Statement for the Record for the House Africa & Global Health Subcommittee Hearing: Multidrug Resistant Tuberculosis: Assessing the U.S. Response to an Emerging Global Threat

February 27, 2008

On behalf of the undersigned organizations:
Aeras Global TB Vaccine Foundation
American Lung Association
American Public Health Association
American Thoracic Society
Association of Public Health Laboratories
Families USA Global Health Initiative
Global Alliance for TB Drug Development
Global Health Council
RESULTS
Treatment Action Group

We would like to thank Chairman Payne for holding this important hearing and we appreciate the opportunity to submit a statement for the record. We applaud the World Health Organization (WHO) for the release of its new analysis of the prevalence of drug resistant TB globally, *Anti-Tuberculosis Drug Resistance in the World.* This important report provides the data necessary to assess the scale of the drug resistant TB crisis and prepare an appropriate global response. Recent publicized cases of drug resistant TB in the U.S. have demonstrated the ease with which this disease travels across borders and serves as a timely warning of the public health preparedness challenges we face in controlling TB globally in all forms.

Introduction

Tuberculosis (TB) is the second-leading infectious disease killer in the world, taking 1.6 million lives per year. Currently, about a third of the world's population is infected with the TB bacterium.[i] 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.

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, have emerged and 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.

TB Has Not Been Controlled in the U.S.

In the U.S., many people think tuberculosis (TB) is a disease of the past. This is untrue. In the early 1990's New York City had a resurgence of TB that cost the city over $1 billion. The 2000 Institute of Medicine (IOM) report, 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.

TB occurs among foreign-born individuals over nine times as frequently as among people born in the United States (according to the latest Centers for Disease Control and Prevention figures). Minorities are also disproportionately affected by TB. According to the CDC, although the overall rate of new TB cases is declining in the U.S., the annual rate of decrease in TB cases has slowed significantly, from about 6.6 percent (1993 to 2002) to 3.1 percent currently (2003 – 2006).[ii]

We support enactment of the Comprehensive TB Elimination Act, sponsored by Reps. Green (D-TX) and Wilson (R-NM) and Sens. Brown (D-OH) and Hutchison (R-TX), and the Stop TB Now Act, sponsored by Reps. Engel (D-NY), Wilson (R-NM) and Sens. Boxer (D-CA) and Smith (R-OR), to provide full funding for TB control as

recommended by the Institute of Medicine 2000 report, *Ending Neglect: The Elimination of Tuberculosis in the U.S.* To strengthen domestic TB control, including efforts to prevent the spread of XDR TB in the U.S., we recommend a funding level of $300 million in Fiscal Year 2009 for the Centers for Disease Control's Division of Tuberculosis Elimination program.

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 from late 2005 until early 2006, XDR TB killed 52 out of 53 infected patients.[iii] 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 burden, 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) Improve the capacity to conduct clinical research to evaluate the efficacy and safety of new promising compounds against drug-resistant forms of tuberculosis; and develop new drugs to target resistant microbes that can be safely used in conjunction with antiretroviral therapy.

Need for New TB Tools

New research on diagnostic, treatment and prevention tools is urgently needed. The standard method of diagnosing TB was developed 100 years ago and fails to adequately detect TB in children and those co-infected with HIV/AIDS. Moreover, the newest class of drugs to treat TB is over 40 years old. The current TB vaccine, BCG, provides some protection against severe forms of TB in children, but is unreliable against pulmonary TB, which accounts for most of the worldwide disease burden. We support enactment of the Comprehensive TB Elimination Act, S.1551/H.R. 1532, sponsored by Sens. Brown (D-OH) and Hutchison (R-TX) and Reps. Green (D-TX), Wilson (R-NM) and the Stop TB Now Act, S. 968/H.R. 1567, sponsored by Sens. Boxer (D-CA) and Smith (R-OR) and Reps. Engel (D-NY), Wilson (R-NM), which will both expand research efforts into new tools to combat TB. The bill includes authorization for research at the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) into new TB drugs, diagnostics and vaccines.

Global TB Control Efforts

The World Health Organization declared TB a global health emergency in 1993. The Stop TB Partnership released the Global Plan to Stop Tuberculosis 2006-2015 at the World Economic Forum in January 2006. If all elements of the plan are implemented, an estimated 14 million lives will be saved between 2006 and 2015. The Global Plan estimates that $56 billion is needed over ten years to halve the TB deaths and disease burden by 2015. This includes $47 billion for country needs and $9 billion or research and development into new TB diagnostics, drugs and an effective vaccine.

The components of the plan and corresponding implementation strategies are as follows:

1. Pursue high-quality directly-observed treatment strategy (DOTS) expansion and enhancement through:

a) Political commitment with increased and sustained financing
b) Case detection through quality-assured bacteriology
c) Standardized treatment, using internationally recommended drug regimens and quality-assured drugs with appropriate supervision and patient support
d) Monitoring and evaluation system, and impact measurement

2. Address TB/HIV, MDR-TB and other challenges

a) Implement collaborative TB/HIV activities
b) Prevent and control MDR-TB
c) Address prisoners, refugees and other high-risk groups and situations

3. Contribute to health system strengthening

a) Actively participate in efforts to improve system-wide policy, human resources, financing, management, service delivery, and information systems.
b) Share innovations that strengthen systems, including the Practical Approach to Lung Health (PAL)
c) Adopt innovations from other fields

4. Engage all health care providers

a) Public-public and public-private mix (PPM) approaches
b) Implement the International Standards for Tuberculosis Care (ISTC)

5. Empower people with TB, and communities

a) Advocacy, communication, and social mobilization
b) Community participation in TB care
c) Implement the Patient's Charter for Tuberculosis Care

6. Enable and promote research

a) Program-based operational research
b) Research to develop new diagnostic tools, drugs and vaccines

Recommendations

The best way to prevent the future development of drug-resistant strains of tuberculosis is through establishing and supporting effective tuberculosis control programs in the U.S. and globally. As we provide resources to respond specifically to the XDR TB emergency, we must keep in mind the ongoing need for consistent support of global TB control programs through the U.S. Agency for International Development (USAID) and the CDC.

To increase USAID's resources and authority to combat TB globally, we support enactment of the Stop TB Now Act, S. 968/H.R. 1567, sponsored by Sens. Boxer (D-CA) and Smith (R-OR), and Reps. Engel (D-NY) and Wilson (R-NM) and the House legislation sponsored by Rep. Lantos (D-CA), the United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Act, that the Stop TB Now Act has been incorporated into. As authorized in the Stop TB Now Act, we recommend a funding level of $450 million for USAID's global TB program and $100 million for CDC's global TB activities in Fiscal Year 2009. We recommend an appropriation of $400 million in Fiscal Year 2009 for the Global Fund to Fight AIDS, TB and Malaria. Enactment of the global TB control legislation, the Stop TB Now Act and the domestic TB control legislation, the Comprehensive TB Elimination Act, will provide researchers and public health officials the tools needed to help eliminate TB in the U.S. and around the world.

We appreciate the opportunity to submit this statement for the record.

[i] Tuberculosis. World Health Organization (WHO) Factsheet No. 104, March 2006.
[ii] CDC. *Reported Tuberculosis in the United States, 2006*. Atlanta, GA: U.S. Department of Health and Human Services, CDC, September 2007.

[iii] "Virulent TB in South Africa May Imperil Millions." New York Times. 28 Jan. 2007. 21 Mar. 2007.