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Public Witness Hearing  
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Testimony Concerning FY 2010 Funding at the Department of Health and  
Human Services for Programs Related to Tuberculosis and Global  
HIV/AIDS at the Centers for Disease Control and Prevention, and the  
National Institutes of Health

The Infectious Diseases Society of America's (IDSA) is pleased to submit testimony about the urgent need to increase funding for the Department of Health and Human Services' programs that address two deadly global pandemics-- HIV/AIDS and tuberculosis.

IDSA represents more than 8,000 infectious diseases and HIV physicians and scientists devoted to patient care, education, research, prevention and public health. Nested within the IDSA is the HIV Medicine Association (HIVMA), representing more than 3500 physicians, scientists, nurse practitioners and other health professionals working in HIV medicine. In 2008, IDSA and HIVMA launched the Infectious Diseases Center on Global Health Policy and Advocacy to address global HIV/AIDS, tuberculosis, and HIV/TB co-infection. Under the leadership of a scientific advisory committee of world-renowned scientific experts in these areas, IDSA works to educate policymakers, U.S. government program implementers and the media about evidence-based policies and programs and the value of U.S. leadership in combating these deadly and synergistic epidemics.

### **Global HIV/AIDS Pandemic**

There are 33 million people living with HIV/AIDS in the world, with 22 million of them or 67 percent living in sub-Saharan Africa. AIDS kills 2 million people annually. U.S. leadership has been the catalyzing force for preventing millions of infections, ensuring access to lifesaving HIV treatment for 3 million persons in developing countries, and providing care and support to millions of additional people, including orphans and vulnerable children. Despite tremendous progress, only about one-third of persons in developing countries who are clinically eligible for antiretroviral therapy are receiving it, and an ongoing and robust prevention campaign is essential to reduce the more than 7,000 new HIV infections that still occur on a daily basis.

NIH-funded HIV research at the NIH research led to the development of lifesaving antiretroviral therapy, identified the efficacy of antiretroviral therapy during pregnancy to prevent mother-to-child transmission, demonstrated the HIV prevention benefits of male circumcision, and is paving the road to the availability of an effective microbicide. The Centers for Disease Control and Prevention (CDC) have been a critical implementing partner in the US response to the global HIV epidemic, working with health ministries in developing countries to launch HIV prevention and treatment programs, conducting public health evaluation research, and supporting heavily impacted countries in their efforts to monitor and to employ evidence based strategies in response to their particular epidemics.

### **Tuberculosis**

Tuberculosis is the second leading global infectious disease killer, claiming more than 1.7 million lives annually. Worldwide, one-third of the world's population is infected with TB and nearly 9 million people develop active TB disease each year. In recent years, highly drug-resistant forms of TB have emerged. Drug-resistant tuberculosis is a direct result of human failure-- failure to adequately detect and treat TB and to develop the necessary tools to effectively address this ancient and deadly scourge.

In 2006, the CDC and the World Health Organization reported the findings from a survey of TB reference laboratories around the world indicating that 20 percent of M. tuberculosis isolates were multi-drug resistant (MDR)—that is, TB strains resistant to the two most potent drugs in the 4-drug TB regimen. Four percent of these MDR-TB strains were resistant to multiple second-line drugs and were deemed extensively drug-resistant TB or XDR-TB. Mortality from XDR-TB can be as high as 85 percent, and close to 100 percent in individuals co-infected with HIV/AIDS. The increase in MDR-TB and the advent of XDR-TB have triggered grave alarm in the scientific community about the potential for an untreatable XDR-TB epidemic.

The global pandemic and alarming spread of drug-resistant TB present a persistent public health threat to the United States. Tuberculosis is an airborne infection. Drug-resistant TB anywhere in the world easily translates into drug-resistant TB everywhere.

### **Deadly Synergy of HIV/TB Co-infection**

The costly MDR TB epidemic in the US in the early 1990s emerged against a background of HIV infection in high HIV prevalence cities like New York City and Miami. Today, HIV-TB co-infection is ravaging sub-Saharan Africa. TB is the leading cause of death of persons with HIV worldwide. Tuberculosis facilitates HIV disease progression, and persons with HIV have poorer TB treatment outcomes than their non-HIV-infected counterparts. It is widely expected that the World Health Organization will release new data on March 24<sup>th</sup>—World TB Day- showing much greater numbers of HIV/TB co-infected persons and higher TB mortality among HIV-infected persons than had previously been thought.

