care resources required. Treatment costs for multidrug-resistant (MDR) TB range from $100,000 to $300,000, which can cause a significant strain on state public health budgets. Inpatient care has been estimated for California XDR TB patients from 1993-2006 at an average of approximately $600,000 per patient.

Strong State and Local TB Control Programs

The best defense against the development of drug resistant tuberculosis is a strong network of state and local public health programs and laboratories. State, local, and territorial health departments provide important TB control services such as directly observed therapy (DOT, a proven method to improve adherence and thus prevent drug resistance), laboratory support, surveillance, contact tracing, and patient counseling. CDC provides about $100 million annually in support to state, local and territorial health departments to prevent and control TB.

According to the National Tuberculosis Controller's Association, for every confirmed case of TB, state and local health department must identify and test an estimated 14 persons who may have been exposed. Yet after almost a decade of stagnant funding, many state TB programs have been left seriously under-resourced at a time when TB cases are growing more complex to diagnose and treat. The higher percentage of foreign-born TB patients adds to the need for specially trained TB professionals. According to a recent assessment by CDC's Division of TB Elimination, more than 1077 jobs have been lost in state TB control programs over the last three years -- ranging from doctors and nurses to lab personnel and outreach workers.

Despite low rates, persistent challenges to TB control in the U.S. remain. Specifically: (1) racial and ethnic minorities continue to suffer from TB more than majority populations; (2) foreign-born persons are adversely impacted; (3) sporadic outbreaks/clusters occur, outstripping local capacity; (4) continued emergence of drug resistance threaten our ability to control TB; and (5) there are critical needs for new tools for rapid and reliable diagnosis, short, safe, and effective treatments, and vaccines.

Congressional Response to TB

In recognition of the need to strengthen domestic TB control, the Congress passed the Comprehensive Tuberculosis Elimination Act (CTEA) (P.L. 110-392) in October 2008. This historic legislation was based on the recommendations of the Institute of Medicine and revitalized programs at CDC and the NIH with the goal of putting the U.S. back on the path to eliminating TB. The new law authorizes an urgently needed reinvestment into new TB diagnostic, treatment and prevention tools. **The TB Coalition, in collaboration with Stop TB USA, recommends a funding level of $210 million in FY 2010 for CDC's Division of TB Elimination, as authorized under the CTEA.** The CTEA, as introduced, included a separate authorization of $100 million through CDC's TB elimination program for the development of urgently needed new TB diagnostic, treatment and prevention tools to ease the global TB pandemic. We hope that this unique area of need will also be considered in the final FY10 funding levels.

National Institutes of Health

The NIH has a prominent role to play in the elimination of tuberculosis through the development of new tools to fight the disease. However, the Coalition is concerned that the NIH has reduced funding for TB research from $211 million in 2007 to $160 million in 2008. We encourage the NIH to expand efforts, as requested under the Comprehensive TB Elimination Act, to develop new tools to reduce the rising global TB burden, including faster diagnostics that effectively identify TB in all populations, new drugs to shorten the treatment regimen for TB and combat drug resistance, and an effective vaccine.

Conclusion

The global TB epidemic endangers TB control efforts in the U.S. TB case rates in the United States reflect the global situation. The best way to prevent the future development of drug-resistant strains of tuberculosis is through establishing and supporting effective global and domestic tuberculosis control programs and research programs through the

CDC, NIH, and U.S. Agency for International Development (USAID). The TB Coalition appreciates this opportunity to provide testimony. Please contact Nuala S. Moore with the American Thoracic Society with any questions at 202.296.9770 or via e-mail at Nmoore@thoracic.org.