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THE GLOBAL THREAT OF DRUG-RESISTANT TB: A CALL TO ACTION FOR WORLD TB DAY

BRIEFING AND HEARING

BEFORE THE

SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH

OF THE

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CONTENTS

Page

BRIEFER

Mario Raviglione, M.D., Director, Stop TB Department, World Health Organization 8

WITNESSES

The Honorable Eliot L. Engel, a Representative in Congress from the State of New York 25
The Honorable Kent R. Hill, Assistant Administrator, Bureau for Global Health, U.S. Agency for International Development 30
The Honorable Mark R. Dybul, Coordinator, Office of the U.S. Global Aids Coordinator, U.S. Department of State 35
Julie L. Gerberding, M.D., M.P.H., Director, Centers for Disease Control and Prevention, and Administrator, Agency for Toxic Substances and Disease Registry 42
Joia Mukherjee, M.D., M.P.H., Medical Director, Partners in Health 60
Elena Mcewan, M.D., Senior Technical Adviser, Catholic Relief Services 66

LETTERS, STATEMENTS, ETC., SUBMITTED FOR THE RECORD

Mario Raviglione, M.D.: Prepared statement 11
The Honorable Donald M. Payne, a Representative in Congress from the State of New Jersey, and Chairman, Subcommittee on Africa and Global Health: Article from the *New York Times* dated March 20, 2007, by Lawrence K. Altman, M.D. 16
The Honorable Eliot L. Engel: Prepared statement 28
The Honorable Kent R. Hill: Prepared statement 32
The Honorable Mark R. Dybul: Prepared statement 37
Julie L. Gerberding, M.D., M.P.H.: Prepared statement 45
Joia Mukherjee, M.D., M.P.H.: Prepared statement 64
Elena Mcewan, M.D.: Prepared statement 68
The Honorable Donald M. Payne:
Joint statement from the Infectious Diseases Society of America and the HIV Medical Association 79
Statement from the American Thoracic Society 81

APPENDIX

Written responses from Mario Raviglione, M.D., to questions submitted for the record by the Honorable Adam Smith, a Representative in Congress from the State of Washington 85
Written responses from the Honorable Kent R. Hill to questions submitted for the record by the Honorable Adam Smith 87
Written responses from the Honorable Mark R. Dybul to questions submitted for the record by the Honorable Adam Smith 89
Written responses from the Honorable Mark R. Dybul to questions submitted for the record by the Honorable Christopher H. Smith, a Representative in Congress from the State of New Jersey 91

THE GLOBAL THREAT OF DRUG–RESISTANT TB: A CALL TO ACTION FOR WORLD TB DAY

WEDNESDAY, MARCH 21, 2007

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON AFRICA AND GLOBAL HEALTH,
COMMITTEE ON FOREIGN AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:59 p.m. in room 2172, Rayburn House Office Building, Hon. Donald M. Payne (chairman of the subcommittee) presiding.

Mr. PAYNE. Good afternoon. Our briefing will convene at this time. For those who are unfamiliar with the procedures in the Foreign Affairs Committee, when we have representatives of multilateral organizations come before our committee, they are not here as witnesses. So we will begin with a briefing.

After my opening statement and the opening statement of our ranking member, we will hear from our guest from the World Health Organization. Following that, we will then convene the Subcommittee on Africa and Global Health.

Thank you all for joining us here at the second hearing of the Subcommittee on Africa and Global Health in the 110th Congress. Even though this is our second hearing, it is really the first time that we have a full staff complement, and I would just like to begin by introducing the staff director of the subcommittee, Noelle Lusane, who has been with my office for a number of years and has ascended to the position of staff director.

We have with us newly joining the staff Heather Flynn, who is professional staff. She comes with a tremendous amount of experience from being director of the Africa component of the Foreign Relations Committee for Senator Joe Biden, and we have with us Fay Johnson, who is a staff associate. Fay worked with the Human Rights Council Caucus for a number of years and brings in a tremendous amount of expertise, so we are very pleased to have such an outstanding group of staff members. As they say, so go the staff; so go the member. It is good to have them with us.

The purpose of this hearing is to bring attention to the emergence of drug-resistant tuberculosis and call for U.S. action to address it as we approach World TB Day, which is March 24.

I am honored to be joined today by Ranking Member Chris Smith, our new vice chair, Diane Watson of California, and other distinguished colleagues on the Africa and Global Health Subcommittee.

Tuberculosis is a highly contagious disease easily spread from person to person through the air. According to World Health Orga-

nization estimates, someone is infected with the organism that develops into TB every second of every day. An infected person may not develop full-blown TB, but in 2004 of the 9 million who were newly infected, 2 million died.

The good news is that it is entirely curable. However, the treatment requires patients to be on a drug regimen for 6 months. If they do not complete the regimen, or if they complete it but take an incorrect number of pills during the treatment, the infection can develop into what is known as multi drug-resistant or MDR–TB. MDR–TB is not responsive to either of the two first-line TB drugs, and the treatments that are available take longer and are more expensive than regular TB medications.

Last year, the public became aware of an ever greater threat: A new, more dangerous MDR–TB strain known as extremely drug-resistant TB or XDR–TB, which is not only resistant to the two first-line drugs, but also to three of the 6 second-line drugs, so this becomes much more complicated as we see and much more dangerous and much more difficult to cure. XDR–TB has been identified in South Africa, in countries that were part of the former Soviet Union and in the six G8 countries, including the United States of America.

MDR–TB is particularly lethal to those with immune suppressed systems such as people infected with HIV. This is why drug-resistant tuberculosis threatens to undermine both the enormous progress and the billions of dollars invested in AIDS treatment in southern Africa, as well as efforts on TB control worldwide.

XDR–TB and its deadly linkage with HIV and AIDS first gained global recognition last August with reports of an outbreak in a hospital in South Africa where 52 of 53 patients with XDR–TB died, half within a matter of 16 days. This tragedy serves as a sober example of what may happen across Africa if we do not act to prevent another outbreak.

Given XDR–TB resistance to both the low-cost first-line anti-TB drugs and to several of the classes of second-line drugs used, we are faced with a burgeoning epidemic, driven by HIV infection, that is lethal.

Since the outbreak, South Africa medical authorities have documented some 400 cases in dozens more hospitals in South Africa. What is troubling, however, is that no one knows for sure that these 400 cases represent the extent of the outbreak because XDR–TB typically kills quickly, and doctors' ability to identify it is severely limited.

Experts believe that XDR–TB has moved beyond South Africa into other countries in the subregion where the capacity to identify it and control it is significantly weaker than in South Africa, therefore making it a much more difficult problem and where high HIV rates will continue to drive the epidemic.

All of us here today must work together to take the necessary steps to enhance the medical establishment's ability to identify, treat and stop the spread of drug-resistant TB primarily in Africa and to head off further incursions of XDR–TB into the United States.

Unfortunately, while we here in this room understand the gravity of this emergency, many of our colleagues even here in the

House of Representatives still do not understand it. Funding for international TB control has been flat-lined in recent years, and despite the emergence of XDR–TB not a single dollar was provided to address the outbreak in the House emergency defense supplemental budget of 2007. Waiting until fiscal 2008 to provide resources to respond to this killer disease is a very serious mistake, one that may cost people their lives here and abroad.

I look forward to hearing proposals from our witnesses today regarding how the United States should respond to the emergence of XDR–TB, especially in southern Africa, and how we can work together to ensure that our response is commensurate in resources and speed with this crisis.

I commend my colleague, Mr. Engel, who will be here shortly, for introducing H.R. 1567, the Stop TB Now Act of 2007, on March 19, which sets out the investment that our country must make in this effort. I am a co-sponsor of the bill and will do all that I can to help facilitate its passage here in the House.

I also want to acknowledge that the Office of the Global AIDS Coordinator plans to spend $120 million on TB control this fiscal year. This is a step in the right direction, but much more remains to be done. We must act quickly to support international efforts to find, control and treat XDR–TB and to strengthen basic TB control programs. Failure to do so will result in a potentially devastating health catastrophe.

Today's proceedings will be a bit unusual. For the reason of protocol, as I mentioned, we will begin with the representative from the World Health Organization who cannot officially serve as a witness. So we will start with our briefing by Dr. Mario Raviglione, director of the Stop TB Department at the World Health Organization. After hearing from him, we will officially bring our hearing to order and hear from our first panel.

Our witnesses for this hearing are an impressive group. Testifying on the first panel is the Honorable Eliot Engel of the 17th District of New York. Mr. Engel and I were in the same incoming congressional class in 1989, and I have enjoyed working with him over the years.

He serves as the distinguished chairman of the Western Hemisphere Subcommittee, of which I am a member, and has worked extensively on halting the spread of HIV here in the United States. Mr. Engel is now expanding his efforts to help fight the spread of diseases globally.

Panel II will consist of three witnesses: The Honorable Mark Dybul, the U.S. Global AIDS Coordinator. Ambassador Dybul has been with the Office of Global AIDS Coordinator almost since its inception serving as deputy to the first coordinator, Ambassador Randall Tobias.

Dr. Julie Gerberding, director of the Centers for Disease Control and Prevention, has a long career in the medical field. Dr. Gerberding is the first woman director of the CDC, and she has extensive training and expertise in the area of infectious diseases.

Finally, Dr. Kent Hill has been the assistant administrator of the Bureau for Global Health at the U.S. Agency for International Development since 2005. Prior to that he was assistant administrator

for Europe and Eurasia, an area of the world in which MDR–TB has become a serious threat.

Dr. Joia Mukherjee, medical director of Partners in Health, and Dr. Elena McEwan, senior technical advisor with Catholic Relief Services, will testify on our third panel.

Since 1989, Dr. Mukherjee has worked in the area of health care access and human rights all over the world, including in Africa, Latin America and the United States and serves as a consultant to WHO in the area of HIV and MDR–TB.

Dr. McEwan has extensive research and field experience dealing with TB. She worked for several years in Nicaragua training the Ministry of Health staff and community health care workers in dealing with TB and other health issues.

We welcome each of our witnesses and our guests, and with that I turn to the distinguished ranking member of the committee, Mr. Smith, for his opening statement.

Mr. SMITH OF NEW JERSEY. Thank you very much, Mr. Chairman, and I want to thank you, Chairman Payne, for calling this very important hearing/briefing on the important and timely global health issue of drug-resistant tuberculosis.

It is shocking that this disease, which is curable, continues to kill some 2 million people each year. Perhaps the reason for this apparent contradiction is that 98 percent of those who die from TB live in the developing world and are from the poorest and most marginalized sectors of society.

TB is particularly pernicious in that it targets young adults who are just starting to form their families and who are the producers and sustainers of their society. The emergence in recent years of drug-resistant TB has raised the specter of higher death rates: More children will lose their parents and communities will fall deeper into poverty and despair.

Combined with the fact that TB is the leading cause of death of persons with HIV/AIDS, this disease is having a particularly devastating impact on Africa. However, it is important to note that no region, indeed no country, including our own, is immune from the effects of tuberculosis.

We should all be alarmed that strains that are resistant to a single drug have been documented in every country surveyed by the World Health Organization. Given the ease with which TB can be spread, TB is truly a disease without borders, and it is in our national, as well as our humanitarian, interest to more aggressively seek its eradication.

Therefore, it is highly appropriate that this Subcommittee on Africa and Global Health commemorate World TB Day 2007 this March 24 with the rest of the world and raise our voices with that of others who seek an emergency response to this increasingly dangerous threat to global health.

I agree with my colleagues here in the Congress who are advocating for significantly more resources to be directed toward TB prevention, detection and treatment and research for new drugs. In addition, this hearing provides us with the opportunity to examine the best means for directing our resources.

The World Health Organization recently came out with a very interesting study entitled Appreciating Assets: A Contribution of Re-

ligion to Universal Access in Africa. The study focused on the treatment of HIV/AIDS, using Zambia and Lesotho as two study sites, and the findings provide useful indications for addressing other health issues, including TB, throughout Africa.

The study found that approximately 30 to 40 percent of national health services were provided by faith-based organizations. In some areas, these percentages went as high as 70 percent.

The benefits of a faith-based infrastructure for addressing HIV/AIDS would seem to apply also to tuberculosis. For example, assisting in monitoring adherence to the drug regimen could be overseen by the volunteer community, as well as education to the general public. Since churches, mosques and synagogues are being encouraged to undertake HIV/AIDS initiatives, TB can be more readily included as well.

I look forward to our witnesses' views on additional means by which the faith-based infrastructure in Africa and elsewhere might be utilized, as well as supported and further strengthened by donors.

I would just point out parenthetically that back in the early 1980s I was the sponsor of the Child Survival Fund and through this committee offered an amendment that provided $50 million to the Child Survival Fund when unfortunately OMB was looking to zero out the account.

I traveled down to El Salvador and witnessed firsthand in excess of 200,000 children getting vaccinations against preventable diseases such as polio, diphtheria and other child killing diseases. It was the faith-based community that provided not only the conveyance of the message to get the children to those vaccination sites, but also to encourage volunteers, and, I might add, there were massive numbers of volunteers that ensured that those kids and their parents were on site to get the shots.

This scenario has been replayed throughout the entire world. As a matter of fact, one time I traveled with Jim Grant, the former head of UNICEF, and again we saw that the faith-based community was absolutely essential in ensuring that the vaccinations occurred. There is a long track record of this kind of partnership, and I think the TB epidemic could be likewise mitigated if we were to more faithfully and aggressively employ the faith-based community.

It is well known that the Global Fund is a major contributor to TB detection and treatment programs around the world. The United States has given over $2 billion to the Global Fund or just over 30 percent of the Fund's revenues.

I was concerned to read reports earlier this month that the Global Fund has permanently terminated two grants to Uganda for malaria and tuberculosis. When I visited Uganda in January 2006, a suspension of five Global Fund grants due to gross mismanagement had just been lifted, and I was informed that the problems appeared to have been resolved.

The fact that this now turns out not to be the case and that several other countries have also had Global Fund grants terminated raises serious questions about how the Global Fund is operating.

I know from my visits to Africa and from numerous reports we receive in Congress how well our bilaterally funded PEPFAR pro-

grams are working and performing. The information and accountability that Congress has come to take for granted through these bilateral programs is not available through the Global Fund, and yet many of the primary recipients of Global Fund grants are governments with a history of corruption and fraud and/or limited capacity to properly manage large sums of money in their health sectors.

One could argue that the absence of a robust reporting and monitoring mechanism in the Global Fund at both the primary and subrecipient levels is an open invitation for waste in these countries and a tragic loss of opportunity to save lives. The implementation of a system that provides accountability and transparency would seem vital—absolutely necessary in my view—to continue expanded donor support of the Global Fund in the future.

I look forward to exploring these questions further and to learning more about what we can do to address TB from our very distinguished panel of witnesses.

Mr. Chairman, I yield back to you.

Mr. PAYNE. Thank you very much, Mr. Smith, for those very compelling remarks.

At this time I would give the opportunity for the vice chair of the committee, Ambassador Watson, if she would like to make an opening statement.

Ms. WATSON. Thank you so much, Mr. Chairman, for holding this meeting, and I want to congratulate you as chair of this subcommittee.

I can't think of any other Member in the Congress who has demonstrated consistent commitment to our United States relationship with Africa, and I thank you so much for over two decades that you have devoted your service to the continent of Africa, among other services too.

I want to thank Chairman Lantos for inviting me to serve as your vice chair for the subcommittee. I am delighted to have an opportunity to work closely with you and the other members on issues concerning Africa and on global health.

I am so pleased that the United States is finally awakening to the strategic value of the human potential in Africa, and I hope that my service to this committee will help to address a long list of issues of concern with our relationships with the continent and Africa's people on such issues as basic education, corruption, governance, child welfare, protecting local intellectual property and small business development.

All these issues speak to our biggest challenge and that is finding the most effective methods and investments to support the people of Africa as they seek to develop their own human potential. The issue today speaks to developing that human potential and of all the issues that impact the world's poor health are perhaps both the most fundamental and the most distressing.

We can talk about alleviating poverty through micro loans and trade opportunities, but if people aren't healthy those opportunities will remain in the distance and unobtainable. To put it another way, the only capital a poor person possesses is their human capital. Disease and ill health effectively deny them use of that capital.

As we know, tuberculosis is a disease which many of us thought was defeated. We have had effective treatment for TB for half a century. In fact, in most of the world TB is disappearing, yet in Africa TB infection is on the increase, and the real problem here is not technology. As with so many public health problems we face, the real problem is the health care delivery system. Too many of the world's poor lack access to effective health care.

I am eager to hear from our witnesses, and I commend them for their interest in the new technologies and pharmaceuticals which are always welcome, but as long as people in Africa and elsewhere lack access to treatment, as long as African nations continue to be hobbled by limited health delivery infrastructures and as long as their qualified health professional brain trusts continue to drain away to the west, new pharmaceuticals will not make a dent in this problem.

Mr. Chairman, I want to work with you to ensure that the United States is doing all that it can to ensure that we are investing the resources and the energy not just in providing emergency medical relief, but in helping African governments build effective, efficient and appropriate health care infrastructure to address the needs of their people.

Thank you very much.

Mr. PAYNE. Thank you very much for those remarks.

A new member of our committee from the great State of California, Congresswoman Woolsey, has joined us. Do you have an opening statement?

Ms. WOOLSEY. Thank you, Mr. Chairman. I am looking forward to this hearing and from the witnesses today, especially about how the United States can contribute to the treatment and eradication of TB.

Already in this Congress under your leadership, Mr. Chairman, and the leadership and help of Speaker Pelosi we have dramatically increased our support for programs aimed at TB, particularly the drug-resistant strain.

I am especially interested in how this epidemic is affecting the world's children, how we can put in place responsible prevention programs and treatment for the very youngest victims, and I am thinking that if we can actually come to some solutions regarding TB that we thought was eradicated maybe we can follow the same hows and wherefores and use those to eradicate HIV/AIDS, so whatever we do right here we can follow later.

Thank you, Mr. Chairman.

Mr. PAYNE. Thank you very much.

At this time we will have the briefing, as I indicated to the audience before the members came. Because we have representatives from an international organization, it is customary that they brief the Congress and not testify before the Congress and so it is just a technical move.

At this time we will hear from Dr. Raviglione, who is director of the Stop TB Department of the World Health Organization in Geneva, Switzerland. Dr. Raviglione joined WHO in 1991 as an associate professor officer sponsored by the Italian Government to work on TB and HIV and AIDS and TB epidemiology in Europe.

Later he became responsible for setting up the Global Drug Resistance Surveillance Project and the new TB surveillance and monitoring system. In 2005, he received the prestigious Princess Chichibu TB Global Award for his achievements in TB control.

Dr. Raviglione? Thank you.

STATEMENT OF MARIO RAVIGLIONE, M.D., DIRECTOR, STOP TB DEPARTMENT, WORLD HEALTH ORGANIZATION

Dr. RAVIGLIONE. Many thanks, Mr. Chairman. Good afternoon to everyone. It is a real honor to join you today and to represent the World Health Organization in providing this briefing on the TB and XDR–TB epidemics.

I would like to begin by thanking Chairman Donald Payne, Ranking Member Chris Smith and all other distinguished members of the committee, besides the committee staff, for organizing today's hearing.

The global threat of drug-resistant TB is an incredibly important issue, and if we fail to address it urgently it could reverse the enormous progress we have made in TB and also in AIDS care and control over the years.

I will address, as requested, the global epidemic, the impact of WHO and partners' efforts in fighting the global killer. This includes efforts by the Stop TB Partnership, which represents over 500 institutions today and in which U.S. institutions play a key role. I am also pleased to be asked to note in what ways the U.S. Government can contribute further in TB control worldwide and particularly in TB control in Africa.

Mr. Chairman, the global burden of TB is enormous, despite its being a curable disease in most cases. It is a disease found in all countries of the world without any exception. The developing world is the most affected, of course, but so are the poorest and most vulnerable communities in high income countries. Most affected are the young, the economically productive adults.

The 2007 WHO Global TB Control Report will be launched tomorrow in fact in New York and some other cities in Europe and lead up to World TB Day this week. Our data and trend analysis are embargoed until tomorrow, but I would like to share some critical information.

In 2005, which is the last year for which we have data, 8.8 million persons fell ill with TB, and 1.6 million died of it, which means 4,400 every day. Nearly 200,000 deaths were among HIV infected people. While 60 percent of TB cases occur in Asia, sub-Saharan Africa has by far the highest rate per capita.

The good news, however, is that we have seen enormous progress in TB control. In 1995, when we established for the first time the global monitoring project, less than 15 percent of all infectious cases were detected by good programs. The picture has changed dramatically with now 60 percent of the cases being detected, and 84 percent of them successfully treated. These are millions of cases.

This is a remarkable progress toward the global operational targets established by the World Health Assembly of detecting 70 percent of cases and curing 85 percent of them.

More concretely, 26 million patients have been treated in 11 years under the DOTS strategy, which is what we recommend. In

addition, the global DOTS facility, which is managed by the Stop TB Partnership, has supplied best priced, high quality TB drugs to over 9 million patients in over 60 countries in the last 6 years.

The partnership and WHO also support the Green Light Committee that you have mentioned, which is enabling access to safe and effective treatment for MDR–TB in over 40 countries to date.

Over the past 15 years, the World Health Organization has extensively supported its member states to adopt effective TB control and adapt it to their own conditions in achieving measurable progress. Today, 187 countries de facto have adopted DOTS.

However, in 2006, to face the new challenges, WHO launched a new and more comprehensive Stop TB strategy, as we call it today. This is built on DOTS' successes and explicitly addresses the challenges of TB associated with HIV, multi drug-resistant tuberculosis and so on. It ensures that TB control is integral to the strengthening of health systems and services. It calls for engagement of all nonstate practitioners and communities and promotes research for better diagnostics, drugs and vaccines.

Last year the Global Stop TB Partnership, of which WHO, CDC and USAID are key partners, launched a 10-year business plan that we call the Global Plan to Stop TB 2006–2015. The Global Plan is a uniquely detailed blueprint to cut TB deaths and disease by 50 percent in the next decade and make TB incidence decline toward elimination, which incidentally is the Millennium Development Goal related to TB. If fully financed, it will save an extra 14 million lives and enable access to new tools.

The Global Plan also emphasizes the crucial importance of technical support to countries so that the large financial investments by the Global Fund, the World Bank, bilaterals and so on are as effective as possible.

Mr. Chairman, the bad news, the news that should alarm us and call us to urgent action, is the keynote of today's hearing: The global epidemic of multi drug-resistant TB and its deadly synergy with AIDS.

MDR–TB, which originates from the failure of programs to ensure appropriate treatment support to patients, has been found in every one of the more than 110 countries that have been surveyed so far by the World Health Organization, although the highest levels are detected in countries with the weakest TB programs, so it is not the failure of programs. It is the failure of implementing proper programs.

XDR–TB, which is an extremely resistant, more deadly form of MDR–TB, has been reported so far in 35 countries as far as we know as of yesterday at WHO, including all of the G8 countries. Put simply, XDR–TB is the worst thing I have encountered in my 15 years working in TB. I am actually struck by how swiftly it passes between and kills those with HIV with death rates that have been registered at 90 percent or above.

Standard TB, TB that responds to drugs, can in fact be treated in those with HIV, and treatment can extend their lives for years, buying precious time in which to access antiretroviral therapy for those not yet receiving it. But most low income countries lack the capacity to diagnose XDR–TB and MDR–TB due to lack of laboratories, let alone to clinically manage the disease today.

XDR–TB linked with HIV means that these strains kill far more quickly and spread far more rapidly, including to the general population and to the health workers, as has been seen in South Africa, for instance. Moreover, XDR–TB killed people living with HIV who were on antiretroviral treatment, therefore upsetting all the care gains that are achieved by antiretrovirals.

XDR–TB has already created a major alarm in South Africa. A few weeks ago, to give an example, eight XDR–TB patients were transported by health care workers who were wearing full body protective suits to a South African hospital. At the sight of them, roughly 100 patients, 100 very sick patients, as it is common in South African hospitals, got up from their beds and walked out, just to tell you what the situation is.

Now, what must we do? In March 2006, CDC and WHO reported for the first time XDR–TB. To further clarify, you said it already, but it may be good to repeat it, XDR–TB is TB that is resistant to both first-line drugs and the most effective classes of second-line drugs, the back-up drugs. Treatment is, therefore, highly complex, costly and often ineffective when the proper infrastructure to give this treatment is lacking.

Following the description of XDR–TB among patients living with HIV in the KwaZulu-Natal Province of South Africa last year and its 90 percent mortality, in October 2006 the World Health Organization created a task force to urgently identify the priorities for a worldwide response.

Priorities were more or less as follows: First and foremost was the call for immediate strengthening of basic DOTS programs to prevent drug resistance from evolving. Then it called for rapid diagnostic methods in laboratories, for access to proper treatment regimens and supervision, for infection control measures as it is suspected that many cases acquire XDR–TB in hospitals.

In responding to XDR–TB, southern Africa is the top priority today, and over the last 6 months WHO has been guiding development of country and global XDR–TB response plans.

To pursue an effective and comprehensive XDR–TB response immediately, the Global Plan to Stop TB first of all must be fully implemented. The Global Plan remains badly under funded despite investment by affected countries themselves—normally 50 percent of the budget comes from the endemic countries themselves—and the important contributions of the Global Fund.

For instance, in 2007 the Global Plan requires over 5 billion U.S. dollars globally for implementation, technical support and research. Of those, over $1 billion is needed urgently in order to effectively respond to MDR– and XDR–TB worldwide.

Responding will jump start the response by providing newer diagnostics and drugs and by expanding surveillance, training and infection control practices. This is necessary especially in Africa where previously modern programs for TB control are now depleted and fragile due to both HIV and, more recently, XDR–TB.

A clear example is that of laboratory capacity—that needs to be emphasized actually—which is essential for finding drug-resistant TB and for surveillance purposes. In all of Africa there are only 25 reference laboratories with the capacity to grow TB cultures and test them for drug resistance, and most of these 25—I believe it is

19 if I remember correctly—are in South Africa itself, so it means that the rest of Africa has very few reference laboratories.

Increased investment is needed to provide faster access to life-saving drugs, and also needed is more investment in the systems that support their safe and effective use because we cannot take any risk to lose what is left. Otherwise we are in a pre-antibiotic era.

When I say investment, Mr. Chairman, I do mean investment because TB control is one of the most cost effective known health interventions. Investing in TB control, besides averting unnecessary deaths, saves money in the long run, while inaction levies cost.

Mr. Chairman, the last item that you requested me to address is the role that the U.S. Government can play in TB control, including preventing the spread of XDR–TB. WHO, first of all, is highly appreciative of the U.S. Government's financial support for TB control since the late 1990s to affected countries, to WHO itself, to the Stop TB Partnership, to the technical partners worldwide.

The officials of USAID, CDC and the Office of the Global AIDS Administrator who will be speaking today I am sure will describe in detail their commitments today. However, the Global Plan and MDR–TB and XDR–TB response plans require that all partners expand their support substantially.

We therefore encourage the U.S. Government to consider significantly increased financing through all of its institutions currently engaged in TB control. Increased disease control financing already committed this year for PEPFAR and the Global Fund has been tremendously important.

However, scaled up support for TB implementation, for technical assistance to countries, for surveillance and research via USAID, CDC, OGAC and NIH will also be essential to reach the affected countries, to prevent global spread of TB and to quickly find the new tools that will replace the existing ones and that we badly need if we want to really seriously talk about elimination one day.

U.S. leadership has transformed efforts in the AIDS arena. We can and must do the same for TB. A study published in the *New England Journal of Medicine* in 2005 in fact showed that investing in TB control abroad actually prevents illness and deaths and saves money at home over the long run.

The consequences of inaction will be millions of lives lost, the undermining of progress on both AIDS and TB control and the potential to push us back to the pre-antibiotic era when TB was a death sentence in most cases.

Many thanks, Mr. Chairman and honorable colleagues.

[The prepared statement of Dr. Raviglione follows:]

PREPARED STATEMENT OF MARIO RAVIGLIONE, M.D., DIRECTOR, STOP TB DEPARTMENT, WORLD HEALTH ORGANIZATION

I. INTRODUCTION

I would like to begin by thanking Chairman Donald Payne and Ranking Member Chris Smith and the committee staff for organizing today's hearing The Global Threat of Drug-Resistant TB: A Call to Action for World TB Day. This is an incredibly important issue; it is an honor to join you today and to represent the World Health Organization in providing this briefing on the TB epidemic, TB control progress and challenges, including Extensively Drug-Resistant TB, known by its ac-

ronym, XDR–TB. I also will address, as requested, the impact of WHO and partners' efforts in fighting this global killer. This includes efforts via the Stop TB Partnership, representing over 500 institutions today, and in which US institutions play a key role. I am also pleased to be asked to note in what ways the U.S. Government can contribute further in preventing and treating all forms of TB.

For more information on the status of the TB epidemic, overall TB control efforts, and global response to XDR–TB, I ask that the following documents be entered into the record of this session as references[1]

II. THE GLOBAL TB EPIDEMIC

The global burden of tuberculosis is enormous despite this being a disease which is preventable and curable. It is a disease present in all regions of the world, but the developing world is most affected as are the poorest and most vulnerable communities in high-income and low-income countries. Most affected are young adults in their most productive years. The 2007 WHO Global TB Control Report will be launched officially tomorrow in lead up to World TB Day, 24 March. Our data and trend analysis are embargoed until tomorrow, but I would like to share some critical information. In 2005, 8.8 million persons fell ill with TB, and that 1.6 million people died due to TB. Nearly 200,000 deaths were among HIV-infected persons. While 60% of the global burden is in Asia, the highest burden per capita is in sub-Saharan Africa. The total number of new cases continues to rise worldwide. Based on 2004 data, last year we reported that incidence was stabilizing or falling in most regions worldwide, except Africa. We will report further on changes in global and regional trends tomorrow. Multidrug-resistant TB (MDR–TB) has emerged in most countries worldwide, with the highest levels in countries of the former USSR and in parts of China.

XDR–TB, which is a more deadly form of MDR–TB, has been reported so far in 35 countries, including the Group of 8. Importantly, XDR–TB has been reported in Southern Africa among people living with HIV infection (PLHIV) is cause for serious concern due to very rapid spread and case fatality rates of above 90%. Most low-income countries worldwide lack the capacity to diagnose XDR–TB, let alone clinically manage the disease.

XDR–TB is a wake up call that there are serious consequences from failure to implement effective TB control and treatment for all forms of the disease. Strengthened TB control must happen alongside expanded HIV care, infection control, and bolstering of general health systems in the countries most affected. The global public health and security consequences will be serious if multidrug-resistant TB is not controlled now.

III. THE IMPACT OF COORDINATED STRATEGY AND RESPONSE

Overall, there has been considerable progress in global TB control this last decade. This year, WHO reports to the World Health Assembly on how well the world did against global 2005 TB control targets. In 1995, only 16% percent of estimated infectious TB cases were detected under effective TB control programs, and for the vast majority of patients no information was available on whether they lived, died or were cured. In 2005, the picture was dramatically different: 60% of estimated TB cases worldwide were detected, but still short of the targeted 70%, and global treatment success was 84%, instead of 85%. 26 countries in all regions, and the Western Pacific Region as a whole, have achieved the 2005 targets. Although a near-miss, these results have had an impact on the TB burden with stabilization and decline in burden already reported for five of six regions in our 2005 report. This is largely the result of an expansion of access to effective treatment. 26 million patients have been treated in 11 years under DOTS, the WHO-recommended TB control approach. DOTS has five elements: political commitment with increased and sustained financing; case detection through quality-assured bacteriology; standardized treatment, with supervision and patient support; an effective drug-supply and management system; monitoring and evaluation system, and impact measurement.