### **CDC- Tuberculosis**

Last year, Congress passed landmark legislation—the Comprehensive Tuberculosis Elimination Act of 2008—Public Law 110-873. This bill authorizes a number of actions that will shore up state TB control programs, enhance US capacity to deal with the serious threat of drug-resistant tuberculosis and escalate our efforts to develop urgently needed new “tools” in the form of drugs, diagnostics and vaccines. Realizing these goals will require additional resources; at a minimum, it is critical that the funding authorized for FY 2010 in this important new law-- \$210 million – be appropriated for the CDC Division of TB Elimination. While this represents an increase over current funding, the scientific community, including the National Coalition for the Elimination of Tuberculosis, has estimated that \$528 million will be needed annually to implement strategies through the CDC that will advance the goal of TB elimination.

Funds are desperately needed to increase the clinical trial capacity of the Tuberculosis Trials Consortium (TBTC) to evaluate promising new drugs for MDR TB and to support clinical trials for vaccine candidates that hold the hope of eliminating the scourge of TB from the face of the earth. Additional financial support is also needed for the Tuberculosis Epidemiologic Studies Consortium (TBESC) -- critical partnerships

between TB control programs and academic institutions aimed at designing, conducting and evaluating programmatically relevant research.

Strengthening CDC's Division of TB Elimination to conduct research and support state TB control programs will protect our communities, and help ensure that another devastating outbreak of drug-resistant tuberculosis that plagued several American cities in the late 1980s does not recur. Ultimately, modest federal investments will prevent the necessity to expend huge resources treating MDR-TB and XDR-TB, which can cost \$468,000 per case to treat.

### **CDC- Global AIDS Program (GAP)**

CDC's Global AIDS Program (GAP) helps resource-poor countries prevent HIV infection; improve treatment, care, and support for people living with HIV; and build health care capacity and infrastructure. To meet these objectives, CDC sends clinicians, epidemiologists and other health professionals to help foreign governments and health institutions with a range of prevention, care and support activities. Working closely with health ministries in developing countries, CDC helps build sustainable public health capacity in laboratory services and systems, including country capacity to design and implement HIV surveillance systems and surveys.

The CDC GAP also plays an important role in helping governments monitor and evaluate the impact of HIV prevention, care and treatment programs. CDC GAP also works with the Office of the Global AIDS Coordinator as the lead on HIV prevention, and also works to evaluate the impact of US HIV prevention, treatment and care and support funding. For example, CDC GAP is currently conducting a public health evaluation (PHE) to assess the impact of PEPFAR funding on developing country health systems and access to other health care services. A funding level for CDC's GAP program of at least \$218 million is essential.

### **National Institutes of Health**

The National Institutes of Health is the world's flagship biomedical research institution, supporting basic science research, behavioral research, drug and diagnostic development and research training. Unfortunately in recent years, NIH funding has eroded, and stagnant funding has resulted in decreasing support for original research and cuts in clinical trial networks. With only one in four approved research applications receiving funding, the pipeline for critical discoveries is dwindling and young scientists are being forced to turn their attention to different professional pursuits.

IDSA is extremely pleased that the recently enacted stimulus bill contained an infusion of billions of desperately needed dollars for the NIH research enterprise. Congress rightfully acknowledged the role of scientific research in stimulating the economy. It is vital, however, that the long overdue increases in funding enjoyed by the NIH in the economic stimulus bill are maintained and enhanced in this year's funding bill—funding that will ultimately translate into improvements in individual and public health, both domestically and globally.

## **HIV/AIDS Research**

The successes of the HIV research investment is a testament to the value of research investment. A robust and comprehensive research portfolio was responsible for the rapid and dramatic gains in our HIV knowledge base, gains that resulted in reductions in mortality from AIDS of nearly 80 percent in the U.S. and in developing countries where treatment has been made available. Remarkable discoveries helped us to reduce mother-to-child HIV transmission to nearly 1 percent in the U.S. and this intervention has prevented HIV infection in hundreds of thousands of children worldwide. A continued robust HIV research effort is essential to accelerate our progress in developing more effective prevention strategies, and supporting the basic research necessary to continue our work developing a vaccine that may end the deadliest pandemic in human history. Research to improve treatment strategies to aid prevention and to maximize the benefits of antiretroviral therapy, especially in underserved populations in the U.S. and in resource-limited settings is a high priority.

