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THE TOM LANTOS AND HENRY J. HYDE GLOBAL LEADERSHIP AGAINST HIV/AIDS, TUBERCULOSIS, AND MALARIA REAUTHORIZATION ACT OF 2008

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Mr. BIDEN, from the Committee on Foreign Relations, submitted the following

REPORT

together with

MINORITY VIEWS

[To accompany S. 2731]

The Committee on Foreign Relations, having had under consideration the bill (S. 2731) to authorize appropriations for fiscal years 2009 through 2013 to provide assistance to foreign countries to combat HIV/AIDS, tuberculosis, and malaria, and for other purposes, reports favorably thereon with an amendment and recommends that the bill, as amended, do pass.

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I. SUMMARY

S. 2731, the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 [hereafter the Reauthorization Act], authorizes $50 billion for United States bilateral and multilateral

programs to combat human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS) [hereafter referred to as "HIV/AIDS"], tuberculosis (TB) and malaria for fiscal years 2009 through 2013. This Act seeks to build on the remarkable successes achieved during the last 5 years by the President's Emergency Plan for AIDS Relief (PEPFAR) and by the promising start of the President's Malaria Initiative and to support a transition from an emergency approach to more country-driven strategies that will better allow public health professionals on the ground to combat the local HIV/AIDS, TB, and malaria epidemics that they confront.

This Act sets out ambitious targets for HIV/AIDS prevention, treatment, and care while removing funding directives that have served as stove-pipes for those interventions and limited the flexibility of professionals in the field who plan and implement the programs. Of the three goals, it prioritizes prevention as the most critical element in slowing the pandemic and reversing its course. In pursuing this goal, the Act requires a balanced approach to the prevention of the sexual transmission of HIV—emphasizing the importance of behavior change programs to promote abstinence, fidelity, the reduction of concurrent sexual partners, and the delay of sexual debut along with programs to promote the correct and consistent use of condoms.

HIV/AIDS epidemics do not occur in isolation. Persons and communities affected by HIVAIDS are also affected by other economic and health challenges that can have a direct effect on prevention, care, and treatment outcomes. Continuing the guidelines established in the U.S. Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (P.L. 108–25) [hereafter the 2003 Leadership Act], this Act promotes the further coordination of care and treatment programs with other life-changing interventions such as nutritional support, and more cohesive integration of these disease-specific programs within the broader United States health and development agenda. S. 2731 increases the focus on women and girls, particularly in terms of addressing the factors that make them more vulnerable to the transmission of HIV. It emphasizes the need for improved internal coordination and enhanced harmonization with other international actors and partner countries and authorizes, although it does not mandate, bilateral and regional framework or "compact" agreements. It seeks to strengthen health capacity in developing countries affected by these epidemics, by promoting the training and retention of personnel and improvements in infrastructure, management, finances, and health systems. The legislation enhances oversight and emphasizes the importance of operations research to evaluate and maximize the impact of United States assistance. Finally, the Reauthorization Act would repeal a provision in law that differentiates HIV/AIDS from all other diseases and currently makes HIV infection the only statutory grounds for barring prospective international visitors from entry into the United States.

II. Background and Purpose of the Legislation

In his State of the Union address on January 28, 2003, President George W. Bush announced a dramatic proposal: To spend $15 billion over 5 years to combat HIV/AIDS globally, particularly in sub-Saharan Africa, the region hardest hit by the pandemic, and he

called for the creation of the President's Emergency Plan for AIDS Relief (PEPFAR). Congress responded promptly, authorizing the full amount requested by the President and expanding the diseases covered through the 2003 Leadership Act which was signed into law May 27, 2003. Congressional support for the program has been strong and steady; Congress has appropriated over $19.7 billion since then to combat these three diseases through bilateral and multilateral programs.

The 2003 Leadership Act provided a roadmap for an ambitious plan to achieve objectives in the prevention, care, and especially the treatment of HIV/AIDS.[1] To oversee these programs, the 2003 Leadership Act established within the Department of State—a Coordinator of United States Government Activities to Combat HIV/AIDS Globally [hereafter the Global AIDS Coordinator], to be appointed by the President with the advice and consent of the Senate. The Office of the Global AIDS Coordinator (OGAC) leads interagency implementation and administration of U.S. global HIV/AIDS policy. The 2003 Leadership Act required a 5-year emergency plan (for fiscal years 2004–2008) designed to coordinate all U.S.-funded bilateral HIV/AIDS programs, including those established by the President's Emergency Plan for AIDS Relief, and administered through seven implementing agencies,[2] to address the emergency. The bill specifically mentioned 14 countries within the Coordinator's oversight and authorized the President to name additional countries to this list.[3] The 2003 legislation also included provisions to address TB and malaria and authorized participation in the Global Fund to Fight AIDS, Tuberculosis and Malaria [hereafter the Global Fund]—a multilateral financing mechanism to manage and disburse resources to fight the three diseases. The Global Fund now provides grants in 138 countries. The United States remains the leading contributor to the Global Fund, having pledged over $3.7 billion to date.