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[1] WHO. Global tuberculosis control: surveillance, planning, financing. WHO report 2007. Geneva, WHO, 2007 (WHO/HTM/TB2007.376). Available as of 22 March at http://www.who.int/tb

Stop TB fact sheets: http://www.stoptb.org/resource—center/fact—sheets.asp

The Stop TB Strategy. Geneva, WHO, 2006 (WHO/HTM/TB/2006.368) http://www.who.int/tb/features—archive/stop—tb—strategy/en/index.html

Stop TB Partnership and WHO. Global Plan to Stop TB 2006–2015. Geneva, WHO, 2006 http://www.stoptb.org/globalplan/assets/documents/GlobalPlanFinal.pdf

WHO. Control of XDR–TB Update on progress since the Global XDR–TB Task Force Meeting, 9–10 October 2006 http://www.who.int/tb/xdr/globaltaskforce—update—feb07/en/index.html

The World Health Organization has worked intensively over the past 15 years to support its Member States to adopt effective TB control practices and achieve measurable progress. WHO develops policies, standards and strategies for TB control; provides direct support to countries in their control efforts; monitors and evaluates TB control progress and impact, supports relevant research; and fosters advocacy and partnerships. Worldwide, in the last 10 years, 187 countries have adopted DOTS.

In 2001, to speed up TB control action worldwide, the Stop TB Partnership was established and its Secretariat housed in WHO. It consists of 500+ institutions committed to a world free of TB; it has a Coordinating Board, a Global Drug Facility and 7 Working Groups. It has proved, as noted in independent evaluations, a model of collaboration and consensus-building. WHO is fully committed to its sustained success. The first Global Plan to Stop TB, 2001–2005, resulted in achievements in all areas addressed, from service delivery to research. The second Global Plan, 2006–2015, proposes actions across all regions and all seven major areas of work of the Partnership, from DOTS expansion, to TB/HIV and MDR–TB response, to development of diagnostics, drugs and vaccines and overall advocacy, communication and social mobilization. The Plan received the endorsement of world leaders, including the G8 nations. If fully financed at US$ 56 billion over ten years, it could save 14 million lives and enable access to new tools to fight and eliminate TB. However, the Plan remains woefully under-funded with a budget gap of $30 billion.

The Partnership's Global Drug Facility which enables financing as well cost-effective pooled procurement to ensure access to anti-TB drugs and innovative patient treatment kits. It has supplied over 9 million patient treatments in six years in DOTS programs. The Partnership and WHO share roles in supporting the Green Light Committee which is enabling access to safe and effective treatment for multidrug-resistant TB in over 40 countries to date. Technical assistance, coordinated by WHO, has enabled support to countries to develop proposals to the Global Fund to Fight HIV/AIDS, TB and Malaria, with an unprecedented 62% success rate in the last round. All of these new supply and collaboration mechanisms work closely with agencies financing TB control including USAID, other bilateral agencies, the Global Fund to Fight HIV/AIDS, TB and Malaria and the World Bank.

To build on DOTS successes, and explicitly address the new challenges of HIV/TB and MDR–TB, WHO developed the new Stop TB Strategy. This was done in collaboration with a wide range of Stop TB partners. The Strategy aims to meet 2015 TB targets. It recognizes that millions more patients, often the poorest and most vulnerable, need access to early detection, care and support. The Strategy calls for active engagement in overall health system strengthening efforts, especially those aimed at resolving the human resources crisis in the health sector in many low-income nations. The World Health Assembly called for this new approach in its resolution on TB in 2005 and has been asked by its Executive Board to consider a draft resolution this May which endorses the Stop TB Strategy, including urgent response by all Member States and WHO to HIV-associated TB, MDR–TB and XDR–TB, and calls for increasing TB diagnostic capacity worldwide and TB monitoring and surveillance, among other concerns.

Key HIV–TB collaborative efforts are defined within the Strategy. Furthermore, the Strategy provides guidance for the mainstreaming of treatment for multidrug-resistant TB. It aims to widen the collaboration between public and private providers which can expand TB case detection by up to 36% in cases documented to date. The Strategy promotes the International Standards of TB Care, an evidence-based set of norms that has been endorsed by national TB programs and over 40 medical associations around the globe.

The empowerment of persons with TB and communities is central to the Strategy. We are seeing in the last few years the important impact of enabling a voice for those affected to express their needs, and to participate in TB control planning and care.

Lastly, the Stop TB Strategy calls for enabling and promoting research. WHO is working with the Stop TB Partnership to foster a "TB Research Movement" to fill the major gaps along the continuum of basic to applied research, and rapid development of diagnostics, drugs and vaccines. All areas of research are needed to reach patients faster, fight new forms of TB and to eliminate this age-old disease.

IV. PREVENTING AND TREATING XDR–TB

I would now like to return to the new threat posed by XDR–TB. In March 2006, CDC and WHO reported for the first time on XDR–TB. XDR–TB is defined as a disease resistant to the most effective classes of second-line drugs, in addition to first-line drugs. Treatment is complex, and given available drugs, cure rates for XDR–

TB rarely exceed 40–50%. A cluster of XDR–TB cases in a hospital in South Africa, was identified during the period January 2005–March 2006. It was characterized by extremely high case fatality rates. 52 of 53 patients died. Of the 44 patients tested for HIV, all were positive. Given high case fatality rates and low cure rates, preventing transmission raises a host of challenges for public health practice, medical ethics and patient care.

In October, 2006, WHO urgently convened a task force on XDR–TB. The Task Force devised a framework with priorities for XDR–TB response. First and foremost was the immediate strengthening of TB control in countries as reflected in the Stop TB Strategy and Global Plan to Stop TB, alongside the scaling-up of universal access to HIV treatment and care. Other recommendations focused on improved diagnostic and treatment approaches, laboratory strengthening, infection control and protection of health workers, surveillance and advocacy, communications and social mobilization.

Based on this framework, first priority was given to planning for response in Southern Africa. Over the last months, WHO has been guiding development of a global XDR–TB response plan, with inputs from all regions.

To pursue immediate XDR–TB response this year, full implementation of TB control measures laid out for this year in the Global Pan is needed. The funding gap is close to US$ 3 billion for implementation, technical support and research. Furthermore, for MDR–TB and XDR–TB response specifically, WHO estimates $650 million is needed this year. This includes about $250 million originally planned under the Global Plan plus $400 million more for the urgent requirements of affected countries. This will help jumpstart response through provision of newer diagnostics, drugs, surveillance, training and initiation of treatment programs, and infection control practices. However, this also depends on support for the strengthening of public health services, lab and personnel, and for expanding the availability of human resources.

Throughout Africa, there are DOTS-based TB programs and some served as model national programmes in the 1980s and early 1990s. However, their capacity now is depleted, fragile and insufficient, due to weak health systems, political and social instability, the HIV epidemic and related weakening of the health workforce and services. In Africa today, the 74% TB treatment success rate is 10 points below the global average, and only 50% of estimated infectious TB cases are detected. While new financing is helping expand TB–HIV joint interventions and service delivery, TB control budgets are far below those required to make progress towards the targets, as mapped out in the Global Plan. Increased investment is needed in the mechanisms that are enabling fast access to life-saving drugs, and also needed is more investment in the systems to support their safe and effective use.

In all of Africa, there are only 25 reference laboratories with capacity to conduct cultures and related drug-sensitivity testing. Laboratory capacity is essential for drug-resistant TB treatment and surveillance. There are only two "supranational" laboratories currently assisting African countries to enable capacity-building and quality assurance of their functions. At least five must be fully functional to enable adequate support. Financing sources, such as the Global Fund, USAID, and PEPFAR, are helping but further investment in implementation, technical assistance and research is critical now.

V. ROLE FOR EXPANDED US GOVERNMENT ENGAGEMENT

The last item that you requested that I address is the role the US Government has and can play in TB control, including preventing the spread of XDR–TB. WHO is highly appreciative of the substantial financial support provided by the US Government annually for TB control since the late 1990s to affected countries, WHO, the Stop TB Partnership, and technical partners. The officials for USAID, CDC, and the Office of the Global AIDS Administrator who will be speaking today I am sure will describe in detail their commitments to date. In addition, the NIH is a major source of finance of TB research today.

However, the Global Plan and MDR and XDR–TB Response Plans require that all partners expand their support substantially. We therefore encourage the U.S. Government to consider increased financing through all of its institutions currently engaged in TB control. Increased disease control financing already committed this year for PEPFAR and the Global Fund to fight HIV/AIDS, TB and Malaria has been tremendously important. However, scaled-up support for TB implementation, technical assistance, surveillance and research via USAID, CDC, OGAC and NIH and collaborators will also be essential to reach affected countries and to prevent global spread of all forms of TB.

N.B. For more information on the status of the TB epidemic, global response to XDR–TB, and overall TB control efforts, I ask that the following documents be entered into the record of this session as references—the 2007 WHO Global Report on TB Control, WHO fact sheets on the TB epidemic and response, and the report of the October 2006 WHO Task Force on XDR–TB.

Mr. PAYNE. Let me thank you very much for that very comprehensive briefing, and let me commend you for the work that you have done for so many years with this dread disease.

An article that appeared in the *New York Times* yesterday with headlines which read "Rise of a Deadly TB Reveals a Global System in Crisis," which was very compelling. Do you agree that the health care systems to deal with TB are in crisis worldwide? If so, what is it that you believe we need to do?

Dr. RAVIGLIONE. Yes. Well, I read the article by Larry Altman who often talks to us. I got relieved after the first sentence because the way it read in the title it seemed to suggest that what has been done to date has failed completely, but, as I addressed already, this is a failure of implementing proper TB control and not an expression of the failure of the DOTS strategy or the strategy that we are trying to put in place in countries.

Clearly the health systems and services in the majority of countries are weak, and we know that. That is why in some cases TB control programs have been particularly weak, say, where TB control is not based on sound laboratory diagnosis or where the treatment is never accompanied by someone, a supervisor or a friend or someone in the community that can remind and support the patient throughout the 6 months of treatment.

When you have these types of conditions that is when you fail and you have the eventual onset of multi drug resistance and of XDR–TB. In fact, the rest of the article really describes that in detail and points to all these weaknesses.

Mr. PAYNE. Thank you. As a matter of fact, I am going to without objection have the article put into the record.

[The information referred to follows:]

The New York Times

RISE OF A DEADLY TB REVEALS A GLOBAL SYSTEM IN CRISIS

March 20, 2007

The Doctor's World

By LAWRENCE K. ALTMAN, M.D.

LOS ANGELES — The spread of a particularly virulent form of tuberculosis in South Africa illustrates a breakdown in the global program that is supposed to keep the disease, one of the world's deadliest, under control.

The program was intended to detect tuberculosis cases, make sure patients were taking their antibiotics, test patients for resistance to those drugs and monitor the spread of the disease.

But international tuberculosis experts say the system is in deep trouble for an array of reasons: misuse of antibiotics; other bad medical practices, like failing to segregate high-risk patients in hospitals and clinics; and cuts in government spending for such basics as adequate supplies of drugs and laboratories to do the testing.

Such factors have led to the rise of drug-resistant tuberculosis bacteria, a menace the world has only begun to appreciate.

Mycobacterium tuberculosis, the microbe that causes the disease, was discovered 125 years ago this month. Today, the bacteria infect 8.8 million people a year and cause 1.6 million deaths. They are spread in tiny droplets when patients cough.

Tuberculosis is curable, as long as the bacteria are susceptible to antibiotics. It becomes deadlier when it attacks people who are also infected with H.I.V., the AIDS virus. And when the tuberculosis bacteria become extremely drug-resistant, the death rate soars.

That was the case in Tugela Ferry, a rural town in KwaZulu-Natal province in South Africa, when an outbreak of extremely drug-resistant tuberculosis — XDR-TB for short — killed 52 of its 53 victims, all of whom were also infected with H.I.V. The outbreak was detected in 2005, but it did not receive international attention until it was reported at the international AIDS meeting in Toronto last August.

The **World Health Organization** calls the extremely drug-resistant form "a grave public health threat" because of its potential explosiveness among the millions of H.I.V.-infected people in poor countries. It seems to be a lesser threat among people who do not have H.I.V., though it could be dangerous to the millions with weakened immune systems from treatment for cancer and other diseases.

XDR-TB is defined as tuberculosis that is resistant to the two most important antituberculosis drugs (isoniazid and rifampin), along with two other drugs: a member of the fluoroquinolone class and at least one of three others (capreomycin, kanamycin and amikacin).

A step lower on the resistance scale is a form of the disease called MDR-TB, for multidrug-resistant tuberculosis. An outbreak of that form struck in New York City in the early 1990s, and cost at least $1 billion in emergency measures to control and manage tuberculosis patients.

Experts say the tuberculosis outbreak in South Africa is the deadliest one that they can recall.

Although South African officials, who have known about the outbreak for a year, promised a prompt and full investigation, even experts there acknowledge that efforts are lagging.

"Unfortunately, we do not know much more than a year ago" mainly because "a systematic survey in each of the provinces has not yet started," Dr. Karin Weyer of the South African Medical Research Council told the Conference on Retroviruses and Opportunistic Infections here recently.

Dr. Weyer said in an interview that she had hoped that rapid surveys and screening tests would have been completed by now to show better the geographic extent of the disease.

Using statistics from recent years, Dr. Weyer said her team estimated that 6,000 new cases of multidrug-resistant tuberculosis occurred in South Africa each year and that the rate of treatment failure was about 10 percent. Assuming that most failures were due to the extremely drug-resistant form, a conservative estimate is 600 cases of XDR-TB in her country each year, Dr. Weyer said.

In data that her team examined, about 85 percent of patients infected with XDR-TB and H.I.V. died, she said. The fatality rate in H.I.V.-negative patients seemed lower, but could not be determined until they complete long-term therapy.

What is known is that the deadly XDR-TB strain has been found in more than 40 hospitals in all nine provinces of South Africa, she said.

The rest of sub-Saharan Africa is at risk, she went on, because "control of airborne infection is either totally inadequate or even absent" in virtually all of those countries.

The outbreak is not limited to Africa. Dr. Paul Nunn, a tuberculosis expert at the **World Health Organization**, told the meeting here that one or more cases of XDR-TB had been found in at least 28 countries. Extrapolating from data about the multidrug-resistant form of tuberculosis, Dr. Nunn estimated that two-thirds of the XDR-TB cases were from China, India and Russia.

The recipe for spreading the disease is the same throughout the world: inappropriate use of antibiotics. When first-line drugs fail to kill the disease, Dr. Nunn said, doctors turn to a second group of drugs that are less widely used, and, they hope, more effective because the bacteria have not had a chance to become resistant to them.

"The little evidence we have suggests that this is not so much spread of resistant strains, but the creation of similar patterns of resistance in different strains around the world," Dr. Nunn said, "because the drugs used are more or less the same everywhere, and unfortunately, so are the defects in the performance of TB control."

South Africa has more laboratories to test tuberculosis strains for susceptibility to first- and second-line drugs than other sub-Saharan countries, Dr. Nunn said. He added, "Most African countries do not have a laboratory capable of carrying out first-line drug susceptibility tests, let alone for second-line drugs, which is technically more demanding."

For those and other reasons, like a lack of doctors, health officials say they fear that tuberculosis may be spreading silently in other countries.

Experiments performed years ago have led some experts to speculate that drug-resistant tuberculosis bacteria are poorly transmissible. But that theory seems weakened by new studies from South African researchers working with colleagues from Harvard and the Centers for Disease Control and Prevention in Atlanta.

The researchers put caged guinea pigs in a ventilation stream leading from rooms housing patients with multidrug-resistant tuberculosis and possibly the extremely drug-resistant form. Skin tests showed that 80 percent of the animals were newly infected after four months, Dr. Weyer said.

XDR-TB may be just as infectious as regular tuberculosis and may be highly transmissible. And that is worrisome, Dr. Weyer said, because "most public health facilities in the developing world lack airborne infection control procedures."

How the guinea pig findings translate to humans is uncertain because other studies have not been done or completed.

In one study, South African researchers tested 1,694 relatives and friends who had contact with 386 XDR-TB patients identified in Tugela Ferry. Among those contacts, only 12 cases of multidrug-resistant tuberculosis were found, and none of XDR-TB, Dr. Weyer reported.

The findings suggested that significant spread was not occurring in the community. But it was too soon to know, because even a drug-susceptible tuberculosis infection usually remains silent for years before it causes illness, Dr. Weyer said.

"This is the kind of exercise that we would like to see happening" in other areas and for longer periods to get a better understanding of the risk of transmission and getting sick, Dr. Weyer said.

The risk that the initial tuberculosis infection will progress to illness is compounded at 10 percent a year for those with H.I.V., compared with a lifetime risk of 10 percent among those who do not have the virus.

In medical journals and at scientific meetings, some doctors in South Africa and elsewhere have advocated enforced confinement of XDR-TB patients. But civil liberties aside, many experts say, these advocates have not thought through the practical aspects of such isolations. Enforced isolation "is much more difficult to implement than one would think," Dr. Weyer said.

Because XDR-TB is believed to be incurable, such patients could be detained for life or until they die. All the while, infected patients may spread the disease to others.

Moreover, the disease is an occupational hazard for the health workers caring for patients; 4 were included among the 53 in the Tugela Ferry outbreak. Two additional cases in health workers were identified later.

So Dr. Weyer raised these questions, among others: What facilities would be used? Who would volunteer to take care of XDR-TB patients? How would these workers be protected? And without getting permission, how would health officials legally detect the many health workers who are infected with H.I.V.?

She offered no answers. And earlier this month, as if to illustrate the logistical hazards of caring for XDR-TB patients, 100 people walked out of a hospital in East London, South Africa, after paramedics wearing head-to-toe protection brought in eight patients with the disease.

Some South African hospitals are using engineering- and infection-control practices, like installing ultraviolet lights to kill tuberculosis microbes. Management studies show that health care facilities must be redesigned to prevent unnecessary contact between tuberculosis and H.I.V. patients in crowded clinics, X-ray departments, waiting lines and other areas, Dr. Weyer said.

On April 1, she said, South Africa plans to start field-testing 40,000 patients to determine the effectiveness of two new rapid tests to detect drug-resistant tuberculosis, and whether the results will lead to improved treatment outcomes. Elsewhere, researchers will test 60,000 patients under the direction of the Foundation for Innovative New Diagnostics in Geneva, Dr. Weyer said.

About 20 experimental drugs are being tested. But even if one is found effective in large-scale trials, it is unlikely to be marketed for a decade.

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Mr. PAYNE. You mentioned in your testimony the need to immediately strengthen the TB control in countries, and scale up universal access to HIV treatment and care. You also recommended fo-

cusing on improved diagnostic and treatment approaches, laboratory strengthening, infection control and protection of health workers, surveillance and advocacy, communications and social mobilization.

Can you elaborate on exactly what you mean by strengthening TB control? In other words, what specific activities is TB control comprised of?

Dr. RAVIGLIONE. Yes. The first thing in strengthening TB control in terms of the basic elements of TB control are those which we promote as part of DOTS strategy.

First, it means that every country must have government commitment, and government commitment is normally expressed with a clear understanding of what the TB problem is and how the health system can actually face it. It means having human resources where they are necessary. It means having laboratories where they are necessary.

The second component or element of the DOTS strategies is a laboratory system that allows proper detection of the cases of TB. Otherwise they are just left out in the community to infect others and perpetuate this plague.

The third component of basic TB control is to have a system that allows patients to take the drugs throughout the 6 months that are required for treatment, and that is what we call a supervised and supported type of approach. Once again, I go back to the notion of the community being involved.

The fourth element is to have a drug supply system that works because, while in the United States you can find drugs everywhere, I can tell you that if you go to an African country you will not find drugs against TB everywhere—fortunately, in a way, because in some cases they could be misused. You find them only where there is a system through the government that puts the drugs where they are necessary.

Finally, the last component of a good, basic TB control is a monitoring and surveillance system that allows us to count the number of cases and to count how many of them are cured at the end because that allows them to feed back to the district, to the regions and so on to say you are failing somewhere here and there.

So those are the basics. That is what we mean when we say strengthening TB control, on top of which there are all the other elements that you have listed that come essentially from the recommendations that were made by the WHO task force in October and that include, in the specific case of having to face MDR– and XDR–TB, the immediate strengthening of laboratories. I mentioned already the problems with the basic labs in Africa.

It means having new drugs, or rather I would say the second-line drugs that are available today in the North also available in the South, but given under proper conditions because we cannot afford to lose them to resistance.

It means to have rapid service that can tell us more about how widespread this epidemic is, and it means having infection control measures in hospitals so that we can prevent the transmission of this disease. So this is what we mean.

Mr. PAYNE. Very good. Finally, I just was curious to know. Years ago in this country, you know, people infected with TB were isolated. People didn't want those infected around.

I mean, it is certainly contagious so you do have to try to keep infected people from the general public, but do you find in, say, European countries or in other places that there is still the tendency of people wanting to put those infected in a closet and lock the door?

Dr. RAVIGLIONE. Well, certainly it varies depending on the communities and the countries, but the stigma against TB is obvious.

The fear now in Africa particularly is that the stigma of TB, of XDR–TB in particular, can add on the stigma of AIDS, and having a double stigma for a patient, that would be really fatal.

We know for instance, as I was mentioning, that in a way in South Africa there is some sort of panic that needs to be controlled whereby people don't want to share rooms anymore with potential suspects of TB or XDR–TB. Health workers don't go and work anymore in clinics where there must have been some case of drug-resistant TB, so it is a real serious problem.

The fight against stigma will be won only by some of the activities that are included in the Global Plan, for instance, the advocacy and social organization activities which, by educating the public, by informing the public, then can allow somewhat of a relief against this potential stigma.

Mr. PAYNE. Thank you very much.

I yield to the ranking member.

Mr. SMITH OF NEW JERSEY. Thank you very much, Mr. Chairman.

Doctor, thank you so very much for your testimony. You talked about how the plan is woefully under funded with a budget gap of $30 billion. I am wondering, is that the most recent number? Is it constantly being recalibrated? Obviously there was a Global Plan I, and now you are into the second phase.

Could you provide the committee, either now or perhaps convey it after you leave, with a breakdown by countries and by regions, how the EU, Canada and the United States are doing so we can get a sense of how our partners, in trying to mitigate this horrific outbreak, are collaborating and matching their words with their deeds?

For the record, as Ambassador Dybul points out in his testimony, the TB/HIV money from the United States has increased more than sixfold in just 3 years. In the 2007 budget, the administration's request provides an additional $50 million. I think we are trying, but we need to know what more we need to do. It would be good to get a sense of what the others are doing. If you could shed some light on this, I would be very appreciative.

Ambassador Dybul in his testimony points out that to date, little surveillance data has been available from sub-Saharan Africa on MDR– and XDR–TB, and I am wondering if you could elaborate. Are plans in the works to try to enhance prevalence studies so we know how tragic this is, how widespread it really is?

Also, in your talk about the reference labs, the reference labs in all of Africa, obviously that is an under capacity, but I wonder if you could tell us how many labs are needed and whether or not

those that currently exist are scatter sited throughout Africa or whether they are predominant in places like South Africa or other places so that proximity is a real issue for many people because such a lab is nowhere to be found. Insight in this area would be helpful.

Finally, regarding the problems that we have with integrating our efforts; Ambassador Dybul again makes mention, strong mention, of how important it is with antiretroviral efforts to boost the immunity; not just to combat HIV/AIDS, but also to combat tuberculosis. I wonder if you could tell us your vision of integrating not only antiretroviral, but other important health care components, including safe blood.

Last year, I chaired a hearing on the crisis of access to safe blood in Africa, not only in terms of quantity, but also in terms of quality, and the fact that there needs to be a regimen established whereby donors are not getting paid, but donote because they want to somehow advance and provide clean blood.

A WHO representative told us that, as a matter of fact, if such a regimen was established, if Africa had access to safe blood, 44 percent of maternal mortality would go away almost overnight because that is one of the major reasons why women die.

It seems to me that this is another opportunity to integrate many of these important health components, and I wonder if you could give us some insights on that, but especially as it pertains to the antiretroviral effort and putting these two together, TB and HIV/AIDS.

Dr. RAVIGLIONE. Let me try to answer as many as I can. First of all, the gap question. Yes. When we say the global gap is $31 billion, we mean out of the Global Plan of $56 billion over a decade. That included already 2006.

We estimated a year ago, a year and a half ago, when the Global Plan was published that the gap would have been more or less $31 billion if the countries, in endemic country governments, would continue to place the same amount of money that they had placed themselves, the Nigerias and South Africas of the world, into TB control.

Then also if bilateral donors, the Global Fund, the World Bank and other banks would continue as sort of international support with the same trend, you know, that we saw in the past few years, so that would leave a gap of about $31 billion to be covered over a decade.

Now, if we focus down on say 2007, as I said, we estimate that the total amount of money that is necessary for TB control, which it is important to notice also, covers the health systems component. It is not just for drugs or diagnostics for TB specifically. It includes research.

The total amount of money this year would be around $5 billion, and of those we believe that the gap is today around $2 billion, including the gap for research. Of the $5 billion, if you can follow me for another second, of the $5 billion, roughly speaking, $4.2 billion or so are for implementation of country activities, whether they are in the area of basic TB control, the TB/HIV interaction, drug resistance and so on. Eight hundred million dollars of this $5 billion is

for research. The estimate of the gap is in the area of something around $1.5 billion or so for control and $.5 billion for research.

By regions we can provide. I don't have it here, but they are part of the Global Plan. The Global Plan is divided by regions. By country is more difficult. What we can do though, since we monitor the financial flows, at the end of the year we will be able to say how much the countries, at least the highest countries, have put on TB. That is being monitored now.

Mr. SMITH OF NEW JERSEY. How about the donor countries? If we could get that?

Dr. RAVIGLIONE. Yes. We do have statistics that show the flow of money from donor countries, and in fact it is published in our report. Country by country we can say which donor has put what money where.

If you want to know specifically about the XDR–TB——

Mr. SMITH OF NEW JERSEY. Yes.

Dr. RAVIGLIONE [continuing]. Issue now, when we launched the first alarm in October/November of last year saying we need $95 million immediately for southern Africa, the southern countries, of those $95 million we estimate that $15 million were for technical assistance. That means WHO and other agencies that provide technical assistance. Eighty million dollars of this $95 million were for countries themselves, which means the Global Fund, USAID and other mechanisms that exist today in the world that can put money into countries.

Of the $15 million that we were estimating for technical assistance by WHO and partners, I think we have accumulated something in the area of $4 million from the U.K. largely, from the Italian Government and also there is a pledge of a mobilization of money from USAID, I believe it would be repeated later on, from USAID reprogramming funds in South Africa.

If you just take that as a parameter there have been grants now specifically for this issue that came from USAID and so on for WHO. That is a good thing because I understand it fully and I can tell you the amount exactly.

For the rest of the world we will have to see at the end of the year because we don't know how much the Global Fund throughout the year or OGAC or other agencies are going to put into this thing, but we foresee that there would be a mobilization of further funding.

Mr. SMITH OF NEW JERSEY. Would you address the issue of the labs and what kind of proximity do people who have TB——

Dr. RAVIGLIONE. Yes. The issue of the labs is the following. The 25 reference labs I was mentioning are those that are capable of doing culture and drug susceptibility testing.

You cannot diagnose drug-resistant TB unless you culture a bacillus that causes TB and you do an antibiogram so you test each single drug. There are only 25 such labs in Africa that we estimate. Nineteen, if I remember correctly, are in South Africa.

What needs to be done, therefore, is to place at least one laboratory in each of the relatively small countries or medium sized countries and probably more in countries such as Nigeria or Ethiopia that are bigger and need more laboratory capacity. Definitely what

is necessary is an immediate upgrade of the laboratories themselves.

For instance, recently there has been a mission in Lesotho. George Soros has mobilized $3 million last week to support specifically Lesotho, and I believe my colleague here from the Partners in Health will say a few words about it.

What we found out in that assessment that was done 3 months ago is that the laboratory needs to basically be built from zero. What is left there are a couple of microscopes and that is it for the entire country, which is a small country, but still it tells you what the situation is.

Either the strains have to be sent to South Africa to be tested or we will never be able, unless we build the laboratory there, to detect the presence of drug resistance in Lesotho. Similarly in Swaziland. There was a mission 2 weeks ago in Swaziland by WHO and others.

The integration of interventions. Definitely the Global Plan foresees and has a chapter on the TB/HIV, as we call it, necessity to collaborate. What we mean effectively is programs that deal with HIV and programs that deal with TB must work together because otherwise it makes no sense if you have two diseases, if you like, you are HIV infected and at the same time you have TB, and you are receiving antiretrovirals in one clinic, and in the afternoon you have to go to another clinic to receive the TB treatment, for instance.

What the plan foresees are a number of interventions which must be integrated at the clinical level where this intervention is happening. For instance, every TB patient in African countries that are affected by HIV heavily should be tested for HIV because there is a chance of offering antiretrovirals at a certain point in their evolution of the disease.

Every HIV-positive individual that is tested today should be screened for active TB because you would be surprised how many TB cases you find among those that go for just being HIV tested. They go to be HIV tested because they have something. Okay. So someone tells them go and be HIV tested. Then you find TB over there already, so we call that active case finding.

Or, once you identify an HIV-positive person there is the possibility of offering chemoprophylaxis against tuberculosis because the risk of developing TB is very high among those individuals and so the chemoprophylaxis could be implemented for a number of months until you "sterilize" the person and you reduce the risk of this person developing TB later on.

This can be done concomitantly with antiretroviral treatment. Nothing prevents anyone from giving antiretrovirals daily and a legal drug, which is Isoniazid, for TB for 6 months during the life of this individual that will sterilize him or her from TB, so all of these interventions can actually be done in the field. They need an integrated approach at the clinical level.

Mr. PAYNE. Thank you very much.

Ms. Woolsey?

Ms. WOOLSEY. Well, Mr. Chairman, when we were children I think the people with TB were sent to sanitoriums or sanitariums or something. Anyway, but nobody could get in or out.

In reading that HIV/AIDS positive health workers actually work with TB patients seems like quite a challenge when you want to integrate the programs. I mean, wouldn't those HIV-positive health workers be really concerned that they contract TB, and then wouldn't the TB patient be quite worried about contracting HIV/AIDS?

That has to be crucial when there is a shortage of workers it would appear, and certainly the area has limited resources and sanitation equipment, et cetera, et cetera. How is that happening?

Dr. RAVIGLIONE. It is a big issue, of course, and this is why we insist now on the need for infection control, if you like, guidelines in each country that prevents these types of things from happening because, you know, HIV-positive individuals should not be exposed by any means to patients that are potentially infectious to them because if they catch the infection with TB they evolve very rapidly toward disease.

In addition to that, if you have an XDR–TB or an MDR–TB case that potentially infects others then you are left with much less chances of cure than you would have with normal TB.

If an HIV-positive person contracts TB, gets TB, and evolves toward disease you can still cure the person with a very high percentage of cure that is similar to that of the known HIV-positive individuals, but if you catch an MDR–TB or an XDR–TB then the story is more complex because automatically the cure rates are lower, although you still have a good chance of curing them.

Still, what you say is basically we should avoid having this type of situation. That comes out of clear guidance given by governments to their own clinical facility levels.

Ms. WOOLSEY. And screening procedures in hiring practices?

Dr. RAVIGLIONE. Yes, provided they do not then originate discrimination against the individuals.

Ms. WOOLSEY. Well, that is the point.