The National Institute on Allergies and Infectious Diseases (NIAID) is the principal funding resource for basic and clinical HIV research, but critical HIV research is conducted through a range of NIH Institutes under the leadership of the Office for AIDS Research (OAR).

## **Tuberculosis Research**

NIAID is also a critical player in tuberculosis research. In 2007, NIAID developed a research strategy for drug resistant tuberculosis, but limited resources have slowed implementation of this strategy. According to the NIH Research Portfolio Online Reporting Tool, RePORT, NIH funding for tuberculosis research, including vaccine research totaled \$160 million in fiscal year 2008—a modest level for an infectious disease that kills millions through a pathogen that is showing increasing resistance to available medications. In fact, funding for TB research has gone in the wrong direction since NIH spent \$211 million on TB research in FY 2007. A doubling of funding for TB research would be a reasonable response to the world disease burden and the current scientific opportunities.

We must increase our investment in TB research as highlighted in the enacted Comprehensive TB Elimination Act of 2008. We must have the resources to conduct clinical trials on new therapeutics for both drug-susceptible and drug-resistant TB, to test new diagnostics in point-of-care settings, and to evaluate promising TB vaccine candidates. We urgently need treatment regimens that are shorter in duration and less toxic. Research related to pediatric tuberculosis, including drug development, must be stepped up.

It is also imperative that research activities focused on HIV/TB co-infection continue with enhanced funding. Tuberculosis is the leading cause of death among persons with HIV/AIDS worldwide. TB is more difficult to diagnose in persons with HIV and a number of important anti-TB drugs interact with HIV antivirals. Critical questions remain about

how best to sequence HIV and TB treatment in co-infected individuals—questions with life and death ramifications for millions of individuals, especially those living in sub-Saharan Africa. Tuberculosis threatens to undermine the tremendous progress that has been made in saving the lives of persons in developing countries through the provision of antiretroviral therapy.

### **Global Fund to Fight AIDS, Tuberculosis and Malaria**

Historically, one-third of US funding for the Global Fund has been appropriated through the NIAID budget and IDSA strongly supports a significant US contribution to the Global Fund. US support for the Global Fund to Fight AIDS, Tuberculosis and Malaria is a crucial part of US global health diplomacy. The Global Fund is a country-led, performance-based partnership that embraces transparency and accountability, and fosters multilateral cooperation. The Global Fund provides a quarter of all international financing for AIDS globally, two-thirds for tuberculosis, and three-quarters for malaria. Through these efforts, the Global Fund has helped save 3.5 million lives in 140 countries

In Pakistan, for example, an American-based international aid group called Mercy Corps has, using Global Fund resources, partnered with the private sector on a broad TB public education campaign, training thousands of health workers, and strengthening lab capacity to test for TB. This work has dramatically increased Pakistan's ability to detect TB cases, and now Pakistan is counting on the Fund's strong, continued support to ensure medication is available to people with TB. Continued progress on TB is essential to development in Pakistan, since 80% of Pakistanis afflicted with tuberculosis are in the most economically productive years of their lives, and the disease sends many self-sustaining families into poverty.

The Global Fund projects an \$8 billion need for new and continuing programs in 2010, but only \$3 billion in pledges are in place. The Labor, Health and Human Services Budget, through NIH, has been a crucial source of funding for the US contribution to the Fund, providing \$300 million in FY 2009. The Global Fund has requested that the US triple its total contribution for FY 2010. The portion of the US contribution provided by NIH should therefore be tripled to \$900 million. The economic, strategic and moral case for this contribution to the Global Fund is clear, and the US must do its part to help close this funding gap.

The IDSA and the HIVMA have many funding priorities to champion in the Labor-HHS-Education Appropriations bill including funds to address antimicrobial resistance, child and adult immunizations, pandemic influenza, the Ryan White CARE Act, and domestic HIV prevention. Thank you for the opportunity to highlight our funding priorities for research and programs related to global HIV and TB in the Labor-HHS-Education account.