Dr. RAVIGLIONE. That is the point, but that depends on the culture in different countries and the way they do things and so we can only recommend. I will put it that way.

Ms. WOOLSEY. Okay. Thank you very much.

Dr. RAVIGLIONE. It is a difficult issue.

Mr. PAYNE. Just one last quick question. How expensive is a lab? What do you need? I mean, do you need a doctor? Do you need a nurse? Do you need technicians? What would a simple, basic laboratory be?

Dr. RAVIGLIONE. Yes. A laboratory that functions for TB today should have the capacity to do smear microscopy. That is how you immediately detect the infectious cases with a sensitivity that is not very high, but it is the only thing we have.

In essence, if someone comes coughing today to my clinic the first thing I can do is to ask for the sputum and look at the sputum. Within 1 hour or 2, I can say you have TB or you are less likely to have TB, although I cannot exclude it.

That is a problem when we are in HIV high prevalence areas because many patients, many people, living with HIV do not expel the bacilli so you cannot see them, so the basic thing needed is to have microscopy around.

The second thing now is to have culture capacity because in this type of situation either you culture or you will never make the diagnosis. You only have a presumptive diagnosis. With culture you increase your capacity and sensitivity to detect the cases of TB.

Third now, in the era of multi drug-resistant TB in some of these countries you also need to have on the culture the antibiogram, as I was saying before. That is the one that allows you to understand if there is or if there is no resistance.

To put together these things, you know, you basically need a good technician that knows all these techniques. You need safety measures in the laboratory. You need microscopy. You need modern ways of doing case detection with the culture systems that are available in the North. There are machineries today available, tools available in the North that are not available in Africa with the exception of South Africa.

You need new ways of diagnosing rapidly the presence of drug resistance, which we are testing now or they are testing right now in South Africa. That would be an acceleration of the research work that within, hopefully, a year or 2 would allow us to spread much more rapidly the use of this particular testing.

So it is a three-step type of thing: Basic smear microscopy, microscopes, capacity to culture and possibly rapid methods of culture which are available in the North, and, three, capacity to detect rapidly the presence of resistance.

Mr. PAYNE. Well, let me thank you again for taking the time to come. I think your testimony has been invaluable. We hope to evaluate it and see whether we can bring this problem more broadly to the Members of the Congress and to see if we can really get people to take this much more seriously than it has been.

Once again, let me thank you for your time.

Dr. RAVIGLIONE. Thank you.

Mr. PAYNE. At this time we will have our first panel. We have Congressman Eliot Engel from the 17th District of New York, who is chairman of the Subcommittee on Western Hemisphere, which I am a member.

Additionally, Congressman Engel and I were sworn into Congress the same year in 1989 and so we are classmates as it is called. I am very proud to see my classmate doing an excellent job domestically and internationally.

Currently Congressman Engel has introduced H.R. 1567, the Stop TB Now Act of 2007, which I strongly urge all members to support. At this time, thank you very much, Mr. Engel.

We will now officially bring the hearing to order. Our briefing has ended. Thank you, Congressman.

STATEMENT OF THE HONORABLE ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. ENGEL. Thank you very much, Mr. Chairman and Mr. Ranking Member. You know, it is very difficult from this angle. We are used to sitting on high and it is very intimidating to kind of look up, so now I know why all the witnesses at all our panels seem intimidated.

Mr. Chairman, we are classmates, and we did come to Congress together. They say time flies when you are having fun. I guess that is why time has flown a great deal. We have embarked on many journeys together, as have Mr. Smith and I, and so it is great to see the two of you up there. As I mentioned before, it is less intimidating up there than it is down here.

I want to thank you both, Mr. Chairman and Mr. Ranking Member, for holding this hearing today and providing me with the opportunity to testify before you in support of international tuberculosis control and treatment efforts. I am grateful for both of your strong commitments to this important issue.

Failing to improve our international TB control efforts will wield a devastating blow to our ability to manage what I believe is a mounting global health crisis. It is remarkable in this day and age with treatment available that TB is the biggest infectious killer of young women in the world. In fact, TB kills more women worldwide than all causes of maternal mortality together.

As you know, TB is also the biggest killer of people with AIDS worldwide. Someone in the world is newly infected with TB every second, and TB accounts for more than one-quarter of all preventable adult deaths in developing countries. The statistics are just staggering.

I strongly believe that the global community, with the U.S. in the lead, must do more to adequately address this disease by investing in quality TB control programs using the groundbreaking Global Plan to Stop TB as a guide. It is for that reason that I have introduced the bipartisan Stop TB Now Act of 2007 with my colleagues Heather Wilson and Adam Smith, which will set forth what we believe is the United States' fair share toward achieving the goals of the Global Plan.

The Stop TB Now Act will strengthen U.S. leadership in international TB control by providing increased resources for the development of urgently needed new TB diagnostic and treatment tools to USAID and CDC. My bill calls for a U.S. investment of $400 million for international TB control in fiscal year 2008 and $550 million in fiscal year 2009.

Chairman Payne, I and everyone else wishes to thank you for your co-sponsorship of this important measure. I would also like to thank many of the global health groups that we have worked with on this legislation who have also endorsed H.R. 1567 such as Results, the American Thoracic Society and the Global Health Council.

If we don't make bold and wise investments in international TB control, not only will we fail to save millions of lives and miss out on the many accompanying benefits of controlling this killer, but this disease will also become far more difficult and costly to treat the longer we wait.

Extremely drug-resistant TB, or XDR–TB for short, highlights this danger. It has been found on six continents, is a growing epidemic particularly in southern Africa and is already reported to be here in the United States.

Regular nondrug-resistant TB is curable with drugs that cost just $16 in most developing countries. Cases of drug-resistant TB, however, can cost thousands of dollars to cure with treatment that

is far more difficult for patients and practitioners. Drug-resistant TB is a manmade problem and is caused by an array of factors, including the misuse of antibiotics, inadequate funding for laboratory testing and inadequate access to needed drugs.

We, all of us, the global community, have the power to prevent drug-resistant TB and the power to treat and control regular TB, and yet we have obviously chosen not to do so on the scale that is necessary. It boggles my mind why that is a fact.

I know that you, Mr. Chairman, decided to hold this hearing because you wanted to highlight the fact that in Africa the intersection between TB and HIV/AIDS is particularly chilling. People with HIV/AIDS obviously have compromised immune systems, and therefore TB and drug-resistant TB hits them especially hard.

In 2004, more than 740,000 people who contracted TB were coinfected with HIV and AIDS, a staggering statistic. Globally 90 percent of people living with AIDS die within 12 months of contracting TB if not treated. This is simply unacceptable.

We must all be concerned that with drug-resistant TB spiraling out of control, especially in HIV/AIDS patients in Africa, the reductions in mortality rates from HIV/AIDS, thanks to antiretroviral treatment, are now in severe jeopardy.

If we do not take urgent action now, progress made on the front lines of the fight against HIV/AIDS is in very serious danger of being undermined by drug-resistant TB. As Nelson Mandela said in 2004, and I quote, "We cannot win the battle against AIDS if we do not also fight TB."

The Stop TB Partnership's Global Plan to Stop TB 2006–2015 projects that Africa alone will require $19.4 billion to strengthen and maintain country level TB control efforts through 2015. This represents nearly 44 percent of the global total needed for countries to find and properly treat people with TB, because finding the people is obviously a difficulty as well.

While significant resources are being provided and will be provided by African governments themselves, the remaining funding gap for Africa stands at $11 billion over the next decade of additional resources needed to scale up a response to drug-resistant TB.

XDR–TB is a wake-up call for the longstanding need to strengthen TB control and to build the necessary capacity in health services to respond to drug-resistant TB. Again, and I conclude, my bill, the Stop TB Now Act of 2007, seeks to authorize the funding level required from the U.S. in order to meet the goals of the Global Plan to Stop TB and therefore be able to address this TB problem globally.

I urge the subcommittee members in attendance today to cosponsor my bill, and I respectfully ask Chairman Payne and Ranking Member Smith to bring this bill up for consideration in this subcommittee.

I pledge to work with you as the chairman of the Western Hemisphere Subcommittee because this is a problem in the Western Hemisphere as well, in Latin America as well, and we can work together to ensure that we have adequate funding, both of our subcommittees and the other subcommittees on our Foreign Affairs Committee as well.

I thank you again for allowing me to testify before you today and for holding this important hearing. As advocates across the globe come together on March 24—very, very soon—in just a few days in recognition of World TB Day, your efforts today to further the dialogue on TB control efforts with testimony by experts from the Centers for Disease Control, Office of the Global AIDS Coordinator, United States Agency for International Development, World Health Organization and Partners in Health will certainly not go unnoticed.

We will all benefit from the information gathered today, and I again thank you for the opportunity to give testimony.

[The prepared statement of Mr. Engel follows:]

PREPARED STATEMENT OF THE HONORABLE ELIOT L. ENGEL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Chairman Payne and Ranking member Smith, I wish to thank you for holding this important hearing today and for providing me with the opportunity to testify before you in support of international tuberculosis control and treatment efforts. I am grateful for this opportunity and for your strong commitment to this important issue.

Failing to improve our International TB control efforts will wield a devastating blow to our ability to manage what I believe is a mounting global health crisis. It is remarkable in this day and age, with treatment available, that TB is the biggest infectious killer of young women in the world. In fact, TB kills more women worldwide than all causes of maternal mortality. As you know, TB is also the biggest killer of people with AIDS worldwide. Someone in the world is newly infected with TB every second, and TB accounts for more than one quarter of all preventable adult deaths in developing countries. The statistics are simply staggering.

I strongly believe that the global community, with the U.S. in the lead, must do more to adequately address this disease by investing in quality TB control programs, using the groundbreaking Global Plan to Stop TB as a guide. It is for that reason that I have introduced the bi-partisan Stop TB Now Act of 2007 with my colleagues Heather Wilson and Adam Smith which will set forth what we believe is the U.S. fair share towards achieving the goals of the Global Plan. The Stop TB Now Act will strengthen US leadership on international TB control by providing increased resources for the development of urgently needed new TB diagnostic and treatment tools to USAID and CDC. My bill calls for a U.S. investment of $400 million for international TB control in FY08 and $550 million in FY09.

Chairman Payne, we wish to thank you for your co-sponsorship of this important measure. I also would like to thank the many global health groups that we have worked with on this legislation, who have also endorsed H.R. 1567: the RESULTS Educational fund, The American Thoracic Society and the Global Health Council.

If we don't make bold—and wise—investments in international TB control, not only will we fail to save millions of lives and miss out on the many accompanying benefits of controlling this killer, but this disease will also become far more difficult and costly to treat.

Extremely Drug Resistant TB or "XDR–TB" for short highlights this danger. It has been found on six continents, is a growing epidemic in southern Africa, and is already reported to be here in the United States. Regular (non drug-resistant) TB is curable with drugs that cost just $16 dollars in most developing countries. Cases of drug-resistant TB, however, can cost thousands of dollars to cure, with treatment that is far more difficult for patients and practitioners. Drug-resistant TB is a man-made problem and is caused by an array of factors including the misuse of antibiotics, inadequate funding for laboratory testing and inadequate access to needed drugs. We (the global community) have the power to prevent drug-resistant TB and the power to treat and control regular TB, and yet we have not chosen to do so on the scale that is necessary.

I know that you decided to hold this hearing because you wanted to highlight the fact that in Africa, the intersection between TB and HIV/AIDS is particularly chilling. People with HIV/AIDS have compromised immune systems, and therefore, TB and drug-resistant TB hit them especially hard. In 2004, more than 740,000 people who contracted TB were co-infected with HIV/AIDS. Globally, 90% of people living with AIDS die within 4 to 12 months of contracting TB if not treated.

We must all be concerned that with drug-resistant TB spiraling out of control, especially in HIV/AIDS patients in Africa, the reductions in mortality rates from HIV/AIDS thanks to Anti-Retroviral treatment are now in severe jeopardy. If we do not take urgent action now, progress made on the front lines of the fight against HIV/AIDS is in very serious danger of being undermined by drug-resistant TB. As Nelson Mandela said in 2004, "We cannot win the battle against AIDS if we do not also fight TB."

The Stop TB Partnership's Global Plan to Stop TB projects that Africa will require $19.4 billion to strengthen and maintain country-level TB control efforts through 2015. This represents nearly 44 percent of the global total needed for countries to find and properly treat people with TB. While significant resources are being provided and will be provided by African governments themselves, the remaining funding gap for Africa stands at $11 billion over the next decade—with additional resources needed to scale up a response to drug-resistant TB. XDR–TB is a wake-up call for the longstanding need to strengthen TB control and to build the necessary capacity in health services to respond to drug-resistant TB.

Again, my bill, the Stop TB Now Act of 2007, seeks to authorize the funding level required from the U.S. in order to meet the goals of the Global Plan to Stop TB and therefore be able to address this TB problem globally. I urge the Subcommittee members in attendance today to cosponsor my bill and I respectfully ask Chairman Payne and Ranking member Smith to bring this bill up for consideration in this subcommittee.

Thank you again for allowing me to testify before you today and for holding this important hearing. As advocates across the globe come together on March 24 in recognition of World TB Day, your efforts today to further the dialogue on TB control efforts with testimony by experts from the Centers for Disease Control, Office of the Global AIDS Coordinator, United States Agency for International Development, World Health Organization and Partners in Health will certainly not go unnoticed. We will all benefit from the information gathered today.

Mr. PAYNE. Thank you very much, Representative Engel. Your statement is very clear, and we appreciate your patience. As you know, we had a difficult day today, but I appreciate it and we will see what we can do to move your legislation forward.

Mr. ENGEL. Thank you.

Mr. SMITH OF NEW JERSEY. I do want to thank Chairman Engel. We work together on a number of projects, and I thank you for your leadership here.

Mr. ENGEL. Thank you very much.

Mr. PAYNE. At this time we will have our second panel. I would ask that our witnesses limit their oral testimony to 5 minutes. Your written testimony will appear in the record in full.

The panelists were introduced, so I will just ask them to come forward at this time: Ambassador Mark Dybul, Dr. Kent R. Hill and Dr. Julie Louise Gerberding.

We will go in the order that you were called. We will begin with Ambassador Dybul.

Ambassador DYBUL. Thank you, Mr. Chairman. If we could beg your indulgence.

The leader for our efforts on international tuberculosis is Ambassador Tobias, who is the coordinator for Foreign Assistance, and so if you don't mind we would break with protocol and allow Dr. Hill, who reports directly to Ambassador Tobias, to speak first, then I will speak on HIV TB, and then Dr. Gerberding.

Mr. PAYNE. Without objection. Dr. Hill?

STATEMENT OF THE HONORABLE KENT R. HILL, ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

Mr. HILL. Thank you, Ambassador Dybul. I will try to be as brief as possible.

Chairman Payne and Representative Smith, it is a real privilege to be here on this very important topic. As has been mentioned several times already, March 24 is World TB Day and the theme of "TB anywhere is TB everywhere" is certainly apt for our discussions today.

USAID's efforts in TB are closely coordinated with our colleagues at the Centers for Disease Control and Prevention, the National Institutes of Health (NIH), Department of Health and Human Services and also, of course, with the PEPFAR and the Office of the Global AIDS Coordinator, and I want to thank the World Health Organization (WHO) for the fine briefing that preceded our being here right now.

I want to make a comment at the outset. I know we are here to talk about XDR to some extent and obviously about Africa, but this needs to be put in a somewhat broader context. The situation is, as has been mentioned before, that between 1.6 million and 2 million die a year from TB, and 60 percent of the global burden of TB is in the Asia and Pacific region.

In Eastern Europe and in Eurasia, gaining commitment to internationally recognized TB control standards is still an uphill struggle, though progress has been made. And while the recent outbreak of XDR–TB in South Africa has made the headlines, it should be remembered that 17 of the 21 priority countries identified in the global MDR– and XDR–TB response plan are not in Africa. They are in Asia and in the Pacific, so this is a problem that goes well beyond Africa.

Between 2000 and 2006, on behalf of the United States Government, USAID expended about $.5 billion around the globe to work on TB programs. Our funding level in 2006 is around $90 million, as has been mentioned. It has been that for a number of years. We work in 37 countries, and that includes, by the way, that $90 million or $91 million includes a $5 million contribution to the Global TB Drug Facility, which is an important mechanism with which we work.

Africa accounts for a little over a quarter of the estimated global burden of TB, but deaths due to TB and TB incidence continue to increase largely because of the issue, of course, of HIV co-infection. USAID supports TB programs in 16 countries in Africa, and the proportion of our overall TB assistance devoted to Africa has been rising, and is 22 percent this year. We are projecting by 2008 it will probably go up to at least 28 percent.

Our programs do support the DOTS strategy that WHO introduced in the early 1990s. It includes strengthening laboratory capacity, training of health workers, technical assistance, working with communities and working with the private sector to try to leverage USG funds to get more funds from other donors as well.

USAID is also strengthening coordination of TB programs with HIV care to help ensure that TB patients are tested for HIV and that HIV patients are screened for TB. This is why this close col-

laboration is so needed between USAID and OGAC, for example, related to these issues.

Our programs are making a difference. Let me just give you a couple of examples to illustrate this point. In the Democratic Republic of Congo USAID supports work in 63 districts, and we have gone from a case detection rate of 51 percent to 78 percent in the space of just 2 or 3 years. The treatment success rate has gone from 70 to 83 percent. Similar statistics can be given for Kenya and a number of other countries as well.

The advent of MDR and XDR in Africa is of particular concern because of the high HIV prevalence and the higher death rates that come when people end up with TB who also are HIV-positive. We have been trying to pay attention to what is going on in South Africa and so one of the things we do, because these things don't hit budget cycles right, is that USAID has worked very hard to reprogram resources that are at our disposal to deal with the MDR–TB situation in South Africa.

I won't go into the details of that, but we always try to do that to respond with as much flexibility as we can to where the urgent health needs are.

This past October, WHO established the Global XDR–TB Task Force and USAID has been an active participant. For USAID's response to XDR, we will build on the emergency actions which are already taking place and which we have a long history of working on in MDR.

Let me just say this at this point. It is really critical to understand that much of our effort, which is to stop traditional tuberculosis, is key in stopping MDR or XDR. It is cheaper. If we succeed there, you don't have to face it at the MDR level or the XDR level. We really need to continue to work on this globally to make sure that there isn't that larger pool from which the infections will come, which are difficult or impossible, seemingly impossible, to treat.

USAID, CDC, the Office of the Global AIDS Coordinator and NIH all work together on this. The USG is not only the recognized leading bilateral donor on TB, but it is really tremendously important to make this point. The USG, and USAID included, believe that it cannot do this work without full collaboration with our international partners and other bilateral folks.

The United States Government should take pride in the fact—USAID does for sure—that this major effort by the Stop TB Partnership, which has been reported earlier by the WHO representative that represents 500 entities, has an actual chairman of the coordinating board who is a USG person and is, in fact, a TB expert from USAID sitting behind me, Irene Koek.

So we are engaged at the international level on this. We continue to be flexible, and we will move forward as best we can. We thank you very much for the opportunity to be here with you today.

[The prepared statement of Mr. Hill follows:]

PREPARED STATEMENT OF THE HONORABLE KENT R. HILL, ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT

TUBERCULOSIS

Chairman Payne, Representative Smith and other distinguished members of the Committee, I would like to thank you for convening this important hearing and for inviting me to testify. Thank you for putting the spotlight on Tuberculosis (TB). The timing of this hearing is particularly relevant since March 24 is World TB Day. The World TB Day theme of "TB anywhere is TB everywhere" is a clear reminder that we are talking about a disease that is easily transmitted. TB knows no borders.

I am pleased to be here with Dr. Gerberding and Dr. Dybul, and I appreciate the excellent overview of the TB situation that was provided by Dr. Raviglione. The U.S. Agency for International Development's (USAID) efforts in TB are closely coordinated with other U.S. government agencies, particularly the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS), and Office of the Global AIDS Coordinator (OGAC). On research, we also work closely with CDC and the National Institutes for Health (NIH) in HHS, particularly in operations research to improve program implementation, and new drug development.

I will speak briefly about the problem and challenges of TB, particularly in Africa, and outline USAID's efforts to battle the disease, including our response to Multidrug resistant (MDR) TB and extensively drug resistant (XDR) TB.

TB is not just a public health challenge but it is also a development problem as this devastating disease strikes people during their most economically productive years. The magnitude of the problem is staggering. According to the World Health Organization (WHO), each year nearly nine million people will develop TB and nearly 2 million people will die. Although a cure for TB has existed for more than half a century, the disease is often diagnosed late, treated improperly or not treated at all leading to transmission in the community and death. Unfortunately, the most vulnerable people have the greatest difficulties in accessing good quality care. TB is both a disease of poverty and a contributor to poverty, and it takes a tremendous toll especially on poor families in developing countries.

While the challenge is great there has been tremendous progress in the past few years. The STOP TB Partnership's *Global Plan to STOP TB 2006–2015* has catalyzed countries to be more ambitious than they have in the past. TB control is improving in many regions of the world—notably Asia and Latin America.

TB—The Global Context and USAID's Global Program

I know we are here to talk about Africa—where the TB problem is indeed severe—but it is also important and relevant to keep in mind the global TB situation. Sixty percent of the global burden of TB is in the Asia and the Western Pacific regions—notably in countries such as India, China, Indonesia, Bangladesh, Pakistan, The Philippines, Viet Nam, and Cambodia. While many of these countries have made tremendous progress in recent years, there is still much more that needs to be done to ensure sustainability. In Latin America, while there has been much success in controlling TB, sustaining that progress will require TB services reaching the poorest and marginalized groups in all countries. We also can not forget Eastern Europe and Eurasia, where gaining commitment to internationally recognized TB control standards continues to be an uphill struggle. While the recent outbreak of XDR TB in South Africa has made the headlines and must be urgently and effectively dealt with, 17 of the 21 priority countries identified in the WHO's Global MDR and XDR TB response plan are in Asia and the Western Pacific. We must increase attention to Africa, but we can not overlook the other regions where TB is still a serious problem and where MDR and XDR TB are a looming threat.

Between 2000 and 2006, USAID provided about $500 million for TB programs worldwide. Our FY 2006 funding level was about $90 million which supported bilateral TB programs in 37 countries (of which 19 are USAID high priority TB countries), as well as other key activities including global surveillance and research on new anti-TB drugs and diagnostics. In FY 2006, USAID provided $5 million to the STOP TB Partnership's Global TB Drug Facility (GDF), an important mechanism that provides drugs to countries in need. Our programs are fully aligned with the new STOP TB Strategy, which builds on the WHO recommended "Directly Observed Treatment, Shortcourse" or DOTS by giving attention to DOTS quality and as well as expansion, TB/HIV–AIDS and MDR TB, engaging all care providers, empowering people with TB and communities, contributing to health system strengthening, and research.

Africa's TB Burden and USAID's Response

Africa accounts for a little over a quarter of the estimated global burden of TB, but deaths due to TB continue to rise, and it is the region in the world where TB incidence continues to increase. The factor behind this tragedy is HIV/AIDS and the deadly dynamic of TB/HIV–AIDS co-infection. HIV/AIDS, weak health systems, poor access to primary health care services, and a serious health work force crisis are contributing to the slow progress in TB control in Africa. Both case detection and cure rates are lagging in Africa.

To address these challenges, DOTS needs to be brought closer to patients. Laboratory and human resource capacity must be strengthened, all health providers including the private sector need to be engaged, and communities and civil society must be mobilized. Even with improvements in these areas, deaths due to TB will continue to be unacceptably high in countries with high TB/HIV–AIDS co-infection unless access to TB treatment and anti-retroviral treatment (ART) is dramatically scaled up. Increasing collaboration between TB and HIV/AIDS programs at the country level is an essential component of addressing these challenges.

Africa is a priority for USAID. Between 2000 and 2006, we provided $95 million to TB programs in Africa. Sixteen of the 37 countries where we have TB programs are in Africa, including nine of our high priority TB countries. The proportion of our overall TB assistance devoted to Africa has risen to more than 20% of the total and continues to increase. We provide assistance to eight of the nine of the high burden countries in Africa.[1] Our programs support implementation of the STOP TB Strategy, including DOTS expansion and strengthening, the provision of laboratory supplies and equipment, training all cadres of health workers, technical assistance and engaging communities and the private sector in TB care. Our funding to the GDF benefits many countries in the region.

USAID is also strengthening coordination of TB programs with HIV care to help ensure that TB patients are tested for HIV and HIV patients are screened for TB and then treated for TB if needed. About 13% of our TB budget is used to help strengthen the capacity of TB programs in the area of TB/HIV–AIDS. To help ensure synergies between USG investments in TB and HIV/AIDS, many of our TB high priority 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. Our programs help to strengthen TB services for the general population in these countries and are directly complementary to the assistance provided by OGAC to reach HIV infected populations.

Our programs are making a difference. In Nigeria, USAID supports DOTS expansion in 17 states where prior to 2002, there were no DOTS services. More than 74,000 TB cases have been detected in these states between 2002 and 2005 with the number of TB cases detected increasing by about 26% on average each year. In the Democratic Republic of Congo, USAID support to 63 districts has contributed to an increase in the TB case detection rate from 51% of the estimated cases in 2001 to 78% in 2004, and an increase in cure rates from 70% to 83% as compared to the target of 85%. USAID and PEPFAR are effectively leveraging TB funding and HIV/AIDS funding. In Kenya, TB/HIV collaborative activities have been expanded to 80 percent of districts where 37 percent of TB patients are now being tested for HIV. In Tanzania as well, TB/HIV activities are being scaled up quickly.

MDR and XDR TB and USAID's Response

While we continue to deal with the overlapping epidemic of TB and HIV/AIDS in Africa, we are now facing the more ominous threat of XDR TB. This deadly form of the disease not only threatens the lives of people living with HIV/AIDS, including those receiving ARVs, but it also threatens to undermine progress in TB control that has been made in recent years, and threatens HIV/AIDS programs and will compromise PEPFAR activities.

Resistant TB is not new. Previously, the problem was mainly confined to Eastern Europe and Asia; however, with increased access to anti-TB drugs in recent years resistance has developed in all regions. Limited capacity to conduct surveillance has hindered our understanding of resistance trends. The advent of MDR and XDR in Africa is particularly concerning because of the high HIV prevalence and the rapid

[1] The 22 High Burden countries (HBCs) are responsible for 80% of the global TB burden. USAID assists the following HBCs in Africa: Nigeria, South Africa, Ethiopia, Kenya, Democratic Republic of Congo, Tanzania, Uganda, and Mozambique. The only HBC in Africa where we do not work is Zimbabwe where USAID programs are limited due to the difficult conditions there; programs are focused on HIV/AIDS, democracy and humanitarian assistance, with the bulk of this being emergency humanitarian assistance, mostly food aid.

progression from TB infection to disease and death among people with HIV/AIDS. Crowded living conditions, congregating of patients together in clinical facilities for treatment, and the lack of infection control measures makes the spread of TB, including these more deadly strains of TB, among HIV-infected individuals more likely.

USAID is actively engaged in the response to XDR, and is a global leader in addressing MDR TB. Recently, the USAID mission in South Africa reprogrammed resources to immediately respond to the needs identified there by training personnel and strengthening MDR TB treatment units, setting up a surveillance system to track MDR and XDR TB cases, and to assist with tracing of contacts. We are stepping up our support for capacity building in infection control and laboratory strengthening in South Africa. USAID also worked with HHS/CDC and the South African Department of Health to establish the Africa Regional International Training and Research Center on MDR TB and HIV that was launched in March 2006.

USAID has been a key supporter of the Green Light Committee (GLC) since its inception. The GLC of the Stop TB Partnership is a unique mechanism that ensures the quality of programs to treat MDR–TB to prevent the development of resistance to second line anti-TB drugs. Projects that are approved by the GLC are eligible to purchase second-line anti-TB drugs at discounted prices. Since 1998, USAID has supported country-level drug resistance surveys and the biannual Global Report on TB Drug Resistance. USAID, working in collaboration with the HHS/CDC and WHO, supported the surveys published in HHS/CDC's March 2006 Morbidity and Mortality Weekly Report that first called attention to the threat of XDR TB. USAID supports capacity building for MDR TB programs and for management of second line anti-TB drugs. USAID also invests in new diagnostics to rapidly detect TB and new drug regimens to increase the effectiveness and shorten the duration of treatment, both of which will help to reduce the emergence of drug resistant TB.

Globally, considerable momentum has been gained over the past several months, culminating in the establishment of a WHO-coordinated Global XDR–TB Task Force this past October. USAID has been an active participant on the Global Task Force, as well as the U.S. Federal TB Task Force. The Global XDR–TB Task Force is about to finalize a global plan to respond to XDR. For our part, USAID will build on the emergency actions we have already taken and on our long history of support for MDR TB. We will focus on: strengthening DOTS programs to prevent further emergence of drug resistance; building surveillance and laboratory capacity; improving infection control; ensuring effective management of MDR/XDR diagnosis and treatment; engaging communities to support patients; and investing in new drugs and diagnostics. We will work with our partners including WHO, HHS/CDC, the Stop TB Partnership, and others to move ahead on these priorities.

Our response to MDR and XDR is not confined to Africa. USAID, working with HHS/CDC, helped establish the International Training Center for MDR TB at the Latvian State Centre for TB and Lung Diseases. In 2004, the Center was named a WHO collaborating center for Research and Training in the Management of MDR TB. The rates of MDR TB in Latvia have fallen from 14% in 1994 to 8% in 2003, making the country a model for others to emulate. USAID has been supporting the expansion of DOTS in Russia since 1998. In Vladimir oblast, for example, treatment success rate has increased from 64% to 80%. Our mission in Russia supports drug resistance surveillance and DOTS Plus pilot projects for effective MDR TB control, which serve as models to be replicated with resources from the Global Fund grant.

U.S. Commitment

The U.S. is on the frontlines of the battle against TB. USAID, HHS/CDC, the Office of the Global AIDS Coordinator, and HHS/NIH have been working closely together over many years in TB and have extraordinarily good working relationships that takes advantage of each Agency's strengths and ensures that USG resources for TB and for TB/HIV are used in the most effective and efficient manner possible. USAID's bilateral programs assist TB programs in Africa, Asia, Europe and Eurasia, and Latin America. As the second leading donor to the GDF, our funding helps to provide drugs to many more countries, and our technical assistance is helping to improve the performance of Global Fund grants. We 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 HHS/CDC represent the US Government on the international Stop TB Partnership Coordinating Board, and a USAID staff member, Irene Koek, is currently serving as Chair of the Stop TB Partnership Coordinating Board.

Moving Forward

We know what needs to be done. The *Global Plan to STOP TB 2006–2015* provides us the road map and the STOP TB Strategy provides the key interventions. USAID remains fully committed to working with all of our partners to renew the charge against TB.

Mr. PAYNE. Thank you very much.

Ambassador Dybul?

STATEMENT OF THE HONORABLE MARK R. DYBUL, COORDINATOR, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

Ambassador DYBUL. Chairman Payne, Ranking Member Smith, thank you for this opportunity to discuss the President's Emergency Plan for AIDS Relief and our efforts to combat tuberculosis.

The partnership between PEPFAR and this committee, both members and staff, over the years is one for which we are very grateful. Thank you for your commitment to U.S. leadership in the fight against HIV/AIDS. Your bipartisan support for this historic initiative has been key to its success.

Thanks to the commitment of President Bush, Congress and the American people, PEPFAR is on track to exceed its original commitment of $15 billion over 5 years and to achieve the aggressive prevention, treatment and care goals.

The majority of those resources are being invested directly into partnerships with host nations, and I know that both of you have been to Africa recently and have seen the good work the American people are doing there, and I hope Mrs. Woolsey has the opportunity to go sometime soon as well.

By working with affected countries to build high-quality health care networks and increase capacity, we are laying the foundation not only for HIV/AIDS work, but also for other health care activities such as tuberculosis, MDR–TB and XDR–TB treatment and prevention.

PEPFAR supports the full range of treatment and care for people who are co-infected with HIV and tuberculosis. Appropriate and full treatment of TB is vital not only to prevent HIV-positive people from dying, but also to alleviate the risk of them developing TB and, therefore, drug-resistant TB.

One study reported an 80 percent reduction in the incidence of TB among HIV-positive people who were on antiretroviral treatment as compared to those who were not receiving antiretroviral treatment, and therefore in a country where 60 percent of all TB patients also have HIV such as South Africa and 50 percent across Africa, if all those who needed antiviral therapy received it it is possible that TB rates could drop by as much as 50 percent. Therefore, HIV therapy is a powerful tool in the fight against tuberculosis.

Our most important work in combating TB takes place through partnerships at the country level to support national health authorities, nongovernmental organizations, including community- and faith-based organizations, to implement more effective TB/HIV programs, and we could not agree more with Congressman Smith about the importance of faith-based organizations to get in the

home and provide therapy and to do so in faith-based hospitals and clinics.

Activities include supporting HIV testing for people with TB and improving TB diagnosis for people with HIV. It is important to note that with some of the additional funds this year we are actually looking at regional reference centers and laboratories so that we can diagnose TB better, and in fact we are supporting reference laboratories in many countries currently.

We support Isoniazid preventive therapy for HIV infected people to reduce their risk of developing TB, improving TB infection control and implementing the WHO-recommended treatment protocol that you have heard about, Directly Observed Therapy-Short Course, or DOTS.

PEPFAR is also supporting expanding the capacity of the local health workforce to deal with these dual epidemics and improving supply chain management systems for medications and other commodities. It is also essential to establish links between TB treatment and antiretroviral treatment, as you have heard about today.

PEPFAR also supports the development of strong tiered public health laboratory networks that we have talked about as well. We will work with partners to train health care providers on the DOTS strategy for treating TB and preventing the development of drug resistance, and here again faith-based organizations are important.

The recent report of an outbreak of XDR–TB among HIV-positive persons is of great concern, and I have to say as an HIV infectious disease physician and researcher I am also very personally concerned about this. It is important to note that XDR–TB is not new. Unfortunately, like HIV, treatment of TB will lead to a certain percentage of persons who will develop resistance.

In fact, more people almost certainly die from XDR–HIV than from XDR–TB. However, it is something we must focus on and be concerned about because, as you noted, Mr. Chairman, 52 of 53 people with XDR–TB died in South Africa, and in fact in that cohort all 44 people who were tested for HIV had HIV. So while XDR–TB is not new, what probably is new is the significant risk of a rapid spread and high death rate because of HIV.

PEPFAR recognizes the significance of the dual epidemics of TB and HIV and the danger they pose for society as worldwide, and this is why, as Ranking Member Smith noted, we have significantly increased our resources more than sixfold in the last several years and will commit $120 million this year.

As of September 2006, PEPFAR supported care for approximately 300,000 TB/HIV-positive persons. Collaboration among U.S. agencies, including CDC, USAID and all the members of PEPFAR, and our close ties with WHO and the Global Fund has led to effective efforts.

Our in-country partnerships include leveraging PEPFAR resources to amplify the effects of other global health initiatives, especially the Global Fund. The United States remains the largest contributor to the Global Fund, which provides significant TB grants. PEPFAR has provided approximately one-third of the Fund's resources, and through 2007 the Global Fund will have committed $1.4 billion to TB grants.

We also support the Green Light Committee for multiple drug-resistant tuberculosis to support global fund grants so that they can move through the Green Light Committee more quickly, and we work with the World Bank, UNAIDS and the International Union Against TB and Lung Disease in the private sector.

In partnership with host nations and the international community, PEPFAR has taken substantial steps toward combating global TB, and we will continue to do so. PEPFAR takes the issue of XDR–TB seriously and, as noted in response, we have increased our 2007 commitment by $50 million, which will include trying to establish some reference laboratories.

In partnership with Congress and the strong coordination within the Executive Branch as demonstrated by this panel today, the U.S. Government and American people are doing their part.

Mr. Chairman and Ranking Member Smith, thank you for your interest in this important issue. I look forward to your questions.

[The prepared statement of Ambassador Dybul follows:]

PREPARED STATEMENT OF THE HONORABLE MARK R. DYBUL, COORDINATOR, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE

TUBERCULOSIS

Mr. Chairman, Ranking Member Smith, and Members of the Subcommittee:

Thank you for this opportunity to discuss the President's Emergency Plan for AIDS Relief and our efforts to combat the spread of tuberculosis (TB) globally. The partnership between PEPFAR and the Committee on Foreign Affairs over the years is one for which I am very grateful. Chairman Payne and Ranking Member Smith, thank you for your commitment to the U.S. leadership in the fight against HIV/AIDS. Bipartisan support for this historic initiative has been a key to its success.

Thanks to the commitment of President Bush, Congress and the American people, PEPFAR is on track to exceed its original commitment of $15 billion over five years. The majority of those resources are being invested directly into partnerships with host nations. By working with our host countries to build high-quality health care networks and increase capacity, we are laying the foundation for nations and communities to sustain their efforts against not just HIV/AIDS, but a wide range of other diseases, including multi-drug resistant (MDR)– and extremely drug resistant (XDR)–TB—long after the initial five years of the Emergency Plan.

Because its effect on the immune system makes HIV-infected people more susceptible to infection, HIV is the single greatest powerful risk factor for developing tuberculosis. In Africa, TB is in lock step with the increase in HIV/AIDS. In fact, TB is the number one killer of people living with HIV—which is why PEPFAR is leading a unified U.S. Government (USG) global response to fully integrate HIV and TB services at the country level. Our goal is to ensure that people who are infected with HIV receive the best treatment and care possible, in order to prevent them from contracting TB in the first place. This is critical to the long-term control of TB at the global level. Anti-retroviral treatment (ART) is a powerful deterrent to the development of TB, because it restores immune function. A strong immune system means that an HIV-positive person on ART is much less likely to contract TB; and even if he or she already has been infected with tuberculosis, the bacteria are more likely to remain dormant.

PEPFAR also supports the full range of HIV treatment and care for people who already are co-infected with HIV and active TB. Appropriate and full treatment of TB is vital, not only to prevent HIV-positive people from dying but also to alleviate the risk of them developing drug-resistant TB. In one study in South Africa, there was an 80 percent reduction in the incidence of TB among HIV-positive people who are on anti-retroviral treatment, as compared to those who are not on ART. With 50 percent of TB cases occurring in Sub-Saharan Africa, ART is a powerful too in the fight against TB.

PEPFAR recognizes the significance of these dual epidemics and the danger they pose for societies worldwide, particularly in settings of high HIV prevalence, and this is why our support for TB/HIV has increased *more than six-fold* in just three years—from *$18.8 million* in 2005, to *$48.6 million* in 2006, to at least *$120 million* in 2007. As of September 2006, PEPFAR had supported care for approximately

301,000 TB/HIV co-infected people in the focus countries. Collaboration among USG agencies, including those working domestically, has been strengthened—as have PEPFAR's ties with our multilateral partners, including the WHO and the Global Fund. Such collaborations are essential for mounting an effective response at the global level.

However, our most important work in combating TB takes place through partnerships at the country level to support national health authorities, non-governmental organizations, and community- and faith-based organizations to implement more effective TB/HIV activities. Activities include providing HIV testing for people with TB and improving TB diagnosis for people with HIV; providing isoniazid preventive therapy to HIV-infected people in order to reduce their risk of developing TB; improving TB infection control to prevent people with HIV from coming in direct contact with someone with active TB; implementing the WHO-recommended International Standards for TB Care, which build on Directly Observed Therapy-Short Course (DOTS) strategy, in PEPFAR HIV care settings, in order to ensure that patients complete their TB treatment; and improving laboratory surveillance systems in order to detect outbreaks of MDR– and XDR–TB.

PEPFAR also supports expanding the capacity of the local health workforce to deal with these dual epidemics and improving supply chain management systems for medications and other commodities. It also is essential to establish linkages between TB treatment and ART services so that people who are co-infected receive the medical attention they need. PEPFAR also supports the development of a strong, tiered public health laboratory network for diagnosing and managing drug-resistant TB and other opportunistic infections. We also work with partners to train health care providers in the DOTS strategy for treating TB and preventing the development of drug resistance.

Our in-country partnerships include leveraging PEPFAR resources to amplify the effects of other global health initiatives, especially the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) and support for the Green Light Committee for multi-drug resistant TB grants of the Global Fund. The USG remains the largest contributor to the Global Fund, which provides significant TB grants. Through PEPFAR, the USG has provided approximately one-third of the Fund's resources—and through 2007, the Global Fund will have committed $1.4 billion to TB grants. We also work with the World Bank, the World Health Organization, UNAIDS, the International Union Against TB and Lung Disease, and the private sector.

As an initial step in addressing MDR– and XDR–TB, the U.S. Government convened the U.S. Federal TB Task Force to develop a coordinated domestic response by U.S. Government agencies to the looming threat of MDR– and XDR–TB. The Administration will convene an interagency team in the near future to formulate a comprehensive response and to assign responsibilities for a unified strategic international approach. The U.S. Government also participates in the WHO Global XDR–TB Task Force, which is finalizing a global plan to respond to XDR–TB. The White House will convene an interagency meeting in the next few weeks to ensure U.S. Government activities are integrated in a unified strategic approach.

The Evolution of Drug-Resistant TB

In discussing XDR–TB, let me start by making two observations: (1) the development of drug resistant tuberculosis is of concern, but not surprising, and (2) it is not new. At the population level, particularly in high HIV prevalence countries in Africa, the combination of poverty, overcrowding, and HIV have led to dramatic increases in TB infection. Beginning in the 1990s, the number of TB cases exceeded the capacity of poorly-financed, under-staffed TB control programs to deliver effective TB management. Drug-resistant TB is the direct result of inadequate TB control. This is why there is a saying in TB circles that poor TB treatment is worse than no treatment at all.

On an individual patient level, drug resistance can develop when someone is infected with an already-resistant organism. It also can develop if a person infected with TB and the disease progresses to active TB, which can happen very quickly among people who are immuno-compromised. This is what has happened in the recent and well-publicized outbreak in South Africa. Another way to develop drug-resistant TB is through inadequate TB treatment, or by not completing a full course of TB therapy. The more this happens, the more TB drug-resistance will develop. We have seen the same problem with resistance to HIV medications when antiretroviral treatment is improperly prescribed or taken.

The implications of MDR– and XDR–TB, particularly for people with HIV, are serious. Most cases of TB are drug-sensitive and can be cured in someone with or without HIV infection after six months of treatment and for just a few hundred dol-

lars. However, people with MDR–TB have a much poorer prognosis, requiring as much as 18 months of treatment, and costing many thousands of dollars. When the second-line drugs for MDR–TB are misused or mismanaged and therefore also become ineffective, then XDR–TB can develop. Because XDR–TB is resistant to both first- and man second-line drugs, it is—for the time being at least—almost untreatable.

There has been growing concern recently about the incidence of drug-resistant TB, and we *should* be concerned. The WHO estimates that there are 425,000 cases of MDR–TB per year globally—nearly 5 percent of the world's annual TB burden. In addition, there are 27,000 cases of XDR–TB, which is of particular concern to us because it is almost universally fatal to people who are HIV-positive.

TB and HIV in Africa

Globally, more than 80 percent of the TB cases occur in Africa and East and Southeast Asia. Not surprisingly, HIV prevalence in TB patients varies widely, from between 30 percent and 80 percent in most African countries, to 7 percent in Russia, 5 percent in India, and less than 1 percent in China. These varying epidemiologic patterns have important implications for TB control and TB/HIV interventions.

Recent findings from a WHO and CDC survey (with support from USAID) of data from 2000 to 2004 found that XDR–TB has been identified in all regions of the world, including the U.S. It is most commonly found in the countries of the former Soviet Union and in Asia, where it seems to be stable. Improved TB control and surveillance will be important to monitor trends in XDR–TB in this part of the world.

However, an immediate concern about MDR–TB and XDR–TB is its explosive potential in settings of high HIV prevalence, such as sub-Saharan Africa. In the U.S. during the early 1990s, we saw numerous outbreaks of MDR–TB in people with HIV/AIDS, but drug-resistant TB has not been seen among HIV-positive people in sub-Saharan Africa until recently. To date, little surveillance data has been available from sub-Saharan Africa on MDR– and XDR–TB, but it appears that new cases may be rapidly increasing. The recently-reported outbreak of XDR–TB in South Africa is especially troubling. It appears that people with MDR–TB had received inadequate treatment and developed XDR–TB. They then subsequently spread their XDR–TB to people with HIV/AIDS in the community or in the local hospital. Because their immune systems were so weak, the people with HIV/AIDS rapidly developed XDR–TB and the consequences have been devastating—52 out of 53 XDR–TB patients in the original report have died. Of these, 44 patients had been tested for HIV, and all were positive. USG agencies, including HHS/CDC and USAID, along with the WHO and local authorities, took the lead in alerting the world to this potential threat.

Guidance on TB/HIV activities supported by PEPFAR has been included in our technical guidance since 2004, but in response to the XDR–TB outbreak in South Africa, PEPFAR has alerted all focus countries to the problem, and we have advised them to take it into account during the development of their FY07 Country Operational Plans, in partnership with national TB and HIV control programs. Teams of epidemiologists, laboratory scientists, and environmental engineers have been dispatched to a range of countries to develop response plans, conduct local assessments and training, and support implementation. Six teams of USG staff along with local staff from TB and HIV control programs in focus countries (Kenya, Rwanda, Ethiopia, Zambia, Namibia, and South Africa) were recently brought to Washington, in collaboration with the WHO and the Bill and Melinda Gates Foundation, to develop accelerated TB/HIV plans. According to the WHO, 10 countries in the region have started or plan to start rapid surveillance studies to determine the extent of MDR– or XDR–TB in their population.

Addressing HIV and drug-resistant TB

Addressing HIV/TB and drug-resistant TB is particularly challenging—especially in impoverished settings that are heavily impacted by HIV/AIDS. In sub-Saharan Africa and elsewhere, TB control programs are already overburdened and unable to deal with the emerging threat of drug-resistant TB.

In tackling the problem of emergent drug-resistant TB, PEPFAR's primary goal is to increase cross-testing of TB and HIV patients. Estimates are that more than half of the people infected with TB in sub-Saharan Africa are co-infected with HIV. For example, in South Africa, 60 percent of all TB patients are HIV-positive—and in Botswana and Swaziland, 80 percent of all TB cases are co-infections. Unfortunately, by the end of 2005, only 10 percent of all TB patients throughout the African region had been tested for HIV, and only 13 percent of the estimated HIV-infected

TB patients had been detected. Therefore, one of PEPFAR's top priorities is to increase consistent cross-testing for TB and HIV.

Another goal is to ensure that eligible TB/HIV patients are put on ART. Studies have shown[1] an 80 percent reduction in the incidence of TB among HIV-positive people who are on anti-retroviral treatment, as compared to those who are not on ART. Thus, in a country where 60 percent of all TB patients also have HIV, if all co-infected people were put on ART, we could reasonably expect allover TB rates to drop by close to 50 percent.

The first step in accelerating TB/HIV collaborative activities and preventing the emergence of drug-resistant TB is to strengthen weak and struggling TB programs. For years, TB programs have been under-resourced and they now face incredible challenges in delivering care to thousands of TB patients, many of whom also have HIV. There are a number of essential components for a strong TB program. Through our focus on supporting and building host country capacity, PEPFAR is focusing on a few of the most important elements.

Laboratories are the most important but weakest link in the fight against TB/HIV. The diagnosis and the provision of high-quality care depend on an efficient public health lab network. International recommendations for diagnosing TB have changed and now include sophisticated investigations such as culture, and effective high-quality microscopy, including fluorescent microscopy. All this requires an effective and efficient laboratory system. The emergence of XDR–TB has further highlighted the need for strong lab systems. Finally, lab support is essential for the delivery of high-quality HIV testing and treatment services. PEPFAR is working closely with host country partners to ensure the establishment of well-functioning public health laboratory networks to diagnose and manage TB among people living with HIV/AIDS.

Despite being one of the 12 WHO-recommended collaborative TB/HIV activities, TB infection control has been heretofore neglected. Given the recent emergence of XDR–TB and increasing evidence of infection risk among not only HIV-infected people but also among health care workers, it is becoming clear that countries must develop the capacity to provide appropriate care and treatment for large numbers of co-infected people. Whether it is drug-resistant or not, TB is an airborne, potentially deadly disease. PEPFAR is mobilizing our resources to meet this challenge head-on, so that health care facilities do not become "amplifiers" of the TB epidemic.

An old public health axiom is "what is measured is done." A strong HIV/TB program relies on a well-functioning monitoring and evaluation (M and E) system. M and E are critical activities, and building an effective M and E system is essential if we hope to capture what is going on in countries and use that information to inform and accelerate implementation of HIV/TB activities. PEPFAR is working closely with host countries and international partners to ensure that an effective M and E system for collaborative TB/HIV activities is central in program implementation.

In higher HIV prevalence areas, people who have symptoms of TB should be offered counseling and testing for HIV. HIV testing is a gateway for effective delivery of collaborative TB/HIV activities, including prevention, care and treatment. Although there is an increasing recognition that this is a critical HIV/TB activity, it is a very challenging endeavor. The WHO estimates that globally only 7 percent of TB patients are tested for HIV and only 13 percent of the estimated HIV infected TB patients were detected. PEPFAR recognizes that, although there have been some success stories in this area, there is an urgent need to expand counseling and testing to places where people with TB come for diagnosis and treatment.

We still have a long way to go, but our efforts are starting to have a positive impact. Recent data from Botswana's national TB program suggest that 68 percent of all registered TB patients now undergo HIV testing. Rwanda has doubled its percentage of TB patients tested for HIV and now around 90 percent receive an HIV test. In some districts of Tanzania with provider-initiated HIV counseling and testing, more than 80 percent of all TB patients opt for HIV testing and learn their status.

We know that the percentage of TB patients who are tested for HIV continues to vary widely. In An Giang province in Vietnam, 100 percent of all TB patients undergo HIV testing—but in the Western province of Zambia, it is only about 50 percent. Often, this is a matter of logistics: even when referred, a TB patient may not go for HIV testing if the HIV counseling and testing center is not in close proximity to the TB clinic. Because of this, PEPFAR is working with partners in many countries—including Botswana, Ethiopia, Kenya, Rwanda, and Tanzania—to expand provider-initiated HIV counseling and testing services, either right in the TB clinics or nearby. We are also supporting efforts to integrate services for people living with

[1] Badri, *Lancet* 2002.

HIV/AIDS (PLWHA). For instance, in Côte d'Ivoire, where ART programs are being decentralized, efforts are underway to co-locate TB and HIV care in the same facilities.

Diagnosing and managing TB in patients with HIV can be a challenge—but it is vital to prevent the high morbidity and mortality associated with TB. Recently released international recommendations include revised case definitions and the use of available investigations (e.g. culture, CXR [?], biopsy) to expedite the diagnosis and treatment of TB among people living with HIV. Managing extrapulmonary TB in HIV-prevalent settings is now emphasized as part of routine national TB control activity.

However, there are several significant barriers to ensuring the provision of ART for HIV infected TB patients, such as the risk of drug interactions between ART and Rifampicin, which complicates the provision of ART for TB patients. Appropriate care also is essential for TB patients, including treatment with Cotrimoxazole—but very few TB patients with HIV are provided with this life-saving therapy. PEPFAR is working with partners to expedite the diagnosis and treatment of TB (including smear negative pulmonary and extrapulmonary TB) and to ensure ART for eligible TB patients.

TB is the leading opportunistic illness and contributor to significant early mortality of people on ART. Therefore, early detection of TB among people living with HIV is crucial. For those without active TB, the provision of isoniazid preventive therapy can prevent the development of TB. Unfortunately, the WHO estimates that less than 5 percent of estimated HIV-positive children and adults in the African region were screened for TB symptoms and signs in 2005, and approximately 0.1 percent of those eligible were started on isoniazid preventive therapy. By the end of fiscal year 2006, PEPFAR had supported antiretroviral treatment for 822,100 HIV-positive people, and supported care for 4.5 million people in the focus countries. PEPFAR, through its support of care and treatment programs, is focusing on improving the screening of TB in HIV/AIDS care settings and supporting isoniazid preventive therapy and TB management using DOTS principles.

In addition to providing TB–HIV diagnostic services, some countries—including Kenya and Mozambique—are exploring ways to provide DOTS treatment to TB patients in HIV clinics such as cotrimoxazole[2] at TB sites, to facilitate simultaneous care for TB/HIV co-infected patients. Some countries, such as Tanzania, are initiating provision of ARVs in TB clinics for patients who are also HIV-positive; this requires a strong national TB program.

In many places, TB screening is taking place as part of the PEPFAR-supported preventive care package for HIV-infected people, and we are working closely with our partners to expand these efforts. With USG support, host country programs have developed simple symptom-screening tools, as well as recording-and-reporting forms to document TB screening. When appropriate, health care facilities are responsible for ensuring the proper diagnosis and management of TB according to the DOTS strategy and national TB program guidelines.

In all these efforts, PEPFAR works closely with national health authorities and local organizations, to build sustainability by expanding and strengthening indigenous healthcare capacity. Of all the adults and children who have received TB treatment with PEPFAR support, just over one-third received it at USG-supported delivery sites; the remainder received care through our support of national, regional, and local programs.

Next Steps: the Road Ahead

In partnership with host nations and the international community, PEPFAR has taken substantial steps toward combating global TB, and we will continue to do so. Just two weeks ago, we co-sponsored a meeting of the WHO's Stop TB partnership, local Ministers of Health, and other key USG and international partners to accelerate the implementation of HIV/TB activities in Ethiopia, Kenya, Namibia, Rwanda, South Africa, and Zambia. One of our first tasks following the meeting will be to work with PEPFAR missions to use additional HIV/TB resources to support host country HIV/AIDS and TB program managers to implement collaborative HIV and TB services.

Another exciting development with enormous potential for fighting TB is PEPFAR's newest public-private partnership, the *Phones for Health* program. It joins African entrepreneurs with local NGOs and multi-national corporations to use cell phone technology to connect health systems in 10 PEPFAR-supported countries by 2010. Working closely with national Ministries of Health and global health orga-

[2] Cotrimoxazole is recommended by the World Health Organization (WHO) for HIV-associated tuberculosis.

nizations, the Phones for Health partnership will develop an integrated set of standard information solutions that support the scale-up of HIV/AIDS, TB, malaria, and other infectious disease initiatives in a cost-effective manner that builds local capacity.

These are just some of the ways in which PEPFAR is proactively engaged in the coordination of TB and HIV programs. Moreover, PEPFAR will continue to maximize its resources with our international and country partners to support the global response in combating and ultimately conquering both HIV/AIDS and tuberculosis around the world.

PEPFAR takes the issue of XDR–TB very serious, and in response, have increased the Fiscal Year 2007 commitment for TB/HIV efforts by providing an additional $50 million more than was originally planned. In partnership with Congress and strong coordination within the Executive Branch, the U.S. Government and the American people are doing their part. Mr. Chairman and Ranking Member Smith, thank you again for your interest in this important issue. I look forward to your questions.

Mr. PAYNE. Thank you very much.

Dr. Gerberding?

STATEMENT OF JULIE L. GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND ADMINISTRATOR, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Dr. GERBERDING. Thank you, Chairman Payne, Representative Smith and Representative Woolsey. I also really appreciate Representative Engel testifying at the hearing and presenting the proposal for the legislation.

On Saturday I will be getting up early in the morning and walking with my colleagues at CDC to commemorate World TB Day. I am doing that because it is such a global health threat and because it is so very, very important, especially in the context of drug resistance.

My colleagues have done a great job of defining for you the descriptive characteristics of the threat as we see it today, and I would like to start by just commenting on a personal perspective on that.

I was privileged to live in Marin County in Mill Valley and train at UCSF as an intern. I started my training in 1981 just as HIV was emerging in our community, so I lived through the very early phases of that pandemic and the horror and difficulties that we all faced in trying to provide care and understand the disease.

That was challenging, but just a few years later we were faced with the second emerging epidemic in the same hospital environment, and that was the emergence of tuberculosis and particularly drug-resistant tuberculosis, fueled in part because of HIV and the immunosuppression that led to activation of tuberculosis, but also the crowded conditions of many of the poorest people who were spreading the disease in their homeless shelters and in other environments.

That proved to be a small tip of the iceberg for what was going on across the United States. In New York alone, MDR–TB affected multiple patients, but in addition about 20 health care workers and prison attendants died, and the estimated cost just to New York City alone was more than $1 billion for the outbreak of drug-resistant tuberculosis, so it is a flashpoint that very quickly can become a macro problem.

When you look at this map of the world and you see the rates of drug-resistant tuberculosis on a global scale, and you may not

be able to see the print here, but the red countries have prevalence rates of drug-resistant tuberculosis among people who had previously undergone TB treatment of up to 40 percent or greater.

That means that there is an incubator already out there on a global basis that when you treat these patients with second-line tuberculosis drugs, you are setting the stage for the excessive or extremely drug-resistant TB, the XDR–TB that we are here today particularly focusing on.

Now, why does this happen? Very simply, there is a rule in infectious disease that if you use a drug you lose in. Now, if you had no TB treatment you would have no TB drug resistance. If you treated all patients with the optimal therapy for cure, you would have very little resistance because you would have successfully eliminated the disease.

The problem we face globally is the in-between zone where we are not optimally treating patients because the system can't support it or the drugs aren't available or the health care facilities just simply aren't adequate, and in the context of HIV we set the stage for worse diseases and prolonged periods of transmission so that we end up with the potential for lots of drug resistance and, as we are seeing more recently on the next graphic, many countries now where XDR has been confirmed.

I am showing this map, but it presents a dilemma to us because we have to get the communication right here. We have to get the right balance between not exaggerating the threat of XDR, crying wolf and claiming a health problem on a global basis that does not yet exist, but at the same time we have to be responsible and recognize that if we wait until we have a conflagration of this disease it is too late.

We learned that in 1981 with HIV. We waited to deal with this problem on a global basis, and we have a chance now to be proactive and interact early and effectively cutting across all of our agencies and our multilateral partners to really nip this in the bud and improve the overall treatment and control of tuberculosis on a global scale.

I think we are poised to do that, and we are delighted with the investments that the Congress has already made available to us through the PEPFAR process, but this is, as you can see from this map, not just an HIV related problem.

We see XDR in countries that have low prevalence of HIV, and the reason for that is because they have other factors that promote emergence and spread, in particular difficulties with sustaining effective first-line tuberculosis therapy, lack of observed therapy, lack of laboratories and lack of access to drugs.

The challenge is real. The time is now. I think as we commemorate the concept of World TB Day that TB anywhere is TB everywhere, we are very delighted and pleased that we have the opportunity to appear before you and highlight this.

I do want to close with a U.S. perspective because CDC has as its primary mission protecting the health of Americans. There are three threats to people here. One is the emergence of drug-resistant TB because of inadequate treatment programs here, which is a risk if we don't sustain our investment in directly observed therapy and the other components of control.

More likely in today's era is the introduction of XDR–TB through immigrant populations who are in situations where they are inadequately screened and treated before they immigrate to the United States. We have already seen this happen with MDR in the Hmong population who did not get effective treatment and screening before they immigrated.

We are doing things to help avoid this in the future, but it remains an important threat, and we have a gap in our ability to control that now, and we are looking at options for how we can intervene.

The third issue for all of us circles back to my experience in San Francisco, and that is the issue of complacency. It is really hard to focus people's attention on a problem when it is not here today, and that is just one more reason why we are grateful for you taking the time to make this a very visible issue for everyone.

Thank you.

[The prepared statement of Dr. Gerberding follows:]

PREPARED STATEMENT OF JULIE L. GERBERDING, M.D., M.P.H., DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION, AND ADMINISTRATOR, AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

Good afternoon, I am Dr. Julie Louise Gerberding, Director of the Centers for Disease Control and Prevention within the Department of Health and Human Services (HHS). It is my pleasure to be here to discuss with you CDC's role in the response to extensively drug resistant TB, globally and in the United States.

Definition

Tuberculosis (TB) is an airborne infectious disease that is spread from person to person, usually through coughing. In the late 19th and early 20th centuries, until the introduction of streptomycin in the forties, TB was one of the leading causes of death in the United States. Currently, the World Health Organization (WHO) reports that one in three people in the world is infected with dormant TB germs (i.e. TB bacteria). Only when the bacteria become active do people become ill with TB. Bacteria become active as a result of anything that can reduce the person's immunity, such as HIV, advancing age, or some medical conditions. Currently TB that is not resistant to drugs can be treated with six to nine months of "first-line drugs" (the most effective), including isoniazid and rifampin; this treatment cures over 95 percent of patients. However, since people in many resource-poor countries lack access to appropriate treatment, nearly nine million people in the world develop TB disease each year and about 1.6 million die.

TB that is resistant to at least isoniazid and rifampin is called multidrug-resistant (MDR) TB. MDR TB requires treatment for 18-24 months with "second-line drugs" that are much less effective, poorly tolerated by the patient, and far more costly. There are currently only six second-line drugs, of which two—fluoroquinolones and injectable macrolides—are the most important. The cure rate is 70-80 percent under optimal conditions, but is usually closer to 50 percent. Many countries with a high TB burden find it impossible to treat MDR TB patients because of the cost of drugs, and the more sophisticated laboratory services and more intensive programmatic support required for administering them. Extensively drug-resistant TB (XDR TB) is a subset of MDR TB caused by strains of bacteria that are resistant to the most effective first- and second-line drugs.

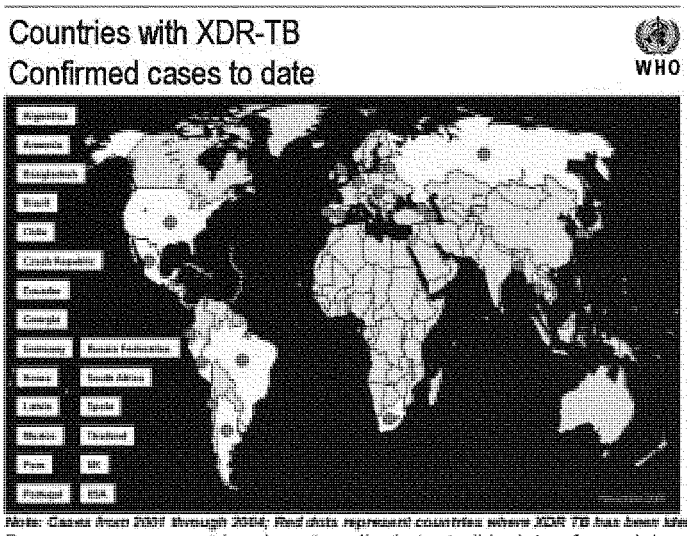
Causes

Drug resistance develops when patients receive incomplete or inadequate treatment. Persons with these resistant strains in their lungs can then pass these resistant bacteria to other susceptible individuals through coughing. We have also learned that weaknesses in a TB program create opportunities for drug resistance to develop: either through the interruption of drug supply, the inappropriate prescription treatment regimens administered by medical providers, the failure to support patients on therapy, the non-adherence to treatment by patients, and the lack of implementation of infection-control precautions.

Scope of the problem

In response to anecdotal reports from physicians who were finding cases of TB that were unresponsive to the first-line and second-line TB drugs, in 2005 the CDC and the WHO jointly conducted a survey, with support from the U.S. Agency for International Development, that examined about 18,000 patient

isolates tested during 2000 to 2004 by Supranational Reference Laboratories. Researchers examined the drug-resistant isolates, and found that 10 percent of the MDR TB isolates actually met the definition for XDR TB. XDR TB was identified in 17 countries from all regions of the world, most frequently in the former Soviet Union and Asia. Data from sub-Saharan Africa were very limited because of poor laboratory capacity within the region as a whole. More representative data showed that in the United States, 2.9 percent of MDR TB cases were XDR TB; in the Republic of Korea, 15 percent of the MDR TB cases were XDR TB; and in Latvia ,19 percent of MDR TB cases were XDR TB. This report, published in CDC's *Morbidity and Mortality Weekly Report* in March 2006, was the first widely circulated publication to use the term "extensively drug resistant TB" was widely published. FIGURE 1 shows the countries found to have XDR TB in the joint HHS/WHO survey.



Note: Cases from 2000 through 2004; Red dots represent countries where XDR TB has been identified.

Because many countries do not routinely test all isolates for resistance to second line drugs, the precise global incidence of XDR TB remains uncertain. However, because of the ease with which drug resistance can occur (because of the use of second-line drugs in suboptimal conditions, funding shortages, changes in program focus away from TB case management, interruptions in drug availability, high HIV prevalence), XDR TB could be much more widespread than this survey shows.

Morbidity and Mortality from XDR TB

Reported mortality rates among persons with XDR TB are extremely high. Among non-HIV infected persons, reports indicate that less than 30 percent of patients can be cured, and more than half of those with XDR die within five years of diagnosis. Among HIV-infected persons, illness is more severe, and mortality

rates are higher and death occurs within a shorter time. Not long after the publication of the CDC-WHO survey results, we learned of a deadly outbreak of XDR TB among HIV-infected TB patients in KwaZulu-Natal Province in the Republic of South Africa.

In this outbreak, of the 544 patients affected with TB, 221 (41%) had MDR TB, and 53 of those met the definition of XDR TB. All but one of the XDR TB infected persons died, (a mortality rate of 98 percent), with a median survival period of only 16 days from the time healthcare workers collected their sputum for analysis. Mortality among those with MDR TB received less attention, but was also high--in excess of 70 percent. Among those patients with XDR TB, 55 percent had no prior history of TB treatment, which indicated they had contracted their TB directly from other infected individuals. Forty-four of the XDR TB patients were also underwent testing for HIV, and 100 percent were found positive. Of these, 15 were receiving antiretroviral therapy, which is an important caution as we succeed in providing anti-retroviral therapy to more and more HIV-infected persons. Given that TB is still a threat to HIV-infected persons, the President's Emergency Plan, the Global Fund to Fight HIV/AIDS, Tubercluosis and Malaria, national governments and other partners must ensure programs to prevent and control TB work closely together to protect vulnerable populations from acquiring this virtually untreatable form of TB.

What is the threat in the United States?

The TB resurgence that occurred from 1985-1992 in our country provides an excellent example of how outbreaks of drug-resistant TB can develop. From 1953 (the establishment of current US surveillance practices) through the mid 1980's, TB cases in the United States declined steadily, from approximately 83,000 to 22,000 new cases per year. But in 1985, CDC began documenting increases in TB incidence. Factors associated with this increase include the dismantling of TB programs, which occurred when health departments stopped receiving TB categorical funds, and shifted resources to other public-health activities. Other factors included the burgeoning HIV epidemic, increased immigration from countries with high TB incidence rates, lack of infection-control precautions in healthcare settings, and the widespread occurrence of MDR TB at a time when the laboratory capacity to readily identify these strains was inadequate. The Congress then appropriated an increase in funds, and the situation was remedied once programs were again able to prescribe appropriate drug regimens for patients, have adequate laboratory capacity to diagnose and manage patients, provide appropriate programmatic support for patients, assure adherence with prescribed regimens, and conduct effective contact investigations.

These intensive control efforts also resulted in a decrease in MDR TB cases in the United States, which fell from approximately 400 per year to about 100 per year. However, the epidemiology of these cases also changed; in 1993, 26 percent of MDR TB cases in the United States occurred in foreign-born persons;

whereas in 2005, 80 percent of MDR TB cases occurred in foreign-born persons. Between 1993 and 2006, 49 cases of XDR TB were reported in the United States to CDC. As with MDR TB, the epidemiology for XDR has changed remarkably over that time period. In the years 1993-1999, 19 (59 percent) of XDR TB cases occurred in U.S.-born persons and 44 percent occurred in persons with HIV infection. In the years 2000-2005, 80 percent of XDR TB cases occurred in foreign-born persons and only 13 percent occurred in HIV-infected persons. While the total number of MDR and XDR TB cases is relatively small, their impact on U.S. TB control programs can be significant in terms of human capital and financial resources. One patient with MDR or XDR TB requires a minimum of 18-24 months of treatment. Recently collected data show that in-patient costs alone are $500,000 per case.[1] The treatment of some individual cases has cost as much as $1 million. The cost of a potential resurgence, however, is far higher. In New York City alone, the estimated cost to control the MDR TB epidemic of the late 1980's exceeded one billion dollars (in 1991-adjusted dollars).[2]

One of the first-line of defense to prevent importation of TB into the United States is the overseas medical screening of immigrants. With the cooperation of the U.S. Department of State and international partners, HHS/CDC is in the process of implementing improved screening procedures (including both cultures and drug-susceptibility testing) that, according to preliminary studies, are three times as sensitive at detecting TB. Individuals identified with active TB are now must complete their treatment before they leave to start their lives in the United States.

MDR and XDR in high HIV-prevalence areas

In areas such as sub-Saharan Africa, TB rates have substantially increased over the past decade, which parallels the rising number of HIV/AIDS immuno-compromised patients, and makes it more difficult to diagnose and treat TB. More than 50 percent of the persons with TB in sub-Saharan Africa are HIV-infected. In countries with a high HIV burden, weak and underfunded TB Control Programs become strained by the influx of new TB patients. In most of these countries, the government does not regulate second-line drugs and they are not widely available. In Botswana, for example, TB incidence was declining until about 1987, when it began to rise sharply as HIV prevalence increased, (as measured by a study of women attending antenatal clinics), tripling by 2002. A significant increase in the prevalence of overall drug resistance among the TB cases followed this jump in the burden of TB patients. The WHO and its partners anticipate that drug resistance in this setting will increase, because of the weakness of the national TB programs in many countries.

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[1] Inpatient care has been estimated for California XDR TB patients from 1993-2006 at an average of approximately $600,000 per patient. These estimates do not include outpatient costs or productivity losses, which are likely to be substantial for those treated for may years, or for the 25 percent of whom died from XDR TB. Jenny Flood, MD, TB Controller, State of California, personal communication.

[2] (Tuberculosis in New York City — Turning the Tide Thomas R. Frieden, M.D., M.P.H., Paula I. Fujiwara, M.D., M.P.H., Rita M. Washko, M.D., and Margaret A. Hamburg, M.D. New England Journal of Medicine, July 27, 1995).

MDR and XDR TB in countries with low HIV prevalence

XDR TB is also a potentially dangerous problem for countries with low HIV prevalence if they do not have adequate national TB programs. The necessary conditions for programs to "grow" resistant TB occurs where physicians routinely prescribe drug regimens were routinely prescribed without the benefit of drug susceptibility testing. Available data indicate the highest MDR TB and XDR TB prevalence occur in Eastern Europe and Asia in low-HIV-prevalence populations. Persons in these countries who are treated effectively are cured of non-resistant TB, but if conditions exist in which MDR TB is created, then the necessary widespread use of second-line drugs can rapidly foster development of XDR TB as well. For example, an anesthesiologist in Russia developed MDR TB after caring for a patient who had highly drug resistant TB. She died soon after diagnosis, despite treatment with second-line TB drugs. As HIV spreads among these patients and other control conditions are not adequate, a country may face an outbreak of untreatable TB.

Response to XDR TB Globally

CDC works closely with other agencies to prevent TB globally, including the National Institutes of Health (NIH), other federal entities like the U.S. Agency for International Development (USAID), the WHO and non-governmental agencies through a variety of programs, including the Emergency Plan and the Global Fund for AIDS, TB and Malaria. In September 2006, HHS/CDC, WHO, and other partners from the Stop TB partnership developed an action plan to address XDR TB. This includes taking the first, all-important step of addressing TB program deficiencies as quickly as possible to "turn off the faucet" of drug resistance. The action plan recommended the following:

1. Conduct rapid surveys of XDR TB to determine the burden of disease;
2. Enhance laboratory capacity to support surveillance and diagnosis, with emphasis on drug-susceptibility testing;
3. Improve the technical capacity of practitioners to respond to XDR TB outbreaks and manage patients;
4. Implement infection-control precautions;
5. Increase research support to develop new anti-TB drugs;
6. Increase research support to create rapid diagnostics for TB and for MDR and XDR TB; and
7. Promote universal access to antiretrovirals under joint TB/HIV activities

As an initial step, the U.S. Federal TB Task Force has been discussing a domestic and international response plan for U.S. Government agencies on XDR TB. The U.S. Government also participated in the WHO Global XDR TB Task Force that has issued a global plan to respond to XDR TB. The White House will convene an interagency meeting in the next few weeks to ensure U.S. Government activities are integrated in a unified strategic approach.

HHS/CDC also supports WHO and the Stop TB Partnership on a number of important activities, including technical assistance to the Global Drug Facility, which works to supply quality medications for TB programs, and the Green Light

Committee, which supports efforts to develop high-quality appropriate, managed access to drugs for MDR TB.

In addition, HHS/CDC's TB Trials Consortium has the leading role in clinical tuberculosis research. Results from these trials have formed the basis for the Treatment Guidelines developed by HHS/CDC and the American Thoracic Society's, and in updating regimens for both HIV and non-HIV infected patients. This research will be increasingly important for the development of new drugs and regimens for drug-resistant TB will be required.

CDC technical experts are also working directly with host country governments and partners to urgently implement improved infection control, rapid case detection, effective treatment, surveillance for drug resistance, and expanded program capacity, on an urgent basis. For example, CDC employees recently assisted colleagues in South Africa by providing technical support in training activities to implement infection-control measures. CDC has also assembled teams of experts, including epidemiologists, microbiologists, and infection control specialists who are prepared for rapid deployment in response to XDR TB outbreaks throughout the world.

Response to XDR in People Living with HIV/AIDS

With the support of the Office of the Global AIDS Coordinator (OGAC) and PEPFAR funding, CDC has been providing technical assistance to host governments in PEPFAR-supported countries. This funding has been used to strengthen collaboration between National TB and AIDS Control Programs and to work with National Public Health Laboratories to strengthen TB diagnostic services. This technical assistance supports a variety of activities, including (1) decreasing the pool of severely immunocompromised patients through ARV treatment, (2) reducing TB morbidity and mortality through early identification of TB suspects and patients in HIV prevention and care settings, (3) integrating TB and HIV services to assure uninterrupted treatment of HIV-infected TB patients, and (4) providing isoniazid preventive therapy as part of a package of care for HIV-infected patients. In addition, CDC has helped to strengthen TB lab capacity, especially at points of service to promote rapid diagnosis of TB; conduct TB drug resistance surveillance; and strengthen TB infection control practices in HIV care settings. In FY 2007, a portion of PEPFAR funds will be used to address prevention and control of XDR TB in HIV-infected persons.

Gaps

HHS/CDC, WHO, and USAID have taken critical steps toward characterizing and controlling the threat of XDR TB. For example, considerable improvement in TB infection-control practices in healthcare settings can be achieved through relatively simple and inexpensive practices (for example, having waiting rooms outside in covered but open areas, installing fans, separating coughing patients, etc.) can achieve considerable improvements in TB infection-control practices in healthcare settings. To provide guidance on TB infection control, CDC, in collaboration with the WHO, OGAC, and the International Union Against TB and

Lung Disease has recently published a guidance document titled "TB Infection Control in the Era of Expanding HIV Care and Treatment," now available on the CDC website.

A larger commitment is required in other areas, especially diagnostic services, treatment, and program management. Research on new tools for prevention, treatment, and diagnosis are needed both domestically and internationally to modernize and accelerate TB elimination. Importantly, the international community lacks new, effective drug regimens to replace drugs that have become ineffective against TB, or that interact unfavorably with anti-retrovirals and other HIV medications. According to the Advisory Council for the Elimination of Tuberculosis, TB drug development is at an unprecedented point. For the first time in 50 years at least four new anti-TB compounds entered human clinical trials, and several others are ready for advanced pre-clinical testing. These new compounds represent new drug classes that are not cross-resistant with existing agents, and can offer promise for resistant cases.

New diagnostic tests for TB are also needed. Currently diagnosis of TB disease relies on the sputum smear examination, which has been in use for 125 years and is poorly sensitive and highly inefficient. New blood tests have entered the market recently, and appear to offer slightly improved performance, although they are more costly and have not undergone evaluation in the programmatic setting. Field evaluation of optimal, efficient diagnostic tests, as well as rapid tests for the detection of TB drug resistance, is critical. Globally, there is limited laboratory capacity for TB and drug-resistance testing.

The global XDR TB response has highlighted the need for laboratories to make services for TB, MDR TB and XDR TB more rapid, sensitive, and reliable. TB patients in developing countries lack access to reliable, quality-assured, and prompt TB laboratory services. As a result, clinicians are unable to make correct patient management decisions. Many laboratory techniques used to confirm a diagnosis of TB and to identify drug resistance were developed in the 1950's, 60's, and 70's. To combat resistance to anti-TB drugs, clinicians must have the most current methods, applied to their fullest capacity. Increasing the availability of genotyping also would allow programs to identify links between patients.

In addition, given the increasing proportion of the burden of TB in the United States among foreign-born persons, there is a strong need to improve the quality of overseas medical screening of U.S. bound immigrants, including the ability to detect and treat XDR TB in this population.

Equally important will be the strengthening of program infrastructures, both domestically and abroad, through training and sustained support. Strong program infrastructure will prevent new agents from becoming drug-resistant.

Thank you for the opportunity to present CDC's findings and activities on XDR TB to date. I would be happy to answer any questions.

Mr. PAYNE. Let me thank all of you for your very important testimony.

Let me just quickly ask you, Dr. Gerberding. You said that we don't want to become alarmist, and XDR–TB or even the MDR, the less severe strain, may not be as alarming as perhaps some may start to think it is.

In looking at the map where XDR–TB is identified, it certainly shows places that have health systems that can detect it. Maybe I am an alarmist, but I would be concerned at these countries that show no XDR problem because in most of them they don't even have a health system, or many of them.

Perhaps am I seeing it wrong or is it perhaps the reverse; that there is no way to know rather than to assume it is greater than maybe what it is?

Dr. GERBERDING. You are bringing up a very important point. If we don't have the laboratory capability to test for tuberculosis and test for drug susceptibility, we don't know what we are dealing with.

CDC and the World Health Organization collaborated on a large survey of a sample of tuberculosis from around the world, and we did learn that there is more drug-resistant tuberculosis out there than we would have previously been aware of, and part of what we are doing now is more aggressively trying to define the scope of the problem, particularly in countries that are most vulnerable due to lack of health systems.

What we can say is that on average, of the drug-resistant TB in the world about 10 percent of it probably meets the definition of XDR, so there is a potential pool of patients with this problem, and it doesn't take very many of them to set off an outbreak, particularly in the context of poverty, poor nutrition, immunosuppression or AIDS.

Mr. PAYNE. And let me just say that you in particular have done a very good job in discussing why the drug resistance is such a threat.

Since you have been involved in this so long, as we look at options to address XDR–TB, how realistic is it in your estimation, and perhaps any of the other panelists might want to chime in, to expect the development of a new drug to treat TB?

Dr. GERBERDING. Thank you. You know, this has been an area that has not historically received the kind of scientific attention that it deserves. Ultimately we need a TB vaccine, and we certainly need new drugs in the TB pipeline.

I am aware of at least four drugs that are new and have test tube ability to combat tuberculosis that have not yet been put into clinical trials. One of the things we need to look at is how can we accelerate getting the drugs in the pipeline into the palms of the people who need them to treat their disease.

That is an area I think where we can really focus some increased attention as we look at this XDR problem.

Mr. PAYNE. As you know, we do have provisions for drugs and the acceleration of a clinical trial process where there can be kind of a truncated process, but I was just looking at the article that was in the *New York Times*.

Unfortunately, I read all of it except the last sentence, which is kind of disturbing. It says about 20 experimental drugs are being tested, but even if one is found effective in large scale trials it is unlikely to be marketed for at least a decade. I guess it is kind of disturbing to feel that we are that far off.

Would anyone like to comment on the drug and the possibility of——

Ambassador DYBUL. I think the problem is for 50 years no one was trying to find a new drug.

Mr. PAYNE. Right.

Ambassador DYBUL. And we had no new drugs because, as was pointed out earlier, the disease was not in the United States heavily and in developed countries so there wasn't a lot of focus on it.

Through some extraordinary public/private partnerships there has now been a good focus on developing new products, the four that are fairly advanced and the others you mentioned.

Of course, the National Institutes of Health has been one of the leaders here among others in public/private partnerships, so the problem fundamentally is the delay we had that people are now making up for. I am afraid you can't make up for that lost time, but people are working pretty hard now to get over that time delay that we had.

Mr. HILL. I would just make a note that in 2006 we did utilize $3 million specifically for the development of drugs. The problem is, and although there are some promising drugs out there, the earliest we expect anything that might work would be 2010.

So we are basically faced with two challenges here. One is how do you continue to work with MDR and now XDR? How do you, in a compassionate way, try to help people who, when they get this and particularly if they have HIV, may well die? How do you make sure that there is proper surveillance and treatment so you at least minimize the risk around these folks, and hopefully folks will not get infected?

You have the somewhat bigger challenge really, which is to do what we know to do with respect to the vast majority of people who are subject to getting TB. We know what those interventions are, and for many of those people the first-line and the second-line drugs will work. We just have to faithfully implement that, train the people to do it, because a lot of the drug resistance comes from the lack of fidelity to the known interventions.

Mr. PAYNE. I know that a lot has been done, and there are so many tremendous problems in the world. We know that the U.S. alone is certainly going to be unable to solve them all, and we are glad that philanthropists are stepping up and bringing in large donations.

I guess just finally, even though we have been stepping up to the plate, as I understand it XDR–TB emerged because we failed to put in place adequate resources and infrastructure to effectively diagnose and treat regular TB.

How much do each of your agencies spend currently to strengthen and expand the health care infrastructure in Africa and elsewhere such that TB is effectively diagnosed and treated? Is there a plan that you all have together where, like we said, if TB is not in the U.S. then you don't have the people to pay for development

of drugs to treat it, so we have seen, for example, malaria not taken seriously until now.

We have a tremendous initiative because well, people who get it really can't afford to pay for the drugs anyway so there was not the surge to go into finding a cure as we do for diseases that occur here. That is the nature of pharmaceutical companies. They are in business to make money, and there is nothing wrong with that.

However, we do find that, for example, they said I think something like Streptomycin was what they used 100 years ago or something. They just stopped making it. Nobody had it. That was that, so it had to start up all over again.

I wonder if you might just comment on that last statement, and then I will yield to the gentleman from New Jersey, the ranking member.

Mr. HILL. Ambassador Tobias, whenever he listens to a proposal for how money is going to be spent, and we saw this in the PEPFAR process, an inevitable and invariable question will be what can you tell me about this program that tells me it will be sustainable? What are you leaving in place that will allow the work to go on even if the money is not there from the U.S. Government?

That is particularly the case with respect to TB. Everything we try to do, that $.5 billion, I have looked at a lot of these programs, and they are designed to work with the Ministries of Health so that the structure that is put into place is not sort of a set of expats who come in on a C–130, drop down a clinic, do the TB treatment and then eventually leave.

This is only going to work if you are strengthening their systems and their health structures in general to make this happen. Our attempt is to do that whenever we get a chance.

I will give you an example of something that is going to start in May that exemplifies this point. In Orel, which is in central Russia, cooperation between the United States, USAID and CDC I think may be involved certainly and the Government of Russia is involved setting up a Centers of Excellence clinic and laboratory to do testing specifically for MDR and XDR.

Now, when we leave and when we are done, they will have that in place. They can replicate that. That is what we try to do. We have done the same thing in Riga, Latvia. We have done it in places in Africa, but it is really key.

Your question is right on point because if we don't impact health systems we can't deal with this problem in the long run.

Ambassador DYBUL. If I could just add to that, Mr. Chairman, because I think you recently saw an excellent example of it.

About a third of our resources go for building local capacity—human resources, laboratory infrastructure, all the infrastructure that is needed—and that is why we talk about partnership. It is not the American people going in and doing it. It is us partnering with the peoples of Africa and Asia and the Caribbean and everywhere else to strengthen their programs.

I know you were up in the Nyanza Province in Kenya in Kericho, one of the great successes in HIV/TB. That clinic I am pretty sure you saw. The district hospital there has a 100 percent testing rate of HIV-positive people for TB and a 100 percent treatment of TB

for people who are HIV-positive. They did that in a year, and that is starting to happen throughout.

That is not the American people. It is the American people supporting those outstanding people in the district hospital in Kenya. We do that through our implementing partners, CDC, USAID. That particular project was actually a Department of Defense project, so you can see what we are doing is fundamentally building that capacity.

As I mentioned, some of the additional resources that we have this year, the extra $50 million, is going to focus specifically on laboratory capacity and reference laboratory capacity so that we can identify these strains and attack the epidemic more carefully.

That is why the HIV component interacts closely with the non-HIV component both with USAID and CDC so we can all work together, but our implementing partners for PEPFAR are CDC, USAID and Department of Defense, so we are right there together from the outset.

Mr. PAYNE. Let me thank you very much. I was very impressed with what I saw in Kenya. As you may know, I spoke at World AIDS Day in Nairobi on December 1 and also visited a laboratory that tested incoming pharmaceuticals to make sure that they were up to strength and were not bogus or counterfeit.

As a matter of fact, because they had that laboratory that was so well run, the quality of the medicine is just 100 percent. I guess people say well, if you are going through Nairobi you better send the right thing. Of course, that doesn't necessarily help the next place. That has to be done in another country.

I actually watched the testing of the various medications that were coming in, and it was extremely impressive. Thank you.

Mr. Ranking Member?

Mr. SMITH OF NEW JERSEY. Thank you very much, Mr. Chairman.

Let me just say, and, Dr. Gerberding, I think you would certainly appreciate this, on the issue of autism, which is not what we are talking about, but it relates to the issue of prevalence. When I got elected in 1980, one out of every 10,000 was the expectated number of children who would be afflicted by autism.

I did a bill in the 1990s that established Title I of the Children's Health Act that set up facilities under the Centers for Disease Control to look at surveillance, and now we know that it is not one out of every 167. It may be as low as one out of every 50 in New Jersey, and one out of every 68 boys is unfortunately suffering from autism or part of the spectrum.

I am a great believer that you put maximum effort in trying to discover what the prevalence of a given disease or disability is because then hopefully the resources and the response will follow.

I was struck by your statement, Dr. Dybul, that to date little surveillance data has been available from sub-Saharan Africa on MDR and XDR–TB, but it appears that new cases may be rapidly increasing. I would appreciate if you could expand on where we are getting that information.

Looking at this WHO map from November 2006, it looks like except for South Africa none of the XDR–TB cases can be confirmed as originating or occurring in Africa, whether it be sub-Saharan Af-

rica or in northern Africa. It is very troubling that we have not captured that information because, again, prevalence gives us an indication.

I am going fast because unfortunately we have a vote. In her testimony, Dr. McEwan makes a strong statement about how important, how essential, faith-based structures are in fighting TB, including health services and parish volunteers and community workers. She also points out that to date, most of the global public effort to address TB are aimed at national government institutions, often overlooking the faith-based organizations and private health care providers that currently deliver 30 to 50 percent of the health care in Africa and around the world in other developing nations.

That, to me, is a missed opportunity to utilize a tremendous asset and to do so immediately for the highest impact. The Global Fund seems to do it either out of prejudice or incompetence, and I am greatly disturbed as to why faith-based organizations are bypassed, especially in light of the suspended and terminated Global Fund grants in Uganda.

It seems to me that when you pull a grant like that, there are victims who then go untreated and unhelped while the money goes who knows where. Maybe you could shed some light on that.

Then again on laboratories, Dr. Dybul, if you could speak to that again because you point out that that is the weakest link, and I am very encouraged that we are providing resources to try to meet that capacity deficiency as quickly as possible.

If you could speak to some of those issues, I would appreciate it.

Dr. GERBERDING. I will take the question related to the prevalence assessment in Africa, but it relates to your last question about laboratories because typically in the most impoverished areas the way TB is diagnosed is only on a clinical basis in that the person coughs up sputum, and you look under the microscope to see if you see what looks like the bacteria.

You don't actually grow it in a Petri dish, and if you don't grow it you can't do the test for the drug resistance, so the reason we don't have information in many of these areas is because we don't have the laboratory capability to do the test.

That is why the CDC with the WHO and others engaged in this process of trying to sample in these various countries the cultures that we did have and to make an estimate of the prevalence in those areas, so our data right now are not optimal.

More work is planned and will be done, and as these laboratories evolve we will be able to give you a much more accurate answer about the true prevalence and particularly is it changing or not changing as we go forward in time.

Mr. SMITH OF NEW JERSEY. Thank you.

Dr. Dybul, if you could add to that your answer? I have gone to the Web site of the Global Fund. They claim to have detected 5 million cases of TB, curing 3 million people through the DOTS program, 24,000 new treatments for MDR–TB.

The Global Fund, to the best of my knowledge, does not collect data on subrecipient programs or achievements, so on what basis do they make those statements?

Ambassador DYBUL. Thank you, Congressman Smith. On your earlier point on faith-based organizations, as I said in my testi-

mony, there is no question faith-based organizations have a key role in there. I think what we have said all along is everyone has a role, and the faith-based organizations have a key role particularly if you are talking about DOTS and systems where you get into the home.

It is the faith-based organizations that are often in the homes in the rural communities that can help deliver antiretroviral therapy and TB, and we are working to build TB onto HIV, as we are working to build bed nets and other distribution systems with the present malaria initiative, putting them together.

I think again the representation of how well the U.S. Government is working together, it is easy to defer the question on laboratories to Dr. Gerberding because CDC is the implementing partner for PEPFAR for developing the laboratories, and that is an innovation in the U.S. Government how closely we are working together on this.

In terms of the Global Fund Web site, I think if you look now that has changed actually. The Web site has been modified, and I believe that actual Web site is no longer posted because there were some difficulties with some of those numbers, and we are all working together because we have an international approach to how we count things.

In terms of subgrants, we have been pushing, as you know, for quite a while to make sure that all grants to the Global Fund are available for people; not necessarily just so we can see who the grantees are, but as we do with subgrantees so we can have accountability and transparency to you, to Congress and to the American people about the work we are doing and the results that they achieve.

More important than the posting of the subgrantees is to actually have a review system so you can look down to the programmatic level to see that results are happening and occurring. We have been working very hard. Dr. Steiger, our member to the Global Fund board, has worked very hard within the board to work on these issues of accountability and transparency.

There has been a lot of progress there. We continue to work with them. There is a commitment there by the Global Fund. As with all of us, we always have more work to do, but it is something that we have been pressing quite a bit.

Mr. SMITH OF NEW JERSEY. I appreciate it. Regarding the Uganda question and other countries where grants are pulled; how quickly are those funds made available again in hopefully what is not a corrupted process where money is being siphoned off?

Ambassador DYBUL. There is a policy around funds coming back to the Secretariat when grants are discontinued. There is a policy in place to maintain antiretroviral therapy because the stoppage of antiretroviral therapy can be a very hazardous thing, so there is a process in place to ensure that people continue their antiretroviral therapy.

We are working closely with the Secretariat to ensure that the policy of monitoring the return of money is occurring. There are a couple countries that we are working with the Secretariat on right now to ensure that the money is coming back.

We would be happy to follow up with you and your staff and other members of the committee as we get more information on the processes and the policies and the money coming back.

Mr. SMITH OF NEW JERSEY. And is the Global Fund finally at long last beginning to open up its coffers to faith-based organizations?

Ambassador DYBUL. Well, I think, as you know, it is an issue that we have all talked about.

Mr. SMITH OF NEW JERSEY. It has been a great disappointment.

Ambassador DYBUL. The fundamental issue there is really the country coordinating mechanism because the countries come forward with grant proposals, and the country coordination mechanism as was conceived and pushed by the United States was an intersectoral approach; not just government, but nongovernmental organizations, everyone contributing, including faith- and community-based organizations.

Representation on the CCM by faith-based organizations is essential to have faith-based organizations funded by the grants. In some countries we have seen success; for example, in Zambia. In others we have not.

The Secretariat has made a commitment to try to do a better job. We have been pushing that pretty heavily. We do believe those CCMs need to be multisectoral so that all people who can contribute to all three diseases are doing so, but I think we have some work to do there and we are working with them as we continue to try to do the same in our bilateral programs.

Mr. PAYNE. Let me quickly turn to Representative Woolsey. We have only a few minutes left, but would you like to ask a question?

Ms. WOOLSEY. Well, Mr. Chairman, do we have time to ask another question?

My question would be in hearing your absolute honest presentations, and it sounds like there is no denial about the problem and we are going in the right direction, so what is missing in this picture? What else do we need to be doing? Because it is not finished by a long way.

Mr. HILL. Let me take a stab at that. I appreciate the question because a lot of times we know what to do, and yet we still seem to have a problem. It is very difficult to deal with.

You know, I think it has been a wake-up call. It was said by one of the earlier speakers today that XDR—MDR even, but XDR in particular—is a wake-up call that we have to really work on. It was Congressman Engel. He said the wake-up call is that we have to do TB in general because we can't just rely on the fact that we know the right interventions. We have to do them.

As good as the cooperation is within the USG, and I think there is good cooperation internationally, we have to redouble our efforts to make sure that we maximize the use of all of our resources. We can't afford to waste a penny. We have to make sure that we do the right thing with the money. We have to do a better job at leveraging the resources.

I think one of the most important innovations of the last 6 years was what soon-to-be Secretary of State Powell said in his opening testimony when he said we need to leverage USG funds. One of the most spectacular successes of the last 5 years is using USG funds.

Billions of dollars have come in to complement work that all of us at this table are doing.

I haven't heard as much about that for TB. We are doing it in malaria. We are doing it with respect to HIV. We probably should expand our efforts in the TB world to get support to significantly increase our resources available because there is only so much we can do with the money we have.

Mr. PAYNE. Thank you very much.

Ms. Jackson Lee, maybe we can have you for a quick question.

Ms. JACKSON LEE. I thank you, Mr. Chairman. I will pose it in a quick question.

I am very moved by the XDR list and notice that only one African country is on it because they are able to determine it I guess by a laboratory.

My question is whether or not you have heard of the Baylor College of Medicine Pediatric AIDS Clinics that are in various countries, Dr. Klein's work, and whether or not entities like that could be expanded—it is private—to do some of the TB work and some of the testing work, finding all aspects that could be utilized. Does anyone want to raise an answer to that?

Thank you for this hearing, and I commit to work with you on this broad question.

Mr. PAYNE. Thank you.

Dr. GERBERDING. I can start with that, and then my colleagues can chime in.

Secretary Leavitt in Health and Human Services has a very strong emphasis on building networks, and I think that academic partnerships are absolutely critical. Even if CDC could possibly be in all relevant countries providing technical support, we alone are just one focus of that, and bringing the smart academicians into the field is a wonderful opportunity to strengthen the capacity and the technical support for capacity development.

But, it also has the secondary advantage of providing a workforce training experience for young people who definitely are increasingly interested in global health issues, but need the opportunity to be able to go and do the good work in a mentored environment in the field, so that is a win/win, and I think I can speak for Secretary Leavitt and say we definitely support that kind of network.

Ambassador DYBUL. We definitely support the concept of that type of network. In fact, we support many such networks from many universities. We also support many faith-based organizations, community-based organizations. You need a mix. You need a big mix.

We leave the decisions on who ought to be doing the work to the field where it ought to be where decisions are made on what the gaps are, what the U.S. Government's role is, and we have many different roles and many different opportunities. So what we encourage people interested in work to do is to go to the countries, not to Washington. Go to the countries and work with the countries to identify the gaps and to fill in those gaps and to work in the countries.

We have many different types of partners, and we definitely support academic partners. We support nonacademic partners. We need everyone in the game, and we have been doing a remarkable

job at supporting such organizations, which is why there has been such great success.

Mr. PAYNE. Thank you very much.

Dr. GERBERDING. Thank you very much, Mr. Chairman.

Mr. PAYNE. Yes. We will adjourn for about 10 minutes. We will actually recess, not adjourn.

We have a vote that is up in about a minute. Hopefully we will make that. There will be two 5-minute votes following that. We will be back here hopefully within a 10-minute or 12-minute period.

We really thank Dr. Mukherjee for waiting. We will come back to reconvene. Thank you.

[Recess.]

Mr. PAYNE. The hearing will be reconvened and we will begin with our third panel.

We will hear from Dr. Joia Mukherjee who, as we already indicated, is the medical director of Partners in Health, an international medical charity organization with programs throughout the developing world. It is good to have you with us.

Also we will hear from Dr. Elena McEwan, who is also an expert in the area of tuberculosis. Quality of Tuberculosis Programs in Three Municipalities in Nicaragua was her thesis, and we will hear from her through our telecommunications system.

We will be glad to hear your testimony. Thank you. Thank you so much. We apologize for the schedule. It is beyond our control. When we schedule hearings we never know what activities will occur. It is day-by-day. I hope you accept our apology.

Dr. MUKHERJEE. No problem. I am glad you all vote. That is a positive sign.

Mr. PAYNE. Thank you.

STATEMENT OF JOIA MUKHERJEE, M.D., M.P.H., MEDICAL DIRECTOR, PARTNERS IN HEALTH

Dr. MUKHERJEE. Thank you, Chairman Payne and Ranking Member Smith and all of your staff for arranging this hearing. It is certainly a topic that is very important to us at Partners in Health. As you mentioned, we are an international medical charity.

I am affiliated with Harvard Medical School and serve on the faculty, but the majority of my work is as a clinician in the treatment of AIDS and tuberculosis. As medical director, I supervise teams in Haiti, Rwanda, Lesotho, Malawi, Russia and Peru and in all places I, myself, see patients.

Our organization has been treating drug-resistant TB since 1994 in Haiti, 1996 in Peru, 1998 in Russia and in the last 2 years in Rwanda and Lesotho. We have never worked in a place that, when we have looked, we haven't found drug-resistant TB.

I would like to submit my written testimony to the record, and I will spare everyone, since the hour is late, from reading this testimony, but I would like to highlight a few things from the clinical perspective.

First of all, drug-resistant TB is indeed treatable, and I think it is very important that we do not register this as a death sentence. We know that it is treatable. We know how to treat it. Our organization, with others, has now been treating successfully highly drug-resistant TB for more than 10 years.

Mechanisms are in place internationally to provide technical assistance and training in the Green Light Committee on drugs and therapeutics for multi drug-resistant tuberculosis, as well as many NGOs like our own that do a lot of technical assistance.

What is different now, as you all know, and I am very impressed with how much you have done your homework, is the HIV epidemic. In the countries of Southern African where both HIV prevalence and tuberculosis prevalence are high, that is where we saw these "outbreaks" of XDR. Yet we have seen XDR TB, as it is now defined, in Peru since 1996. So, I think it is very important.

Dr. Gerberding mentioned that perhaps there isn't a cause for alarm. I am alarmed. I am very alarmed, and I am a clinician. I have treated successfully many, many patients with antiretrovirals, with drugs for resistant tuberculosis, but we all expected that the noxious synergy between HIV and tuberculosis would create these highly resistant strains that in epidemic fashion could be transmitted person to person.

We are surprised in some ways that it has taken this long to see them, but, as you pointed out, Chairman Payne, I think it is for lack of the diagnostic capacity rather than lack of their existence that we have not seen these strains until now.

So I think there are several points that I want to make. First is that the treatment of HIV is critical, and scaling up the treatment of HIV we have made great strides with the Global Fund, with PEPFAR, but it is not enough.

I would like to say that when our organization, Partners in Health, received one of the very first grants from the Global Fund—I think we were the second one that got money dispersed—it was a coordinated grant through faith-based organizations, nongovernmental organizations and the public sector. We have now expanded from what was one very famous charity hospital to nine public clinics in a partnership between NGOs and the public sector.

In my view, I would never discount faith-based organizations or NGOs to deliver these services—I myself work for an NGO—but at the same time it is only with partnerships with the public sector that we can really deal with epidemic diseases. I think this has been true in every epidemic from smallpox to tuberculosis and AIDS.

I think Congressman Woolsey said this, and I agree that maybe we can learn things from tuberculosis for HIV, and we certainly have. Our program in Haiti that has now been replicated in Rwanda, Lesotho and Malawi was actually using the very same health workers who had previously provided treatment for TB to then provide it for HIV.

So first is very tight links with the HIV program and tuberculosis, and you heard many things about that so I won't belabor it.

The second thing is the health infrastructure, and I want to highlight one specific issue about health infrastructure, which is that, again not to dichotomize faith-based and government infrastructure, infrastructure is needed. It is needed in perpetuity. These epidemics did not come up overnight. They came up from years of neglected infrastructure. They came up from years of poverty.

When I see this new epidemic, I am alarmed because I know that the context that this is happening is a context with severe poverty, malnutrition, lack of health infrastructure and trained personnel. So, we need large scale investments in health infrastructure to treat generalized TB, to provide treatment for HIV, but even to provide simple things like the diagnosis and treatment of acute malnutrition in children. In Haiti, for example, in our pediatric ward many of the malnourished children contract TB because they are so weak and in such a weakened state. So, large scale investments are needed.

The health care worker crisis, which I know many of you have looked at and support the African health worker bill, is really fomenting the spread of XDR–TB because we don't have enough trained professionals to make the diagnosis of tuberculosis.

Tuberculosis often goes undiagnosed, and in undiagnosed TB perhaps people will go and seek some therapy in a private pharmacy, receive one or two drugs, not complete a full course. There are just simply inadequate numbers of doctors, nurses, laboratory technicians to do this work, and just as it is needed for HIV, it is also needed for tuberculosis. This kind of investment in human resources is critical.

I agree with Ambassador Dybul who said, you know, it is not really for Americans to kind of zoom in and do this work. Our team now is 4,000 strong throughout the world, and we have fewer than 10 American physicians. The rest is local people, over 2,000 in Haiti and over 1,000 in the rest of the world. The key thing is to train local people who are going to stay in these countries, prevent the brain drain as you have said, Representative Smith, and really build the human and infrastructural capacity to deal with this.

And then the last thing I want to point out just specifically from our Partners in Health experience is the use of community health workers. We have always used a very strong cadre of lay people who are trained by the health system extensively in delivering medicines and providing social support and in doing something we call active case finding, which is going into the homes, seeing who has symptoms and making sure they get diagnosed promptly with tuberculosis, with HIV, with malnutrition, et cetera.

Those community health workers must be paid. It has been standard in public health to find people to do this on a voluntary basis, but, simply put, if you are very poor and you are a subsistence farmer you can't afford to take a day away from doing your farming, which feeds your family, to help your neighbors in this substantive way that we need to tackle these epidemics.

So for us the developing of a global cadre of people in the community that can do the outreach serves two purposes. One is providing adequate case detection and treatment for tuberculosis and AIDS, and two is to make the treatment for tuberculosis go on in the community, not in hospitals. It is often in these congregate settings that tuberculosis is spread, particularly when there are high rates of HIV.

So those are really my four points, which are to tackle HIV, to make sure investments are made in the health and laboratory infrastructure, as well as the human infrastructure, and make sure

that a cadre of community health workers plays a prominent role in treating people and keeping them out of the hospital.

I just want to share with you the experience of Partners in Health, our organization, with the treatment of MDR–TB to highlight some of the important issues here. In 1996, we started a primary health care project in the slums of Lima, Peru. It was just a simple project to weigh babies, make sure people were vaccinated, et cetera.

Lo and behold, we found drug-resistant tuberculosis at that time. It was considered untreatable in 1996, although we had had the outbreaks in New York and Florida and in California in 1990–1991, but this kind of treatment and delivery of this treatment in a poor setting was considered impossible.

Led by a team in Peru, an organization called Socios en Salud, we were able to just treat a handful of patients and show that it could be done. Today that program, in just 10 years, is a full-scale national program run by the Ministry of Health treating over 10,000 people with drug-resistant TB in a country that is by South American standards quite poor.

This was done with a close collaboration between faith-based groups, nongovernmental organizations and the Ministry of Health. Much of the money for this program came initially for the pilot from the Gates program and then in the long-term for the Global Fund to fight AIDS, TB and malaria. This is to me one of the biggest successes of a partnership that shows a pilot project can be expanded.

In 1998, we were invited to the former Soviet Union to treat tuberculosis within the penitentiary system in the Tomsk Oblast. Similarly, we found very high rates of drug-resistant TB and within 2 or 3 years were able to turn over the entire program to the Oblast TB services.

Again, we remain in partnership with them providing consultancy services, and that was the first tuberculosis grant to Russia from the Global Fund to fight AIDS, TB and malaria, and it has one of the highest ratings of efficiency of all GFATM grants, so in both of those cases, and now we are expanding to Rwanda, to Lesotho, Malawi.

As I said, in all of these places we are finding drug-resistant tuberculosis. In Lesotho we have already documented the presence of XDR. We suspect that we will also document it other places. It hasn't been officially reported on the CDC chart, but we have that information. We also have that information for neighboring countries of Swaziland and Namibia.

I think these things can be done. It is very difficult, but we need resources. I think what we have learned from HIV, from the Global Fund and from PEPFAR, is that the resources can be used well. We can quibble about numbers, from which grant they came, but the fact is large-scale investments in global public health have been done successfully and have really changed the paradigm of what can be done in the last 5 years.

When we started treating HIV in 1998 in Haiti, everyone said we were crazy. We published a paper in a scientific journal and got hate mail from our colleagues saying this is not possible. You can't

do it. Now it is taken as a matter of course that people have a right to this type of treatment.

So I think the message of hope that I have is we can do it. However, it is extremely complicated, and we need a lot of money to really make sure that the human and infrastructural capacity is there to do it.

I will end my comments there because I know it is getting late. If you want to discuss some of these things I would be happy to do so.

[The prepared statement of Dr. Mukherjee follows:]

PREPARED STATEMENT OF JOIA MUKHERJEE, M.D., M.P.H., MEDICAL DIRECTOR, PARTNERS IN HEALTH

Tuberculosis infection is present in 1.8 billion people worldwide. With the advent of multi-drug therapy in the 1970s, the treatment of tuberculosis with a "short course" of drugs was possible, and tuberculosis became the first disease whose treatment (and not only prevention) was adopted by the public health community. Since that time, tuberculosis treatment has been under the purview of national governments using the recommended "DOTS" strategy (Directly Observed Therapy Short Course)—a course of six to eight months of therapy with multi-drug regimens and observed therapy to prevent the development of resistance. However, as with any infectious disease, resistance to antibiotics develops, and this has been the case for tuberculosis since the first anti-tuberculosis drug, streptomycin, was discovered in 1945.

Multi-drug resistant tuberculosis (MDR–TB) is defined as a strain of tuberculosis that is resistant to the most potent drugs—isoniazid and rifamipin. In addition, some strains of TB have developed resistance to an even broader array of drugs and have been dubbed extensively drug-resistant (XDR), defined as MDR with additional resistance to a fluoroquinolone and an injectable drug. When the tuberculosis organism is replicating in the body in the presence of low levels of drugs due to irregular or inadequate treatment, resistant mutants of tuberculosis are selected. Once an individual has a strain of drug-resistant tuberculosis, he or she may transmit the strain to others.

XDR–TB has already been found in 28 countries on six continents, including all of the G8 countries. There has been great progress made in recent years to address the emergence of MDR–TB, but the existing plan to fight this disease will need to be broadened and strengthened to tackle XDR–TB and HIV co-infection.

WHAT IS DIFFERENT NOW?

Several issues have converged to draw attention to the specter of resistant tuberculosis. First, people with HIV are exquisitely sensitive to contracting tuberculosis, developing active and progressive tuberculosis infection and dying if the correct anti-tuberculosis drugs are not given promptly. What sparked the current global concern over XDR–TB is that in the South African province of KwaZulu-Natal, where HIV prevalence is high and immunity to tuberculosis is weaker, these highly resistant (XDR) strains were transmitted from person to person. The linkages between TB and HIV programs are critical, and all persons with HIV should be carefully screened for TB. Similarly, all individuals presenting with tuberculosis should be offered an HIV test and the barriers to HIV testing (both logistical and financial) should be minimized. Second, we know that HIV treatment—with highly active antiretroviral therapy (ART)—improves the immunity of people living with HIV and decreases their likelihood of developing active TB if they are exposed to a TB strain of any kind. This therapy has been terribly delayed in resource-poor countries due to insufficient resources and lack of political will. Redoubling the effort to effectively diagnose HIV and treat and retain those who need ART is needed to impact individual mortality from tuberculosis and the spread of drug-sensitive and drug-resistant tuberculosis. Third, the spread of XDR–TB is a consequence of a woefully inadequate health care infrastructure, one that is insufficient to prevent the spread of XDR–TB, facilitate its prompt detection, and administer its appropriate treatment. In dilapidated clinics and hospitals, tuberculosis easily spreads in crowded and poorly ventilated wards. The severe shortages of health workers caused by poor pay, immigration to other countries (so-called "brain drain"), and attrition from AIDS sap the manpower needed to address this epidemic. Investments in health workers and health facilities are fundamental to any effort battling TB and HIV/AIDS.

Fourth, diagnostic capacity is needed. Almost nothing has been invested in providing laboratories in resource-poor settings—such facilities were deemed too costly by the conventional public health approach. Yet drug resistance can only be diagnosed by culturing the tuberculosis organism. Safe and modern laboratories must be built and technical staff trained to find XDR and facilitate its treatment and control. Finally, our world is gripped with two interrelated pandemics—HIV and TB—and the prevention, control and treatment of these diseases require long-term, community-based therapy. Such ambulatory treatment assures adherence to and completion of the prescribed treatment, improving outcomes and preventing the development of resistance. It also decreases the concentration of infectious people in congregate settings. Community health workers are best suited to provide this type of therapy, but this class of health workers does not exist in most places in the world and where they do, they are often asked to serve as volunteers, resulting in high attrition rates and the need for constant retraining. Developing a global cadre of health workers of this type is critical to tackling these pandemics.

IS IT TREATABLE?

In southern Africa, death rates among people living with HIV in South Africa who acquire XDR–TB have been estimated at around 85 percent. This is not because XDR–TB is untreatable, but rather because in most places, patients infected with XDR–TB have not been promptly diagnosed and correctly treated. This failure to provide services has led to the myth that XDR–TB is untreatable or a death sentence. Our organization, Partners In Health, affiliated with the Brigham and Women's Hospital and Harvard Medical School, has been successfully treating MDR–TB since 1994 in Haiti, Peru, Russia, and most recently in Rwanda and Lesotho. Socios en Salud, our "sister organization" in Peru, arguably has more experience in MDR–TB than any other organization in the world, having treated over 10,000 cases of MDR–TB. As early as 1996, we documented high levels of resistance in some of these cases, which would now by definition be labeled XDR–TB. In Peru, however, the highly resistant nature of many of the strains did not garner the same type of media attention because of the low prevalence of HIV. In such settings, the spread is not as rapid as in southern Africa, where a high proportion of the population has HIV and has not received antiretroviral therapy.

WHAT IS NEEDED?

Treatment is possible but it depends on prompt diagnosis and timely administration of appropriate therapy and sustained treatment for 2 years. This requires health care workers who are trained to have a suspicion for drug-resistant TB, HIV testing linked to tuberculosis control efforts, a laboratory that is capable of making the diagnosis, health care workers that can prescribe and follow up the treatment for both XDR–TB and HIV, and a cadre of community health workers that can assure adherence to the drugs in the community. If hospitalization is needed, the treatment and control of XDR–TB require hospital wards with adequate ventilation and staffing.

To combat XDR–TB, the World Health Organization (WHO) is calling for at least $650 million globally in immediate emergency funding for the purchasing of drugs and diagnostics, and some immediate infection control. Experts and global leaders like Archbishop Desmond Tutu of South Africa have been calling on the United States to provide $300 million this year because we simply cannot wait another year to jumpstart these efforts. These figures do not capture all of the broader needs of TB treatment and lab strengthening that is needed to both treat and prevent XDR–TB. In fact, to strengthen basic TB control, the WHO-estimated cost is $5 billion annually, in addition to the immediate funds needed to address XTR–TB.

THE PIH EXPERIENCE:

I would like to offer some optimism in the midst of the pessimism that all of us feel sometimes in thinking about an airborne disease that is very difficult to treat. In Peru, the Socios en Salud and Partners In Health collaboration started in 1996 as a primary health care project. Within one year, much to our surprise, we had diagnosed hundreds of patients with MDR–TB. At that time, MDR–TB was considered "untreatable" in poor countries. Lead by Dr. Jaime Bayona in Peru, what began as a pilot project of an NGO with only a handful of patients became a full-scale national program. It is now the largest MDR–TB treatment program in the world and is run by the Peruvian Ministry of Health with close collaboration with Dr. Bayona and his team. Then and now, community health workers play a critical role in providing directly observed therapy and what we call accompaniment-home visits to as-

sist in adherence, but also to provide social support and to serve as a liaison to the health system.

Similarly, in 1998, we were invited into the former Soviet Union to treat tuberculosis inside the penitentiary system in Tomsk Oblast, western Siberia. About a quarter of the people with tuberculosis in the prison systems were dying of MDR–TB. With our partners in the prison, under the leadership of Dr. Sergey Mishustin, the prison introduced infection control and comprehensive TB treatment for all TB, including drug-resistant TB. The death rates inside that prison dropped to zero within 2 years. As this program is "scaled out" into the civilian sector, community health workers are instrumental in the provision of therapy in this remote rural area.

Though extremely difficult, it is possible to treat highly drug-resistant TB. With political will, meaningful partnerships, training of health workers (including at community level) and investments in laboratory and health infrastructure, it can be done. The new twist is that when HIV and TB collide—especially when HIV and drug-resistant TB collide—there is an even more urgent need to intervene effectively because HIV speeds up the process and makes epidemics of TB, especially drug-resistant TB, faster and more lethal.

That is what we are seeing in southern Africa. Some of the data that we have seen from the South African province of KwaZulu-Natal, which borders the landlocked country of Lesotho, show very high death rates from drug-resistant TB among patients with HIV who are on therapy for HIV. This has led to the incorrect perception that drug-resistant TB is untreatable.

The reality is that HIV was being treated effectively with antiretroviral therapy, but TB infection was left untreated. Until we bring effective therapy for both MDR–TB and HIV together, we will not see the results we want. A program to treat XTR–TB that we are launching in Lesotho with the support of the Open Society Institute and the Ministry of Health of Lesotho builds on a decade of experience, but it will also face new challenges because of the high rates of HIV and co-infection.

It is all the more urgent for us to develop strong infection control programs that move therapy, whenever possible, into the community. Good community-based care has many positive aspects, one of which is to avoid having infected patients congregate inside treatment facilities—what we call "nosocomial infection" in public health jargon. To some extent, we need to use hospitals to treat this disease, but we have to make the hospitals safe for our patients so that they do not become infected or re-infected.

XDR–TB does not need to be a death sentence. If we can combine good infection control, good prevention strategies, and good therapy, we know from our past experience that we can curb this epidemic and save thousands of lives.

Mr. PAYNE. Thank you very much for a very comprehensive testimony.

Now we are going to attempt to connect with our second witness and so we will see what happens. This would be Dr. Elena McEwan coming from Nicaragua. Her main responsibilities include quality assurance for three TB programs in the Ministry of Health and community health workers and TB related topics.

STATEMENT OF ELENA McEWAN, M.D., SENIOR TECHNICAL ADVISER, CATHOLIC RELIEF SERVICES

Dr. MCEWAN. Good afternoon. Chairman Payne, Ranking Member Smith and members of the subcommittee, thank you for inviting me to testify today before the subcommittee on the Global Threat of Drug-Resistant TB: A Call to Action for World TB Day.

My name is Dr. Elena McEwan. I am a senior technical advisor in health for Catholic Relief Services. I am also a member of the WHO TB expert task force, ACSM task force. Let me express my thanks for you and your staff's efforts to facilitate my testimony through the U.S. Department of State and the U.S. Embassy in Nicaragua.

Let me also note the agency's deep appreciation of this committee's efforts both historically and continuing through each new Con-

gress to be advocates for those greatest in need. Chairman Payne, Ranking Member Smith, in particular you have served as champions to the cause of humanitarian work and social justice and welfare throughout the world, and we are grateful.

CRS has programming in 99 countries meeting emergency and development needs in child survival, HIV and TB. Twenty-five percent of CRS expenditures are in health and HIV.

The benefits that millions are receiving from these programs are at risk because of conditions like extremely drug-resistant TB that compromise the effectiveness of inexpensive first-line TB drugs and that endanger the lives of patients, their caregivers and program staff. Our staff is very concerned for their health and that of their families, making staff retention in TB programs challenging.

Increasingly, more of our programming requires TB components and corresponding resources, often leaving managers to juggle needs and priorities. The recent rise in extremely drug-resistant TB is prompting us to review our HIV/AIDS guidelines as a model for developing similar guidelines for TB.

Lessons learned from 60 years of successful community-based health projects uniquely position CRS to address TB. Permit me to summarize the five most important: First, brokering partnerships between faith-based and government health services for more effective and sustainable programming. Faith-based organizations provide 30 to 50 percent of health services in lesser developed countries.

Collaboration and mutual sharing of resources between government and FBO health services are key to ensuring resources and services reach the most vulnerable through local community-based partnerships. For example, a partnership between CRS and the Government of the Philippines is providing community-based TB services in a predominantly Muslim area.

Second, leveraging private funding to support TB services to call attention to urgent and critical needs when public services are limited or unavailable. CRS, the Vatican and the North Korean Catholic Church and a private foundation have partnered since 1997 with private funds to provide TB treatment for over 205,000 people in North Korea.

As a result of this program's early diagnosis and treatment, there are no reported cases of XDR in this area. The program serves as a model for TB approaches in other parts of the country.

Third, mobilize local volunteers to support programs and build community capacity and awareness. Tens of thousands of home-based care volunteers in CRS programs provide crucial services in communities where most people cannot afford even the most basic medication and have little access to formal health care.

This represents a locally sustainable resource for early detection and treatment compliance essential to combating drug resistance. FBOs are adept at this critical community outreach.

Fourth, collaborating with research organizations and global partners. As a physician working for CRS, I have come to appreciate the value added of partnering with research organizations and WHO.

One example of this collaboration is in South Africa where 19 of our antiretroviral sites are being assisted by the CDC to evaluate

service delivery and quality. The findings will be used to design improved and earlier TB screening, prevention and treatment.

Fifth, integrated programs. Single interventions often do not address the full range of complex needs of TB patients. Thus, many of our programs are integrated into larger development activities such as the Food for Peace Title II program in Ethiopia.

As a physician who has been working in TB for many years, it is my professional opinion that in order for agencies like CRS to contribute significantly to the reduction of TB the following actions must be considered: One, increase resources for local health services. Future funding needs to not only strengthen the quality of government programs, but also support linkages and resources to FBOs, local partners and private health care providers.

Two, means for sharing lessons learned and best practices for learning. Future funding should have a mandatory percentage of funds set aside for rigorous documentation of lessons learned and best practices.

Three, long-term integrated programs rather than short term. We recommend that all new TB programs integrate livelihood security and food security with long-term, predictable funding cycles.

Again, Chairman Payne, Ranking Member Smith and members of the subcommittee, thank you for the opportunity to testify before this subcommittee today. I look forward for answering any questions you may have. Thank you.

[The prepared statement of Dr. McEwan follows:]

PREPARED STATEMENT OF ELENA MCEWAN, M.D., SENIOR TECHNICAL ADVISER, CATHOLIC RELIEF SERVICES

Good afternoon. Chairman Payne, Ranking Member Smith, and Members of the Subcommittee, thank you for inviting me to testify today before the Subcommittee on "The Global Threat of Drug Resistant TB: A Call to Action for World TB Day." My name is Dr. Elena McEwan, and I am the Program Quality Support Department Senior Technical Advisor in Health for Catholic Relief Services. My medical degree thesis was: *Quality of Tuberculosis Programs in Three Municipalities in Nicaragua*. From 1987 to 1991, I was the director of TB programs in three municipalities of Nicaragua and my main responsibilities included quality assurance to three TB programs and training Ministry of Health (MoH)staff and Community Health Workers (CHWs) in TB and related topics. From 1991 to 1995, I was employed as a pediatric specialist providing secondary care to children with TB referred from primary hospitals and health centers. Since 2006, I have served as a Senior Technical Advisor in Health and the technical backstop for the United States Agency for International Development USAID funded Tuberculosis Project in the Philippines. I am the co-chair of the Child Survival Collaborating and Resources Group (CORE)'s Tuberculosis Working Group which shares best practices and lessons learned with the larger Private Voluntary Organization (PVO) community and provide updates and training to the field staff and MoH partners. The group also held a Lessons Learned Exchange Workshop in February and is in the process of reviewing abstracts from the field related to TB experience and innovations. I represent CORE on the writing committee that is preparing guidelines of component five of the STOP TB strategy, and I am in the process of providing feedback on the last draft to be published this year.

Let me express, my thanks for you and your staff's efforts to facilitate my testimony through the U.S. Department of State and the American Embassy in Nicaragua. Let me also note Catholic Relief Services' (CRS) deep appreciation of this Committee's efforts both historically and continuing through each new Congress to be advocates for those greatest in need. Chairman Payne, Ranking Member Smith, in particular, you have served as champions to the cause of humanitarian work and social justice and welfare throughout the world, and we are grateful.

Catholic Relief Services was founded in 1943 and is the overseas relief and development agency of the U. S. Catholic Conference of Bishops and the American Catholic community. In FY2006, CRS engaged in program operations in 99 countries

through programs in emergency and disaster relief, child survival, HIV/AIDS and other health programs including TB programs, agriculture, education, microfinance, conflict resolution, and social justice programs. The benefits that millions are receiving from these programs are at risk because of conditions like (Extremely Drug Resistance) XDR TB that compromise the effectiveness of inexpensive first line TB drugs and endanger the lives of patients and their caregivers as well as program staff. Our program staff are very concerned for their health and that of their family thus making staff retention in TB programs challenging.

Increasingly more of our programming requires TB components and corresponding resources often leaving managers to juggle needs and priorities. The relatively recent rise in XDR is prompting us to review our HIV/AIDS guidelines as a model for developing similar guidelines for TB.

CRS as the lead agency of *AIDSRelief* funded under the President's Emergency Plan for AIDs Relief (PEPFAR) is concerned that untreated or poorly managed TB treatment will result in increased morbidity and mortality from Multi-Drug Resistant (MDR) and XDR TB. In countries like South Africa, this is especially unsettling for HIV patients when available life saving Antiretroviral Therapy (ARTs) should be prolonging their lives. Increasingly prevalent MDR and XDR TB put the entire community at risk. The alarming rise in MDR and XDR is in part due to 1) lack of health staff knowledge; 2) equipment and supplies not consistently available; 3) patient's and community's lack of knowledge and awareness; and, 4) lack of adequate collaboration around TB with key stakeholders.

Over the past 60 years CRS, has worked in improving primary health care services and child survival and safe motherhood programs. Lessons learned from these successful projects are enabling us to address TB/HIV-related issues and uniquely position us to work with communities, health providers, religious leaders and research institutions as well as government. These lessons include:

1. Brokering partnerships between faith-based and government health services for more effective and sustainable programming:

An essential element in the fight against TB is mobilizing both faith-based structures, including health services and parish volunteers, and community workers to educate and promote testing and treatment. One example is our four-year USAID funded TB project in Maguindanao Province on the southern Philippine island of Mindanao for 495,000 individuals that builds on a previous Child Survival program in the same area. Maguindanao is one of five Muslim-majority provinces comprising the Autonomous Region of Muslim Mindanao (ARMM).

As part of this project, CRS in partnership with the Integrated Provincial Health Office (IPHO) in Maguindanao is institutionalizing the five components of the Directly Observed Treatment Short Course (DOTS) strategy: 1) sustained political commitment; 2) case detection for quality-assured sputum smear microscopy; 3) TB treatment with standard short-course chemotherapy regimes, including DOTS; 4) uninterrupted supply of quality-assured anti TB drugs; and 5) recording and reporting systems.

2. Leveraging private funding to support TB services to call attention to urgent and critical needs when public services are limited or unavailable:

Since 1997 Catholic Relief Services has donated funds to the Eugene Bell Foundation for tuberculosis treatment for approximately 4,200 Korean patients. The funds have been used for: 1.) capacity building to health staff; 2.) regular re-supply packages for Jongju City TB Care Center in the North Pyongan Province and Anju City TB Care Center in the South Pyongan Province TB; 3.) and an initial "partner package" for Pyongsong City TB Care Center in the South Pyongan Province. The partner package is supplying tuberculosis hospitals, tuberculosis care centers (for chronic and MDR patients) and some local hospital tuberculosis departments with the necessary medicines, microscopic diagnostic kits, X-ray kits, agricultural support kits, vitamins, bedding, pajamas, basic medical equipment, and other necessities on regular basis.

In addition, CRS, the Vatican, and the Korean Catholic Church joined together in supplying a mobile X-ray vehicle for the South Pyongan Province Tuberculosis Hospital. CRS has also provided the needed re-supply packages to keep these mobile X-ray services operational: that is used for general medicine as well as TB-related work. Since beginning in 1997, partner organizations and supporters of Eugene Bell have provided approximately 205,000 Directly Observed Treatment System (DOTS), and tuberculosis medication kits. On the average, the cure rate for Category I patients (first-time tuberculosis patients with mild cases) have a cure-rate of 85–95% with completion of a six-month Direct Observe Treatment (DOT) course. Category II patients (those who suffer relapses or have serious infections) have a cure rate

of 70–80% with completion of an eight-month DOTS program. As yet there is no Category IV (multi-drug resistant tuberculosis patients) program in North Korea. These cases are almost always fatal and the number of MDR cases is rising. Eugene Bell and CRS are trying to promote interest in and find support for an MDR TB program.

3. Mobilize local volunteers to support programs and build community capacity and awareness:

Home-based care is the foundation of all CRS programs. Home care services are crucial in communities where most people cannot afford even the most basic medication and have little access to formal health care. Community volunteers, who are often poor themselves, are the heart of home care programs and are at the forefront of our battle against the HIV/AIDS pandemic. The home-based care workers represent an additional resource for screening and early identification of TB among People Living with HIV (PLWHIV). TB treatment is provided by TB clinics that make treatment decisions and dispense the drugs in a vertical program.

All AIDSRelief projects have a TB component which provides palliative care for those with TB. The MoH provides the drugs and treats TB first as an opportunistic infection and then treats the HIV. In addition, CRS provides lab facilities, pay staff, and provides psychosocial support and services. Co-infection is very high in South Saharan Africa. For example in Angola the prevalence of TB among HIV+ persons is 40% and the prevalence of HIV among TB patients is about 60%.

ART programming has borrowed heavily from the TB DOTS approach to promote treatment compliance using volunteers. In many places where we work there is already a trained cadre of volunteers and community health workers that can be mobilized around TB as well as HIV and basic primary health care.

The country programs where CRS is implementing AIDSRelief program that include HIV/AIDS and TB components are: South Africa, Tanzania, Zambia, Kenya, Uganda, Rwanda, Nigeria, Haiti, and Guyana. These programs include tens of thousands of trained volunteers.

4. Collaborating with research organizations and global partners

The Catholic Church's long-standing commitment to health care throughout the world is noted for its program quality, excellence in care and extensive networks. One way of assuring quality and continual staff training and use of best practices is through collaborating with research organizations and global partners such as World Health Organization (WHO). An example of this collaboration is in our AIDSRelief project in South Africa. All 19 Antiretroviral (ARV) sites screen all patients and refer them to appropriate TB clinics. Because of the link between TB and HIV, the International Research and Programs Branch, Division of TB Elimination at Centers for Disease Control and Prevention (CDC), in conjunction with CRS, and the Global AIDS Program (GAP) South Africa have partnered to evaluate TB screening, referral, and treatment services in two ARV sites: Orange Farm ARV and the Winterveldt ARV that in 2005 provided ARV therapy to 140 patients and provided home-based care to an additional 450 patients with HIV/AIDS. The findings will be used to design improved and earlier TB screening and Isoniazid Preventive Therapy (IPT) uptake at ARV sites. In addition the evaluation will help improve the effectiveness of training home-based care workers to screen for TB. The findings will be shared among the stakeholders in HIV and TB control in South Africa, including the CDC Global AIDS Program and other relevant program partners. This series of activities which leads to earlier diagnosis and treatment is designed to reduce risk of resistance to drugs.

5. Integrated programs:

Single interventions often do not address the full range of complex needs of TB patients. Thus, many of our programs are integrated into larger development activities such as the Food for Peace (FFP) TITLE II. CRS/Ethiopia provides limited assistance for TB through our partners including indirect support through the provision of Title II food to Missionaries of Charity.

CRS' TB program in Angola is part of a larger HIV/AIDS program that is being implemented by our partner, Caritas Benguela. The project goal is to contribute to the prevention of HIV incidence through participatory AIDS education, mass media, and capacity building in Benguela province over one year. In order to improve knowledge in HIV/AIDS, the project has implemented different participatory education and mass media activities in Benguela province over one year, such as posters, pamphlets and billboards, oral presentations, and development of World AIDS Day campaigns. They have also trained and carried out outreach activities with target groups, such as religious leaders of Faith-based organizations (FBOs). They have also provided basic HIV/AIDS and management training to our partners in

Benguela. The TB component of the project also provides training to nurses in the Benguela Province

As a physician who has been working in TB for many years, it is my professional opinion that in order for agencies like CRS, our local health care providing networks, our local church partners and other US PVOs and FBOs to contribute significantly to the reduction of the burden of TB, the following actions must be taken into consideration.

1. Increase resources for sustainable local health services: To date most of the global public efforts to address TB are aimed at national government institutions often overlooking the FBO and private health care providers that deliver 30 to 50% of health services in lesser developed countries. CRS and our partner networks excel at reaching the most vulnerable through community managed services. Future funding needs to not only strengthen quality of government programs but also support linkages and resources to include FBO and private health care providers. These additional resources are needed for expansion of standardized trainings and supervision of volunteers and community health workers to increase community awareness and extend TB services, as well as equipment and quality control. This would extend DOTS from Secondary and Tertiary units to the primary health care settings in communities in which PVOs and FBOs are present. PVOs and FBOs are uniquely positioned to expand TB services to areas underserved if resources were available

2. Support for sharing lessons learned and best practices: Learning and documenting lessons and best practices is a key part of quality assurance and scale up of successful cost-effective interventions. Often projects do not have sufficient funds for doing this type of documentation. To do this effectively we recommend that a percentage of the budget for each TB program be required for learning and documentation. Lessons learned from CRS' Child Survival and HIV work show that well-documented practices can be replicated and further refined across countries and regions.

3. Long-term integrated programs rather than short term: Infections and global health conditions like TB and HIV do not often lend themselves to four or five year annually renewable funding cycles nor to silo funding of specific interventions. Lessons learned in PEPFAR Title II and Child Survival funding require consistent and predictable funding over multiple years. At household level, families need more than drugs and treatment. Because TB is a disease of poverty, support for food security, livelihoods and basic services are needed as well. Therefore we recommend that all new TB programs integrate livelihood security and food security within long-term predictable funding cycles.

Again Chairman Payne and Ranking Member Smith thank you for the opportunity to testify before the Subcommittee today. I look forward to answering any questions you may have.

Mr. PAYNE. Let me thank you very much for your testimony. We really appreciate the fine work that you are doing.

Let me ask you: You were mentioning that there are organizations, faith-based organizations and others, that are working in the area, but I think you bring out a point, and I wonder if you would elaborate on it more.

In order for anyone to work effectively, and either one of the witnesses can answer, there has to be a system, first of all, I believe to be able to set the stage. In your opinion, in the countries you are working in, to the extent that you are all aware, how do you rate the systems?

Do some of the countries have adequate systems? Do any of them have adequate systems? Do most of them have adequate governmental health delivery systems in order to then have faith-based and NGOs and others to assist?

I think the basic thing that seemed to be necessary is that there be a governmental system. Many people feel that working with governments are not the best and that maybe faith-based or NGOs are more appreciated. However, without a governmental system I believe that the delivery system becomes more difficult.

I wonder if either or both of you might comment on that.

Dr. MUKHERJEE. I think that is especially true with tuberculosis and that is because it is an airborne disease. You know, people are often walking around with tuberculosis for a long time before they actually get sick, so it really takes follow-up for a long time and it takes really in-depth case finding.

In Peru we had the very excellent example of an extremely good national TB program and so when we started treating drug-resistant TB we could work to fit that into the national program. Rwanda, similarly, has a good tuberculosis control program. In other places like Lesotho, the tuberculosis program is quite weak and so it is really going to require strengthening the tuberculosis program at large.

Because TB is airborne, you can't just treat it in isolation, and that is one of the problems we have had in Haiti where we treat drug-resistant tuberculosis. But, because tuberculosis control is so weak in the rest of the country, we are getting cases referred in to us of drug-resistant TB. So, it is something you need a very wide net and a net wide enough that really only the nation state itself can have purview, even if it is through different partners throughout.

I think Rwanda is an excellent example of this, where they have taken Global Fund, PEPFAR and the World Bank money, and they have assigned different areas of the country to different streams of money and different NGOs and FBOs to work with each of these areas under one national plan.

I think that is really what we need for tuberculosis. AIDS has led the way in this kind of one national plan strategy.

Mr. PAYNE. Dr. McEwan, do you have any comment?

Dr. MCEWAN. Yes. Thank you for the question. There are different scenarios. It depends on the country.

For example, the Philippines have one of the strongest national TB programs that I have seen, so what we do is we complement the other components of the DOTS strategy; for example, community involvement, behavior change. So there is room for faith-based and NGOs to complement and strengthen the different bottlenecks that a well-established program has like supervision and monitoring.

On the other hand, there are some areas like DRC where the only providers are faith-based organizations, and they are the ones who are providing the services so while we are strengthening the Ministry of Health's capacity to deliver quality services in this case using the DOTS strategy, we also need to take into consideration that the TB patients are going to those services and that we need to make sure that they also are strengthened and they are using the national protocols to diagnose and treat tuberculosis.

Mr. PAYNE. Thank you.

Since you are on the line right now, we have heard in the hearing that Africa lacks the lab capacity to sufficiently find and treat drug-resistant TB. Could you respond to what you know about Latin America in general, and could you indicate to us what the lab situation is in Latin America in general?

Dr. MCEWAN. My experience in Latin America dates from 1998, and we have established a very good program. We were piloting the short course of TB, and we also had a laboratory of reference to do

quality assurance for sputum samples. The problem with Latin America is like most of the developing countries, access to supplies and behaviors prevent people to continue taking the drugs.

For example, implementing the DOTS strategy in Latin America we focused on Component 5 of the Stop TB strategy; that is, empowering people affected with TB in their communities so they can become lobbying groups and be active actors to allocate resources, to influence the local government to locate resources for TB.

So there is a different role in Latin America. Of course, there is some need for improvement in the national TB program—quality control, supervision and so on—but the effort should be in Component 5, community involvement—treating the patients so they can be active actors in their communities to be free of TB.

Mr. PAYNE. Let me just ask both of you again regarding the fight against HIV and AIDS. Can both of you elaborate on how the XDR–TB is threatening to roll back progress made in the fight against HIV and AIDS and tuberculosis in general?

Dr. MUKHERJEE. I think one of the things I would like to add to what Dr. McEwan said was the lab capacity in Latin America is quite weak. Even though there are labs of reference that do quality control, it is usually on sputum and not culture.

We have worked very hard to develop a national reference laboratory that could do culture and drug sensitivity testing in Peru, but even after many years of work to get it to the level of testing for resistance to second-line drugs, it is very difficult and requires resources and training.

I think this is the issue with HIV control. Tuberculosis is far and away the most common killer of people living with HIV. We know that TB, whether it is sensitive or resistant to drugs, is extremely difficult to diagnose in patients with TB.

We need x-ray and we need culture to make the diagnosis of sputum negative/culture positive TB in general, and then we need culture and drug sensitivity to make the diagnosis of resistant tuberculosis.

What is being rolled back is our strategy just to continually treat based on smear—positive smear, not culture—and using first-line drugs for drug-sensitive TB, and that was fine if all we had was drug-sensitive TB, but as the proportion of resistance goes up those people will die.

So we are talking about the most common opportunistic infection in people living with AIDS, and if we are seeing more resistance without those abilities to diagnose this, without the lab infrastructure diagnosis and people trained to do the diagnosis and treatment, we will lose many, many patients.

Mr. PAYNE. Thank you.

Do you have any comment, Dr. McEwan?

Dr. MCEWAN. Yes. As I said, there is some room for improvement, but we also need to recognize the efforts that the national TB program is doing in Latin America.

In most of the countries, for example, in Latin America besides Honduras and Haiti, most of the TB patients are not infected with HIV so there is still a lot of opportunity for early and prompt diagnosis of patients. Most of them are from the rural areas, the poorest people who do not have access to TB services, who do not have

a community that is going to be supportive for treatment adherence.

Those are the things that we need to make sure in order to be cost effective. I am not trying to say that we don't need to also take into consideration the people living with AIDS and HIV, but also let us not forget the vast majority of impoverished people who are living with tuberculosis.

Mr. PAYNE. Thank you very much, both of you.

I will yield to Mr. Smith.

Mr. SMITH OF NEW JERSEY. I thank the chairman for yielding.

Dr. McEwan, you used the word "overlooked" when you mentioned faith-based organizations, and I think that was a very mild and very diplomatic word. I think "exclusion" would be more appropriate, especially over the last several years.

I remember in the 1990s, and I have been in Congress 27 years. We had to fight very hard to try to get some of the HIV/AIDS money, modest as it was during those years, to faith-based organizations. There was an exclusion, so much so that when the President's PEPFAR program was under consideration in the Congress I offered the amendment called the Conscience Clause to allow faith-based organizations to be eligible to receive funding.

I have numerous examples where the exclusion was real, tangible, and on the ground. The venue to provide assistance on the prevention side, as well as the treatment side, such as on providing hospice-like care, particularly how to treat a dying patient in a way that is hospice-like, could not have happened or would not have happened without the amendment.

Thankfully, President Bush was very strong on the importance of inclusion of faith-based organizations, and I know Mr. Payne and I have always been big fans of Catholic Relief Services, whether it be refugee camps or other efforts that you have undertaken around the globe. It is my hope that we are finally past the point where the exclusion could come back and we are now into a period of real inclusion of faith-based organizations.

I raise that again for a couple of reasons. I would appreciate both of your thoughts on this. The churches around the world, the faith-based individuals, very often are the leaders in combating corrupt governments, as well as undemocratic dictatorships, whether it be in Africa, Latin America or anywhere else on the globe.

Who was it in Poland, for example, that led the fight? It was the church and Solidarity, basically, a faith-based orientation at least on the part of Lech Walesa, but you couldn't expect them to go to the government, request grants for health and expect to get them.

I was recently in Vietnam. Vietnam is a PEPFAR country. It is one of the 15 countries on the list. They get hundreds of millions of dollars from the U.S. Government, and yet they have yet to open up in any meaningful way the church assets that are there waiting, ready and able to help with hospices and health care. The government still has this profound animosity toward faith-based groups. Maybe that will change, but it seems to me it bespeaks the problem we are facing.

I was just in Nigeria. Corruption in Nigeria is a very serious problem. I met with a number of top clerics while I was there. It is very hard for them to get funding because they very often are

pointing out the corruption practices that occur in Abuja, and that leads to a disinterest on the part of certain ministries to provide funding. The same goes for a large number of other countries.

I think the point is, and I would appreciate your thoughts about this, animosity, this feeling that is out there leads to disenfranchisement of the faith-based community. Add to that the Global Fund, which has yet to really open up its monies to faith-based organizations.

Many of us have criticized them. They can do a wonderful job, but I do think they have to open up and do more to include faith-based organizations. Where are we going to get these venues? How are we going to create an infrastructure quickly to meet this emergency need without utilizing those hospitals and health care facilities that are already there on the ground?

I have been in hospitals all over Africa, many of them faith-based, some of them not. When asked whether they are involved at all with the Global Fund, whether they are getting money vis-a-vis the Global Fund, the answer is no.

Last year the Catholic Bishops of Africa put out a statement that although they provide 40 percent of the funds of the health care infrastructure in Africa, they get under 4 percent of the money from the Global Fund. Why is that?

It is perplexing to me when you have a massive number of volunteers ready to be mobilized, you have a venue, you have an infrastructure, you have doctors and nurses, LPNs and the like ready to provide service that, to use your word, Doctor, they are overlooked. I think it is a little bit more pernicious than that and a little more, unfortunately, calculated. It has been by design.

I and others are out to change that. I think we have to have multiple partners in this effort, including the governments, including other NGOs, but don't exclude the faith-based because we do it at the peril of the victims who are suffering from TB and from HIV/AIDS and other communicable diseases.

I would appreciate your thoughts on that if you could, both of you, Doctors. Dr. McEwan, would you want to start?

Dr. MCEWAN. Yes. Thank you for the question and remarks.

The message we want to leave is that we at CRS as a faith-based organization, we have the infrastructure in place. We have the years working with communities, with diverse groups from different faith-based culture. One example is the Mindanao Region with 90 percent Muslims.

The other faith-based organizations who are our partners working in different countries, as was mentioned, the infrastructure is already there. We are already providing services to the most poor people.

There is a need to improve the capacity of local government. Of course, that is the ideal situation, but what is going to happen for those patients who the only access they have is the faith-based hospitals and clinics? They are entitled to also receive quality TB services.

That is why we want to improve the best practices, the lessons learned, what every faith-based organization must have, but we need resources because most of the resources we get is for providing services, but not for documenting best practices and lessons

learned. We want to share our experience with the larger community as well.

Mr. SMITH OF NEW JERSEY. Dr. Mukherjee?

Dr. MUKHERJEE. Yes. I don't really have any comments. In every country that I have worked in, the process for getting Global Fund money was very collaborative and went through the country coordinating mechanism, which was not run by the government. The experience I have had is that no one was excluded who wanted to come to the table, and that is just a handful of countries. I don't know all of that.

To me the Global Fund is not really an entity in and of itself. It is a funding source that is country driven, and it is the countries themselves who decide how the money is allocated. But, I can only speak for the countries that I work in.

Mr. SMITH OF NEW JERSEY. Okay. I appreciate that. There are countries, especially dictatorships, where we know they are excluded.

Dr. MUKHERJEE. Yes. This is not my area of expertise.

Mr. SMITH OF NEW JERSEY. Understood.

Dr. MUKHERJEE. And I sincerely apologize, but I actually need to leave to take a plane.

Mr. SMITH OF NEW JERSEY. You have to go? Okay.

Dr. MUKHERJEE. Thank you very much.

Mr. SMITH OF NEW JERSEY. Thank you so much. You have been great.

Dr. MUKHERJEE. Thank you so much.

Mr. PAYNE. Thank you.

Mr. SMITH OF NEW JERSEY. Let me just ask a couple of other questions, and then I will conclude as well.

This really would have been a better question on the—I guess she can't answer it. You are late?

Dr. MUKHERJEE. What is that?

Mr. SMITH OF NEW JERSEY. I was wondering about Russia, about your program, if you have a moment.

Dr. MUKHERJEE. Okay.

Mr. SMITH OF NEW JERSEY. Real quick, Russia has a very high rate of MDRs and XDRs as well.

Dr. MUKHERJEE. Yes.

Mr. SMITH OF NEW JERSEY. But I was wondering what are we talking about in terms of numbers? Do you have a sense?

Dr. MUKHERJEE. I actually don't. I think we can get that information to you to put in the record.

Mr. SMITH OF NEW JERSEY. Okay.

Dr. MUKHERJEE. We have that. I don't have it at the tip of my tongue.

Mr. SMITH OF NEW JERSEY. Okay.

Dr. MUKHERJEE. I know it is about 25 percent of the incarcerated population who has TB has drug-resistant TB. The rates of XDR–TB are extremely high.

There is not as much HIV yet in Russia in that population, so I think we are a little ahead. We have to stay ahead. Otherwise we are going to end up with really untreatable strains.

Mr. SMITH OF NEW JERSEY. I appreciate that.

Dr. MUKHERJEE. Thank you.

[Additional information follows:]

WRITTEN RESPONSE RECEIVED FROM JOIA MUKHERJEE, M.D., M.P.H., TO QUESTION ASKED DURING THE HEARING BY THE HONORABLE CHRISTOPHER H. SMITH

To answer Mr. Smith's question, I would like to cite two reports, one from a fact-finding trip by Murray Feshbach and one from Christopher Dye which was printed in the Journal of Infectious Diseases.

According to data collected from 1999 to 2004, the cumulative number of cases of MDR–TB in Russia can be estimated at over 58,000. About half of the cases are in the incarcerated population. Additionally, 10% of all new TB cases are multi-drug resistant. These numbers are of great concern and although Russia has committed large amounts of their own budgetary funds, received loans from the World Bank and grants from the GFATM, very little progress has been made outside international project sites (PIH, CDC, WHO).

I would like to stress, however, that MDR– and XDR–TB problems in Russia and the rest of the former Soviet Union are, at this point in time, amplified by the HIV/AIDS epidemics like we have in sub-Saharan Africa. The combination of XDR–TB with HIV creates cases that are even more difficult to treat. Moreover, XDR–TB/HIV coinfection further complicates the already challenged diagnostic capacity.

Mr. SMITH OF NEW JERSEY. I hope you make your plane.

Dr. MUKHERJEE. Okay.

Mr. SMITH OF NEW JERSEY. Let me ask, Dr. McEwan: You pointed out the importance of mobilizing local volunteers to support programs and build community capacity and awareness with the emphasis on home-based care. Could you elaborate on that?

It seems to me that again when you have an army of volunteers ready, willing and able to spread the word, to get the message out, to enable testing, to try to find who may be seeking and in need of help. They need to be utilized. Again, as I said at close to the opening of this hearing, I learned firsthand in 1983 and 1984 in El Salvador and in other Central American countries how important the church was in getting people to vaccination sites and then ensuring that they came back, especially if the baby girl or boy developed a fever and the mom might think why am I getting this vaccination, but you need to go back to get additional vaccinations for it to really take hold.

None of it could have happened without the collaboration of the church. You are in Nicaragua right now, and I think a lot of us are glad that Orbando Bravo and Ortega seem to have had a reconciliation, so hopefully there is better collaboration between the Government of Nicaragua now under his leadership and the church.

It seems to me a missed opportunity if we don't ensure that resources follow opportunity, which is so home-based. If you could speak to that maybe and then some?

Dr. MCEWAN. Yes. Thank you for the question.

Component 5 of the Stop TB strategy is empowering people with TB in communities, so we need to start shifting the paradigm at the same time that we are building the capacity of the national TB program to deliver quality services, in choosing, as Dr. Raviglione said, the logistics of the antibiotics, the quality of the microscopes. All this coincides.

There is still lacking the component of the community. We want the communities to support the TB persons who are going under treatment. All of us know that after 2 months of treatment the person feels cured and tries to become a deporter. They stop taking the drugs because of all the side effects.

Mr. SMITH OF NEW JERSEY. That is a very good point.

Dr. MCEWAN. So one of the roles of the communities is to organize TB clubs. That is a way of a support group for these patients to hold on for the 6 months during the treatment. At the same time, those patients who are cured will become or are becoming promoters or counselors of new patients.

But there is another role for the community. What is this? There is social responsibility for two things. Part of this social responsibility is allowing them to be part of the groups at the Ministry of Health levels to evaluate the quality of the program and becoming a lobbying group to allocate resources, to go to their local authorities to influence them to put more resources for TB.

We want the people to get responsible for their own health but also talk to the attitude of others in their community. So that is the morale that we are developing in the Philippines with the Barangay health workers, the local government units, to allocate resources for TB services in the future when the project ends, and that means sustainability.

Mr. SMITH OF NEW JERSEY. Dr. McEwan, thank you so very much for your testimony and for your extraordinary work on behalf of those who are sick and in need. Thank you.

Dr. MCEWAN. Thank you.

Mr. PAYNE. Let me also thank you for your very pertinent testimony, and let me once again commend you for the great work that you are doing.

We hope to stay in touch to update the information we have so that we can keep a focus on this very serious situation that we have in the whole area of tuberculosis and this new, more resistant strain. Thank you once again.

As we conclude, I ask unanimous consent to enter into the record two statements, one a joint statement from the Infectious Diseases Society of America and the HIV Medical Association on XDR–TB and also a second statement from the American Thoracic Society on the global impact of TB. Without objection, they will be entered into the record.

[The information referred to follows:]

Extensively Drug-Resistant Tuberculosis (XDR-TB): Immediate U.S. Action is Required

The Infectious Diseases Society of America (IDSA) and the HIV Medicine Association (HIVMA) are gravely concerned over the recent emergence of strains of so-called "extensively drug resistant tuberculosis," or XDR-TB. Transmitted through the air, these strains are resistant to nearly every TB drug. The World Health Organization (WHO) has called XDR-TB "virtually untreatable." First documented in 2006[1], XDR-TB now has been found in 28 countries including the United States.[2] There are few committed resources to track its spread globally.

In the early 1990s, New York City spent approximately $1 billion to quell an outbreak of multi-drug resistant tuberculosis (MDR-TB) in that city. **The United States once again is at serious risk and, at present, is particularly vulnerable to an XDR-TB outbreak due to recent 14 percent funding cuts at the Centers for Disease Control and Prevention's (CDC) Division of TB Elimination. These funding cuts have been passed on to state and local TB programs, placing fragile community initiatives in grave jeopardy.** CDC-funded TB clinical research consortiums also have been impacted. **At highest risk are populous, TB-endemic nations such as China, India and the Russian Federation, as well as impoverished nations including those of Sub-Saharan Africa.**

IDSA, a national medical society representing approximately 8,400 infectious diseases physicians dedicated to patient care, research and domestic and global public health, and HIVMA, a national society housed within IDSA and representing 3,600 HIV physicians and caregivers, call upon the U.S. Congress to take immediate, comprehensive action to address the XDR-TB threat.

A dangerous, new twist on an age-old threat: Defining XDR-TB

Tuberculosis is an ancient scourge, found in all countries and spread through the air to close contacts. Globally, TB infects nearly 9 million new people per year, and annually accounts for greater than 2 million deaths. Standard cases of TB can be controlled through a six-month course of medications, although rigorous programs are required to ensure patients are compliant.
Multi-drug resistant TB (MDR-TB) emerged in the early 1990's and was defined as occurring when the TB bacteria had developed resistance to isoniazid and rifampicin, the two most powerful or "first line" anti-TB drugs.[3]
XDR-TB is highly drug-resistant not only to first line anti-TB drugs, but also to second line oral (fluoroquinolones) and even injectable drugs (capreomycin, kanamycin, and/or amikacin).[4]

A global threat:

- In 2004, there were about 424,000 new cases of MDR-TB[5]. Transmission of XDR-TB could be expected to eventually reach this scale unless action is taken.
- Resistant strains are posing a threat to highly populous, TB-endemic nations such as India and China, as well as the former Soviet countries.

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[1] In CDC's *Morbidity and Mortality Weekly*, Vol. 55, No. 11; March 24, 2006
[2] Including U.S., Canada, Japan and Norway; http://www.who.int/tb/xdr/xdrmap_feb_en.pdf
[3] http://www.who.int/tb/xdr/faqs/en/index.html
[4] http://www.who.int/tb/xdr/faqs/en/index.html
[5] MDR-TB rates ranged up to 14 percent of all TB cases in some countries, in a 79-country study; Epidemiology of antituberculosis drug resistance (the Global Project on Anti-tuberculosis Drug Resistance Surveillance): an updated analysis, *The Lancet* 2006 Dec 16;368(9553):2142-54

- XDR-TB is highly fatal to HIV-positive individuals, because of their suppressed immune systems. An August 2006 South African study found that 52 of 53 patients with XDR-TB died within 25 days of their diagnosis; most or all were co-infected with XDR-TB and HIV.[6] XDR-TB poses a major threat to AIDS-endemic countries and hard-hit areas including in the U.S.
- Major reference laboratories in TB-endemic countries presently are not equipped to identify resistance to many anti-TB drugs, hindering proper diagnosis.

An imminent threat to U.S. citizens:

- According to the Advisory Council for the Elimination of Tuberculosis (ACET) in an urgent letter to Department of Health and Human Services Secretary Leavitt[7], dated December 14, 2006, XDR-TB poses "an imminent airborne biological threat" to the U.S.
- XDR-TB already is present in the United States. Four percent of all MDR-TB cases in this country fit the definition of XDR-TB. U.S. HIV patients are at particular risk.
- Increased global trade as well as travel and migration of individuals from TB endemic countries places the United States at further risk of an XDR-TB epidemic. More than half of U.S. TB cases occur among foreign-born persons.
- Hospitalizing additional XDR-TB infected patients will tax already strained infection control efforts and place health care workers and patients at significant risk.

ID Physicians' Prescription for XDR-TB: ***Congress must reverse recent TB program funding cuts as well as provide additional long-term resources for targeted activities.***

In the 1990s, Congress responded to the MDR-TB crisis by strengthening funding for TB prevention and control programs, laboratory infrastructure, and programs supporting adherence to therapy. These improvements led to a drastic reduction in domestic TB cases. A reinvigorated and sustained response again is urgently needed to strengthen:

- ***Research & development of countermeasures (vaccines, drugs, and rapid diagnostics)***
  XDR-TB must become a funding priority under the new Biomedical Advanced Research and Development Authority within the Department of Health and Human Services. Further, $350 million in new funding is needed for CDC's and the National Institutes of Health's (NIH) research efforts to support preclinical and clinical evaluation of new vaccines, drugs and diagnostics as well as for operational, basic, translational, and clinical (TB Trials Consortium and TB Epidemiology Studies Consortium) research.
- ***TB control efforts within the U.S.***
  Funding for TB prevention and control must increase substantially in order to address this new, emerging threat. As a starting point, IDSA supports the ACET recommendation of $252.4 million for CDC's Division of Tuberculosis Elimination.
- ***Global TB programs***
  $400 million is needed to scale up treatment efforts (especially in developing countries), strengthen laboratories and infection control practices, and provide access to drugs, commodities and services, via the U.S. Agency for International Development, CDC, WHO and the "Stop TB" initiative, and to support public-private partnerships working to develop TB diagnostics, drugs and vaccines. Furthermore, IDSA supports $275 million for the TB component of the U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and supports increased funding for the GFATM overall in part to help combat HIV-TB co-infection.

For more information: Contact Julie Hantman, MPH, IDSA, at jhantman@idsociety.org.

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[6] Extensively drug-resistant tuberculosis as a cause of death in patients co-infected with tuberculosis and HIV in a rural area of South Africa, *The Lancet* 2006 Nov 4;368(9547):1575-80

[7] Letter from ACET Chair Michael Fleenor to DHHS Secretary Michael Leavitt, December 14, 2006

STATEMENT SUBMITTED FOR THE RECORD BY THE AMERICAN THORACIC SOCIETY

The American Thoracic Society (ATS) thanks Chairman Payne for holding this important hearing to mark World TB Day and for the opportunity to submit this statement for the record.

INTRODUCTION

Tuberculosis (TB) is the second-leading infectious disease killer in the world, taking nearly 2 million lives per year. Currently, about a third of the world's population is infected with the TB bacterium.[1] The disease is predicted to kill 30 million people in the next decade. TB is the leading global killer of women of reproductive age, ahead of HIV, heart disease and war and the leading killer of people with HIV/AIDS. Sadly, projections several decades into the future suggest that the world-wide TB situation will not improve if we continue along as we are doing.

New TB infections are occurring at a rate of one per second. Although only about 10% of persons with tuberculosis infection develop the disease, there were 8.9 million new cases and 1.7 million deaths in 2005.[2] Alarmingly, the incidence of tuberculosis continued to rise in 2005 and the increase was largely driven by the worsening situation in Sub-Saharan Africa where TB and HIV infection form a deadly duo.

The rise in HIV infection levels and the neglect of TB control programs have caused a global resurgence of tuberculosis. Drug-resistant strains of TB, including extensively drug-resistant, termed 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 TB, more drug resistant TB, and even more XDR–TB.

XDR–TB AS A GLOBAL HEALTH CRISIS

The emergence of extensively drug-resistant (XDR) TB has created a global health emergency. At the Pandemics Session of the World Economic Forum in January 2007, Centers for Disease Control and Prevention (CDC) Director Julie Louise Gerberding declared, "The emergence of extensive drug resistant tuberculosis (XDR TB) is an ominous sign of a lethal pandemic that will spread if we don't take action today."

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 most of the drugs used to treat TB, XDR TB is virtually untreatable and has an extremely high fatality rate. In one of the latest outbreaks in South Africa from late 2005 until early 2006, XDR TB killed 52 out of 53 infected patients.[3] 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.

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

1. Pursue high-quality DOTS (*Note:* The DOTS strategy is the internationally recommended approach that embodies fundamental TB control measures) *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

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[1] Tuberculosis. World Health Organization (WHO) Factsheet No. 104, March 2006.

[2] Global Tuberculosis Control—Surveillance, Planning, Financing, Geneva, WHO 2006 (WHO/HTM/TB/2006.362).

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

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 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) Programme-based operational research

b) Research to develop new diagnostics, drugs and vaccines

INTERNATIONAL STANDARDS FOR TUBERCULOSIS CARE

The Tuberculosis Coalition for Technical Assistance (TBCTA), in partnership with WHO, CDC and the ATS, developed the *International Standards for Tuberculosis Care (ISTC)*, which seek to unify approaches to TB care and engage care providers through public-private and public-public partnerships. The ATS is working to implement the ISTC as a primary effective TB control tool throughout the world.

NEED FOR NEW TB TOOLS

New research on diagnostic and prevention/treatment tools and vaccines is urgently needed. The standard method of diagnosing TB was developed 100 years ago and fails to adequately detect TB in children and those coinfected with HIV/AIDS, while the newest class of drugs to treat TB is over 40 years old. The ATS supports enactment of the Comprehensive TB Elimination Act, H.R. 1532, sponsored by Reps. Green (D–TX), Wilson (R–NM) and Baldwin (D–WI), and the Stop TB Now act, sponsored by Reps. Engel (D–NY), Wilson (R–NM) and Smith (D–WA), which will both expand research efforts into new tools to combat TB. The Comprehensive TB Elimination Act 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, including the "Blueprint for Tuberculosis Development." as recommended by the Advisory Council for Elimination of Tuberculosis.

RESOURCES NEEDED TO ADDRESS XDR–TB

Currently, the extent of the global XDR TB burden remains unknown. Globally, 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 those with virtually untreatable forms of XDR TB.

The following specific resources are required to address the following unmet needs:

1) Build state and local public health laboratory capacity to assess the XDR burden in the U.S. All MDR patient samples must be routinely tested for second line drug susceptibility, and all isolates must be genotyped to recognize outbreak patterns.

2) Build supranational TB reference lab 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.

3) 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 out-

breaks; build capacity to institute infection control measures in affected areas—with emphasis on healthcare settings where vulnerable HIV-infected persons congregate; and improve the use of anti-TB drugs and adherence measures that prevent the creation of drug resistance.

4) 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.

5) 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 and be safely used in conjunction with antiretroviral therapy.

CONCLUSION

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 Centers for Disease Control and Prevention (CDC).

To strengthen domestic TB control, including efforts to prevent the spread of XDR TB in the U.S., the ATS recommends a funding level of $152.2 million in Fiscal Year 2008 for the CDC's National Program for the Elimination of Tuberculosis and enactment of the Comprehensive TB Elimination Act, H.R.1532, sponsored by Reps. Green (D–TX), Wilson (R–NM) and Baldwin (D–WI).

To combat TB globally, the ATS supports enactment of the Stop TB Now Act, sponsored by Reps. Engel (D–NY), Wilson (R–NM) and Smith (D–WA), and an appropriation of $300 million for the Global Fund to Fight AIDS, TB and Malaria in Fiscal Year 2008. Enactment of the Stop TB Now Act and the Comprehensive TB Elimination Act will provides researchers and public health officials the tools needed to help eliminate TB in the U.S. and around the world.

The ATS appreciates to submit this statement for the record. Please contact Nuala S. Moore, Sr. Legislative Representative, at 202.785.3355, x. 215, for more information.

Mr. PAYNE. Let me thank all of the participants. The meeting stands adjourned. Thank you.

[Whereupon, at 6:19 p.m. the subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE RECORD

WRITTEN RESPONSES FROM MARIO RAVIGLIONE, M.D., DIRECTOR, STOP TB DEPARTMENT, WORLD HEALTH ORGANIZATION, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE ADAM SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Question:

The burden of TB disproportionately affects the poor. Globally, the highest burden of TB is found in poor countries. 17 of the 22 countries that account for 80% of the world's TB burden are classified as low income (as defined by the World Bank as GNP per capita less than $760). Poverty is rightly recognized as a key cross-cutting issue for TB control. One of the Millennium Development Goals (MDGs) is to cut extreme poverty by half by 2015 and the goals set forth by the Global Plan to Stop TB are to reduce the number of TB cases worldwide. Because of the link between poverty and TB and these recent goals set forth by the international community, it seems that this provides a unique opportunity address both poverty and TB. Given these two goals, how are you working with others to coordinate efforts and align a plan to help achieve both poverty and TB reduction goals?

Response:

At WHO, we have developed the Stop TB Strategy that incorporates the key objective of reducing the suffering associated with TB, especially for poor and vulnerable populations. This Strategy, which guides the blueprint for implementation in the Global Plan to Stop TB, 2006–2015, sets out six components—all of which lay out approaches that can increase access to quality TB prevention and treatment services, and their utilization by poor populations. Among these are engaging actively in health system strengthening initiatives to open up access to services and health personnel; improved treatment support to reduce the impoverishing effects of seeking and receiving care such as via community-based care; strategies for providing services for populations at high-risk of TB including refugees and displaced persons; involving all providers of health care especially those that serve the poor by opening up access to quality drugs, training on effective care and supervision/monitoring of treatment outcomes, empowering communities in the design and implementation of TB control services. WHO's staff and partners working on TB control are working closely with their counterparts guiding analysis and interventions to address the social determinants of health. WHO is pursuing further research on the determinants of TB infection and disease, including those associated with economic poverty and other social vulnerability. WHO continues to examine gender-specific effects of TB, some which are associated with poverty. WHO together with the Stop TB Partnership has published guidance for National TB Programmes on the links between TB and poverty, lessons learnt in responding, and how to work with diverse partners within national poverty reduction strategies and local poverty alleviation efforts. The Stop TB Partnership's DOTS Expansion Working Group includes a sub-group with a funded Secretariat on TB and poverty. This group includes civil society, NGO, government and technical partners.

Question:

It seems obvious that the recent rise in cases of multi-drug resistant TB and extreme-drug resistant TB has been caused by weak basic DOTS programs. Essentially, poorly managed prevention programs are creating cases of MDR–TB and XDR–TB. How are you working to strengthen basic prevention and treatment programs to reduce and even eliminate the spread of MDR–TB and XDR–TB? What resources are

being devoted to health systems in this regard? Please describe the WHO's efforts to ensure that second-line treatments are properly used.

Response:

I would like to emphasize the Congressman's correct assertion that poor management of TB programmes does in fact lead to drug resistance development. To address this, WHO is aiming to a)strengthen basic DOTS services, b) expand DOTS to those areas still not using it (especially in the Former Soviet Union where the drug resistance problem is biggest in terms of concentration of drug resistance) and c) establish or strengthen DR management programs. Under the new Stop TB Partnership Global M/XDR–TB Response Plan, for which WHO has coordinated the development, calls for urgent actions in 2007 and 2008 to respond to these threats. This plan estimates that in 2007 alone $930 million is needed to serve affected countries, including support for laboratory strengthening which is required for early and effective TB diagnosis and detection of drug-resistant disease.

This plan supplements the ongoing needs to scale-up TB control implementation with full quality as envisioned in the Global Plan to Stop TB, 2006–2015. The gap for 2007 for TB control implementation is over $1.1 billion. We know that DOTS-based programs can reach and successfully treat patients as noted by the rapid scale-up of DOTS case detection to 60% by 2005 from single digit coverage a decade earlier, and treatment success rates of 84% from levels that were below 40% in many countries. So, we know basic DOTS programs are feasible. We are working within larger efforts to strengthen health financing, service delivery, logistics and human resources in countries where dysfunction of health systems is particularly critical—such as through basic packages of health services, contracting out to NGOs and private providers, developing comprehensive costed national health plans based on cost-effective services and human resources development, enabling community health workers to provide effective support to their clients, and to work with institutions and all providers to use drugs safely. This includes providing technical assistance via the Green Light Committee that vets proposals for financing multidrug-resistant treatment programs such that access to quality second-line drugs are provided at concessional prices, but that they are provided via trained providers, bolstered logistics systems and that their use is monitored. WHO also plays a key role in reviewing newer technologies as they become available for prevention, diagnosis and treatment to ensure that TB control programs can be strengthened as quickly as possible through more efficient and effective tools.

Question:

TB is the leading killer of people who are HIV/AIDS-positive. Because HIV/AIDS weakens a person's immune system, it makes them more susceptible to become infected with *TB. Each disease speeds up the progress of the other. People with HIV/AIDS are up to 50 times more likely to develop TB in a given year than HIV-negative people, and about 90% of people living with HIV infection die within four to twelve months of contracting TB if not treated. Given these facts, how are you working with other agencies, NGOs, and the international community to integrate HIV/AIDS prevention and treatment programs with TB prevention and treatment programs.*

Response:

WHO has worked with TB and HIV experts, control programmes and practitioners to develop policies on collaborative TB/HIV joint interventions, and related training, management, monitoring and advocacy tools. These policies were developed with and are endorsed by all partners in the Stop TB Partnership Working Group on TB/HIV, by WHO's Strategic and Technical Advisory Group on Tuberculosis as well as WHO's Strategic and Technical Advisory Committee on HIV/AIDS, and by UNAIDS. Their principles have been adopted by the Global Fund for the development of TB and/or HIV project proposals with joint TB/HIV components. Through the Working Group on TB/HIV, for which WHO provides the Secretariat, a wide range of National AIDS and TB programs, NGOs, partners (including PEPFAR (and its cooperating US agencies including USAID, CDC and others), the Global Fund, UNITAID, World Bank, bilateral agencies and others) are all supported via the sharing of information on the adaptation of these policies at country and local level, the development of common monitoring and evaluation indicators, and problem-solving in facing implementation bottlenecks. Approaches on how coordination of TB and HIV programs can be strengthened via planning, supervisory systems, and service delivery and logistics support approaches, using all those engaged in health systems, including communities and the private sector. WHO is collaborating across programs on human resources challenges, via the Treat, Train and Retain program and via task-shifting approaches to involve more diverse service providers, and through contributions to comprehensive human resources development planning.

Data are beginning to be available that document, in Africa and elsewhere the fruits of this coordination, through numbers of patients tested for HIV and TB infection and/or disease, those initiated on preventive therapies or anti-retroviral treatment or TB treatment. The challenge now is urgently increasing resources and support to scale-up far more quickly. One quick source of information on work being done is the WHO TB/HIV website: http://www.who.int/tb/hiv/en/

WRITTEN RESPONSES FROM THE HONORABLE KENT R. HILL, ASSISTANT ADMINISTRATOR, BUREAU FOR GLOBAL HEALTH, U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE ADAM SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Question:

The burden of TB disproportionately affects the poor. Globally, the highest burden of TB is found in poor countries. 17 of the 22 countries that account for 80% of the world's TB burden are classified as low income (as defined by the World Bank as GNP per capita less than $760). Poverty is rightly recognized as a key cross-cutting issue for TB control. One of the Millennium Development Goals (MDGs) is to cut extreme poverty by half by 2015 and the goals set forth by the Global Plan to Stop TB are to reduce the number of TB cases worldwide. Because of the link between poverty and TB and these recent goals set forth by the international community, it seems that this provides a unique opportunity address both poverty and TB. Given these two goals, how are you working with others to coordinate efforts and align a plan to help achieve both poverty and TB reduction goals?

Response:

Jointly addressing TB and poverty requires a 2-pronged approach—namely, to mitigate the impoverishing effects of TB and to enhance the socio-economic status of TB patients as a target population for poverty alleviation.

In terms of mitigating the impoverishing effects of TB, there is a misperception that the treatment of any TB patient is de facto a pro-poor intervention. In fact, research has demonstrated that many of the poorest TB patients are not able to access or adhere to TB treatment. USAID is targeting TB services to better reach the poor and to mitigate the impoverishing effects of TB. Our TB program prioritizes higher funding levels to 19 countries where poverty and TB overlap. Of these, 13 are low-income countries, as defined by the World Bank. In the other six countries, TB occurs disproportionately in the poorest populations.

USAID programs actively support pro-poor approaches for the delivery of TB services. These interventions reduce the burden of time and money for those seeking care. Examples include use of community health workers and engaging non-governmental organizations (NGOs) in remote areas. USAID staff were among the founding members of the TB and poverty sub-group of the STOP TB Partnership, which provides global policy guidance on TB and poverty issues.

In terms of enhancing the socio-economic status of TB patients as a target population for poverty alleviation, USAID has established an evidence base to suggest that TB patients, their families, and communities are efficient targets for poverty alleviation interventions, based on experience with food subsidies for TB patients.

To date, USAID has not yet fully capitalized on opportunities to target TB patients with poverty alleviation interventions, either within USAID or with external partners. Within USAID, the TB program could very well benefit from collaboration on: micro-finance enterprise programs to support TB patients and their families; income-generation activities among HIV-infected and affected populations, including those co-infected with TB, to extend the beneficiaries; and the Food for Peace Program to target food subsidies to TB patients and their communities on a large scale. Externally, additional opportunities for collaboration include: the World Bank to promote the inclusion of the health sector and TB programs, as beneficiaries of debt relief following the development of Poverty Reduction Strategy Papers; and private sector micro-enterprise programs in countries with USAID funding for TB, such as with the Grameen Bank in Bangladesh, to coordinate poverty alleviation interventions among TB patients.

Question:

It seems obvious that the recent rise in cases of multi-drug resistant TB and extreme-drug resistant TB has been caused by weak basic DOTS programs. Essentially, poorly managed prevention programs are creating cases of MDR–TB and XDR–TB. How are you working to strengthen basic prevention and treatment programs to reduce and even eliminate the spread of MDR–TB and XDR–TB? What resources are

being devoted to health systems in this regard? Please describe USAID's efforts to ensure that second-line treatments are properly used.

Response:

USAID shares your concern about the threat of multi-drug resistant (MDR) TB and extensively drug resistant (XDR) TB. Our programs focus on strengthening basic TB treatment services and health systems, although we have been addressing MDR TB since we began working on TB in 1998. While our focused TB programs make major contributions to health system improvement at the country level—including effective drug management and use of information—USAID supports a number of cross-cutting programs to improve health systems for TB, malaria, maternal and child health, and other priority health areas. These include improved approaches to quality assurance, workforce development, use of information, and support for health systems.

The highest priority intervention to prevent the development of MDR TB and XDR TB is to ensure good quality basic TB control services, based on the World Health Organization's (WHO's) recommended Directly Observed Treatment, Short-Course (DOTS) strategy[1]. USAID supports TB programs in 37 countries—including in 17 of the 22 High Burden Countries[2]—where we focus on strengthening health systems to deliver DOTS. Between 2000 and 2006 we provided $334 million to bilateral TB programs and $17.9 million to the Global TB Drug Facility to support grants for TB drugs. Our activities include laboratory strengthening, training, technical assistance, and engagement of private providers and communities in TB care.

USAID has also been a leading supporter of efforts to control MDR TB. We focus on measures to ensure the appropriate use of second-line drugs. USAID supported the development of DOTS Plus—the WHO recommended approach for treatment of MDR TB. We support capacity building for DOTS Plus programs and for management of first- and second-line anti-TB drugs. USAID is also a key supporter of the Green Light Committee (GLC), which is a unique WHO-coordinated mechanism that provides technical assistance to help ensure the quality and effectiveness of programs to treat MDR TB in order to prevent the development of resistance to second-line drugs. Since the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) requires that all grants which include second-line drugs be approved by the GLC, our support to GLC is very critical for helping to ensure the quality of DOTS Plus services funded by the Global Fund.

A key challenge in dealing with MDR TB and XDR TB is building the capacity of health personnel to treat MDR TB and XDR TB patients. In March 2006, USAID, in partnership with the Centers for Disease Control and Prevention (CDC) and the South African Department of Health, established the Africa Regional International Training and Research Center on MDR TB and HIV. Working through the Center, we are helping to train personnel from South Africa and the region. USAID, working with CDC, also helped establish the International Training Center for MDR TB at the Latvian State Centre for TB and Lung Diseases.[3] The rates of MDR TB in Latvia have fallen from 14 percent in 1994 to 8 percent in 2003, making the country a model for others.

Question:

TB is the leading killer of people who are HIV/AIDS-positive. Because HIV/AIDS weakens a person's immune system, it makes them more susceptible to become infected TB. Each disease speeds up the progress of the other. People with HIV/AIDS are up to 50 times more likely to develop TB in a given year than HIV/AIDS-negative people, and about 90% of people living with AIDS die within four to twelve months of contracting TB if not treated. Given these facts, how are you working with other agencies, NGOs, and the international community to integrate HIV/AIDS prevention and treatment programs with TB prevention and treatment programs?

Response:

Because TB, including XDR TB, is particularly dangerous for people with HIV/AIDS, effective coordination between TB and HIV/AIDS programs is an essential component of addressing this issue. USAID provides funding to TB programs in nine

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[1] DOTS is the brand name for the WHO recommended five-pronged approach to TB control: political commitment, diagnosis of TB cases with smear microscopy, standardized treatment with patient support/supervision, reliable drug supply, and monitoring and evaluation.

[2] The 22 High Burden Countries are responsible for 80% of the global burden of TB.

[3] In recognition of the International Training Center for MDR TB's high standards, in 2004 WHO named it an official WHO Collaborating Center for Research and Training in the Management of MDR TB. The Center trains health personnel from the Eastern European region, former Soviet Union states and other regions.

of the Africa focus countries for the President's Emergency Plan for AIDS Relief (PEPFAR). Our TB programs help to strengthen TB services for the general population in these countries and are directly complementary to the assistance provided by PEPFAR to reach HIV infected populations. At the country level, USAID TB programs work with the public sector, NGOs, and Faith-based Organizations, including missionary hospitals that are providing HIV/AIDS treatment and TB treatment. Our assistance focuses on policy development, training (including cross training of staff), and technical assistance in areas such as HIV testing of TB patients, screening of HIV patients for TB, reporting and referral systems, and helping to integrate services where appropriate. Our programs also support the engagement of community-based groups in providing treatment to people with both diseases.

USAID places a high priority on collaboration with PEPFAR, since promoting TB–HIV/AIDS collaborative activities in PEPFAR focus countries is critical for effective care of HIV patients and for addressing the spread of TB. A member of USAID's TB team is the co-chair of the PEPFAR TB–HIV/AIDS working group that is responsible for providing policy and technical guidance to PEFPAR on TB–HIV/AIDS issues, and USAID staff provide technical assistance on TB–HIV/AIDS issues to country programs.

At the international level, USAID is actively engaged in the STOP TB Partnership's TB–HIV/AIDS working group, the international body comprised of leading international TB and HIV/AIDS organizations, including UNAIDS that guides global policy and efforts to address TB–HIV/AIDS. We are also working with the International Union Against TB and Lung Disease and with WHO on research to improve treatment of persons co-infected with both diseases.

WRITTEN RESPONSES FROM THE HONORABLE MARK R. DYBUL, COORDINATOR, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE ADAM SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Question:

The burden of TB disproportionately affects the poor. Globally, the highest burden of TB is found in poor countries. 17 of the 22 countries that account for 80% of the world's TB burden are classified as low income (as defined by the World Bank as GNP per capita less than $760. Poverty is rightly recognized as a key cross-cutting issue for TB control. One of the Millennium Development Goals (MDGs) is to cut extreme poverty by half by 201 5 and the goals set forth by the Global Plan to Stop TB are to reduce the number of TB cases worldwide. Because of the link between poverty and TB and these recent goals set forth by the international community, it seems that this provides a unique opportunity address both poverty and TB.

Given these two goals, how are you working with others to coordinate efforts and align a plan to help achieve both poverty and TB reduction goals?

Response:

Addressing HIV/TB and drug-resistant tuberculosis (TB) is particularly challenging in impoverished settings heavily affected by HIV/AIDS. In sub-Saharan Africa and elsewhere, TB-control programs are already overburdened, and are often unable to deal with the increase in TB cases among people who are living with HIV/AIDS. The U.S. Government (USG) is increasing its support for HIV/TB co-infection to address some of the major challenges that are facing HIV/AIDS and TB programs including: coordination to ensure that high-quality HIV/TB care is available to co-infected individuals; trained human capacity to implement collaborative programs; an adequate policy environment that supports confidential, provider-initiated counseling and testing; task shifting to expand care; strengthening the laboratory network and supply chain to allow for the use of rapid test kits and improved diagnoses of opportunistic infections such as TB; expanding antiretroviral therapy (ART) so eligible TB patients will have access; and better coordinating partner resources to meet key resource gaps.

The USG, through the President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) and other programs, supports a comprehensive approach to HIV/AIDS prevention, treatment, and care, and actively finances efforts to integrate HIV/AIDS and TB care. Appropriate and full treatment of TB is vital, not only to prevent HIV-positive people from dying but also to alleviate the risk of their developing drug-resistant TB. One study reported an 80-percent reduction in the incidence of TB among HIV-positive people who are on antiretroviral treatment, as compared to those who are not receiving HIV therapy. There are a number of models that exist in which the same clinic delivers TB treatment, antiretroviral treatment,

and care; more widespread are facilities in which TB and HIV/AIDS treatment and care clinics are co-located in the same or separate buildings.

Ensuring availability of comprehensive care is a key Emergency Plan goal, and we encourage host Governments and partners to consider and implement joint or co-located TB and HIV/AIDS programs wherever feasible. While promoting increased integration, we recognize these efforts face considerable challenges, particularly in the area of TB infection control, supply chain, and human capacity.

The USG also supports the implementation of the Global Plan to Stop Tuberculosis, carried out in concert with the STOP TB Partnership. These efforts primarily focus on improving the quality of TB-control programs in countries with a high burden of TB, or in those countries that contribute most to the U.S. epidemic. This work involves close collaboration between the U.S. Agency for International Development (USAID), the U.S. Department of Health and Human Services (HHS), the Office of the U.S. Global AIDS Coordinator, and other Federal Departments and agencies. Internationally, the USG works closely with the World Health Organization (WHO), the International Union Against TB and Lung Diseases, and the Royal Dutch Tuberculosis Foundation (KNCV).

Question:

TB is the leading killer of people who are HIVIAIDS-positive. Because HIV/AIDS weakens a person's immune system, it makes them more susceptible to become infected TB. Each disease speeds up the progress of the other. People with HIV/AIDS are up to 50 times more likely to develop TB in a given year than HIV/AIDS-negative people, and about 90% of people living with AIDS die within four to twelve months of contracting TB if not treated.

Given these facts, how are you working with other agencies, NGOs, and the international community to integrate HIV/AIDS prevention and treatment programs with TB prevention and treatment programs?

Response:

As you note, tuberculosis (TB) is the number-one killer of people living with HIV—which is why the President's Emergency Plan for AIDS Relief (PEPFAR/Emergency Plan) is leading a unified U.S. Government (USG) global response to integrate HIV and TB fully into care programs at the country level. The USG's goal is to help ensure people who are infected with HIV receive the best treatment and care possible, to prevent them from contracting TB in the first place, which is critical to the long-term control of TB at the global level. Countries such as Kenya and Rwanda have been leaders in a collaborative response to HIV/AIDS and TB, and the Emergency Plan has been a major source of financial support for their efforts. All of the 15 focus countries of the Emergency Plan include TB/HIV activities in their Country Operational Plans, and many are making significant progress.

The USG recognizes the significance of these dual epidemics, and the danger they pose for societies worldwide, particularly in settings of high HIV prevalence, which is why Emergency Plan financial support for TB/HIV has increased close to five-fold in just three years—from $25.5 million in 2005, to $48.6 million in 2006, to at least $120 million in Fiscal Year 2007 ($50 million more than originally planned). As of September 2006, the Emergency Plan supported care for approximately 301,000 TB/HIV co-infected people in the 15 focus countries.

The USG's most important work in combating TB takes place through partnerships at the country level to support national health authorities, non-governmental organizations, and community- and faith-based organizations to implement more effective TB/HIV activities. Interventions include supporting confidential HIV testing for people with TB, and improving TB diagnosis for people with HIV; supporting isoniazid preventive therapy for HIV-infected people to reduce their risk of developing active TB; improving TB infection control to prevent people with HIV from coming in direct contact with someone with active TB; implementing the International Standards for TB Care, which build on the Directly Observed Therapy, Short Course (DOTS) strategy, to ensure patients complete their TB treatment; and improving laboratory surveillance systems to detect outbreaks of multi-drug resistant TB (MDR–TB) and extensively-drug resistant TB (XDR–TB).

The Emergency Plan also supports expanding the capacity of the local health workforce in the focus countries to deal with these dual epidemics and to improve supply-chain management systems for medications and other commodities. It also is essential to establish linkages between TB treatment and antiretroviral therapy so people who are co-infected receive the medical attention they need, while taking care to ensure appropriate TB infection-control measures are in place.

The USG also supports multilateral TB initiatives, and is the largest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), having con-

tributed nearly one-third of the Global Fund's resources. Through 2007, the Global Fund will have committed a total of $1.4 billion to 141 TB grants. The USG also supports the Green Light Committee, which screens proposals to the Global Fund that involve treatment for multi-drug resistant TB. The USG works with the World Bank, the WHO, the Joint UN Programme for HIV/AIDS (UNAIDS), the International Union Against TB and Lung Disease, and the private sector, and also participates in the WHO Global XDR–TB Task Force, which is finalizing a global plan to respond to the spread of the disease.

Finally, the USG is working with the WHO Secretariat to leverage the WHO's comparative advantage in driving change, supporting and mobilizing Health Ministries and other authorities, and convening and coordinating both national and local partnerships. This will help all partners achieve their goals of testing all TB patients for HIV; ensuring their access to HIV prevention, treatment, and care; and identifying and ensuring TB treatment for HIV-positive individuals found to have TB disease. Multilateral efforts to address TB/HIV include the promising WHO–USG TB/HIV collaborative project in Ethiopia, Kenya, and Rwanda. This two-year, $2 million project supports the WHO's efforts to foster confidential HIV-counseling and testing for clients who attend TB clinics, as well as linkages between TB and HIV/AIDS program areas, to improve access to antiretroviral treatment.

WRITTEN RESPONSES FROM THE HONORABLE MARK R. DYBUL, COORDINATOR, OFFICE OF THE U.S. GLOBAL AIDS COORDINATOR, U.S. DEPARTMENT OF STATE, TO QUESTIONS SUBMITTED FOR THE RECORD BY THE HONORABLE CHRISTOPHER H. SMITH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Question:

Thank you for your response to the question during the hearing concerning Global Fund grants to faith-based organizations. However, this raises further questions concerning the structure and operation of the Country Coordinating Mechanisms. If the CCMs are operating properly, then one would generally infer that they are distributing grants to FBOs in approximately the same proportion as FBOs contribute to health care within the particular country.

What measures could the Global Fund undertake and/or what mechanisms could be instituted to address situations where the percentage of grants by CCMs to FBOs is significantly less than the percentage of health care services provided by FBOs? Is the Administration working with the Global Fund to implement such measures/mechanisms?

Response:

In the Global Fund grant process, the Country Coordinating Mechanism (CCM) develops, consolidates and approves proposals for submission to the Global Fund. The CCM also selects the Principal Recipient (PR) and monitors grant performance once grants are awarded. It is the PR that signs the formal grant agreement with the Global Fund, and the PR distributes funding to sub-recipient (secondary or tertiary) grantees, which in turn use the funds to carry out health-related activities on the ground.

Clearly, a strong multi-sectoral CCM plays a determinative role in ensuring that grant funds are distributed to secondary and tertiary sub-recipients (SRs) that are well-placed to implement programs. In instances in which a Government dominates a CCM, the Government might channel funds towards its own agencies with little consideration of other potential service providers.

The U.S. Government (USG) has undertaken sustained efforts to help strengthen the role and representation of non-governmental organizations (NGOs), including representatives from faith-based organizations (FBOs) and community-based organizations (CBOs) on CCMs. At our urging, the Board adopted a policy that requires CCM members representing the non-government sectors to be "selected/elected by their own sector(s) based on a documented, transparent process, developed within each sector." The USG is also providing direct technical assistance (TA) to help a number of CCMs improve their governance capabilities, as well as their ability to monitor and evaluate grants effectively. We believe these continuing efforts will lead to appropriate non-governmental representatives with an important stake in the health sector playing increasingly influential roles on their CCMs.

The Global Fund Secretariat has also undertaken several activities recently to strengthen the representation of stakeholders on CCMs, including sponsoring several regional conferences to instruct stakeholders on CCM requirements and share best practices. During Round 6, the Global Fund Secretariat took the difficult step

of disqualifying the Round 6 proposals of three country partnerships in Angola, Cape Verde, and Iran because they did not meet these requirements.

Because the PR is often the Ministry of Health, a large international NGO, or a United Nations office, the number of FBO sub-recipients could be a more relevant indictor of the role and impact of FBOs in Global Fund activities than the number of FBO PRs. However, determining the aggregate amount of Global Fund money that goes to sub-recipients that are FBOs is extremely difficult. The Global Fund does not systematically collect or report on this data.

The USG, in its role as Global Fund Board Member, is pushing the Global Fund both to collect more information about SR activities and to include evaluation of the performance of SRs in the mandate of the Global Fund's contracted Local Fund Agents (LFAs). Increased availability of this information will allow the USG and other partners to help the Global Fund better assess the effectiveness of its funding.

Question:

Are CCMs required to provide meaningful representation to FBOs and community organizations on the CCMs? If so, how is such representation ensured, such that CCMs do not simply list an FBO and community organization as a member but also make provisions for these organizations to be actively involved and have substantive input into the grant process?

Response:

The Global Fund adopted "Revised Guidelines on the Purpose, Structure and Composition of Country Coordinating Mechanisms (CCMs) and Requirements for Grant Eligibility" at its 9th Board Meeting in November 2004. These guidelines include the following:

1. *Requirements:*

   a) The Global Fund requires all CCMs to show evidence of membership of people living with and/or affected by the diseases.

   b) CCM members representing the non-government sectors must be selected / elected by their own sector(s) based on a documented, transparent process, developed within each sector.

2. *Recommendations:*

   a) All countries strive to include the following actors in their CCMs:
   - Academic/Educational Sector;
   - Government;
   - NGOs/Community-Based Organizations;
   - People living with HIV/AIDS, TB and/or Malaria;
   - Private Sector;
   - Religious/Faith-Based Organizations;
   - Multilateral and Bilateral Development Partners in-country.

   b) The membership of the CCM comprise a minimum of 40 percent representation of the non-government sectors such as NGOs/community based organizations, people living with the diseases, religious/faith-based organizations, private sector, academic institutions.

As noted in the preceding answer, the Global Fund Secretariat does not provide systematic data on FBOs that are involved in Global Fund grants. Therefore, clear data on the number of FBOs receiving Global Fund financing, or the amount of money they receive, is not available.

From the limited information that is available, however, we know that FBOs take part in Global Fund policy-making and implementation activities in the following ways:

a) The Global Fund has signed grant agreements in at least seven countries designating FBOs as PRs. For example, Catholic Relief Services is a PR in Madagascar, World Vision is a PR in Armenia and Guatemala, and the Churches Health Association of Zambia is a PR for five Global Fund grants in Zambia. In addition, the Lutheran World Federation is the PR for a global HIV/AIDS grant, while the Christian Health Association of Nigeria and the Zimbabwe Association of Church-Related Hospitals are also PRs in their respective countries.

b) FBOs also serve as SRs of Global Fund grants. The lead SR for the Tanzania Round 3 HIV/AIDS grant is the Christian Social Services Commission, a local FBO. Catholic Relief Services is an SR in Gambia, Hope Worldwide is an SR in Jamaica, and Children's Cup is an SR for programs for orphans and vulnerable children in Swaziland, where it is funded by the (Product) RED campaign. Meanwhile, an April 2007 news report from India says "the Global Fund to Fight AIDS, Tuberculosis and Malaria . . . has decided to support 45 new

HIV/AIDS centres to be opened by the Catholic Church in different parts of the country."

c) Representatives of the faith community do serve as members of CCMs in many countries. While the Global Fund Secretariat does not keep a systematic tally of how many CCM members represent FBOs, an examination of organizational names appearing on a comprehensive list of over 3000 CCM members worldwide indicates that at least 150 FBOs have direct CCM representation in at least 70 countries.