In 2003, roughly 50,000 people in all of Africa were receiving antiretroviral (ARV) pharmaceutical treatment for AIDS, though, according to current data, an estimated 21.6 million people in Africa were HIV positive at that time.[4] Some people argued that large-scale, successful treatment in such resource-poor settings was impossible. To counter these arguments and to address this most urgent issue—trying to reverse a sentence of certain death for millions and simultaneously provide an incentive for getting tested for

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[1] The human immunodeficiency virus is the underlying cause of AIDS. Most people who are infected with HIV are not yet in need of ARV treatment; rather they need monitoring of their condition. AIDS is diagnosed when an HIV-positive person's immune system deteriorates to a specific point, most often evaluated on the basis of a person's CD4 count or when he/she acquires certain opportunistic infections or malignancies associated with AIDS. [CD4 cells coordinate the immune system's response to certain micro-organisms such as viruses and may be seen as one barometer of a person's progression toward AIDS—if CD4 counts fall below a certain level, physicians recommend initiating ARV treatment, which must then be continued for life.]

[2] The Department of State, the United States Agency for International Development (USAID), the Department of Health and Human Services, the Department of Defense, the Department of Commerce, the Department of Labor, and the Peace Corps.

[3] The original 14 named countries were Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia. The President added Vietnam to this list in 2004. Currently approximately 60 percent of PEPFAR assistance is directed to these 15 countries.

[4] As the available HIV/AIDS data has improved, the Joint United Nations Programme on HIV/AIDS (UNAIDS) has revised earlier estimates of HIV prevalence. In 2003, when the Leadership Act was enacted, it was estimated that approximately 42 million individuals were infected with HIV; UNAIDS' more recent analysis estimates that 30.9 million people were likely HIV positive in 2003, of whom 21.6 million were in sub-Saharan Africa.

HIV—the 2003 Leadership Act emphasized treatment among the three goals, establishing first through a Sense of Congress provision and subsequently through a budgetary directive that 55 percent of bilateral assistance should go to therapeutic medical care, with at least 75 percent of that allocation to be expended for the purchase and distribution of antiretroviral pharmaceuticals. The legislation also recommended that 15 percent of funds go toward palliative or supportive care [5] and required in the later fiscal years that 10 percent of funding go to provide for the needs of orphans and vulnerable children.

As part of the 2003 Leadership Act, Congress also established parameters to support prevention efforts. The 2003 legislation recommended a spending level of 20 percent for prevention programs and, for fiscal years 2006 to 2008, required that one-third of prevention funds go toward promoting abstinence until marriage. This prevention approach was based on examples of successful efforts in Uganda and elsewhere to reduce the transmission of HIV/AIDS through an "ABC approach"—Abstain, Be faithful, and use Condoms.

The 2003 Leadership Act recognized the importance of a multidimensional strategy and the bill included provisions relating to the empowerment of women, including requiring strategies to enhance their empowerment in interpersonal situations and to increase their access to employment opportunities, income, productive resources, and microfinance programs and authorizing assistance in these areas. The Act also recognized the importance of nutrition and called for the Administrator of the United States Agency for International Development (USAID) to integrate nutrition programs with HIV/AIDS activities as appropriate.

Over the course of the last 5 years, the United States has made tremendous strides in leading the global campaign against HIV/AIDS, particularly establishing treatment programs. With the support of PEPFAR and the Global Fund, over 1.99 million people have received ARVs.[6] Millions more have been the beneficiaries of palliative care and prevention educational and outreach efforts and commodities. U.S. programs have helped to ensure that over 150,000 infants, most in sub-Saharan Africa, who likely would have been infected with HIV in utero or during birth were not. Over 33.7 million people have received voluntary counseling and HIV testing. Faith-based and community-based organizations have played pivotal roles in the success of these programs, delivering services on the front lines of the war against HIV/AIDS.

While these achievements are impressive, the pandemic continues to outpace them. The 2007 AIDS Epidemic Update of the Joint United Nations Programme on HIV/AIDS (UNAIDS) brought the welcome news that global prevalence estimates were lower than earlier projections, but even these revised numbers indicated that approximately 33.2 million people in the world are living with

[5] OGAC guidance on palliative care states "Comprehensive palliative care is essential to the health and well-being of people living with HIV/AIDS (PLWHA) and is an integral part of the President's Emergency Plan for AIDS Relief (the Emergency Plan). Palliative care has traditionally been associated with terminal or end-of-life care. However, current thought and practice and Emergency Plan policy take the broader view that palliative care encompasses care provided from the time that HIV is diagnosed and throughout the continuum of HIV infection."

[6] According to the most recent PEPFAR report to Congress, PEPFAR and the Global Fund jointly support 909,000 people on treatment; PEPFAR alone supports approximately 544,000 people, and the Global Fund alone supports 539,000 people.

HIV; that 2.1 million people died of AIDS-related causes in 2007; and that 2.5 million people became newly infected in 2007, meaning that for every person who enrolled in a treatment program, approximately six more reportedly became HIV positive.[7] Furthermore, most people who are infected with HIV remain untested and undiagnosed.

Sub-Saharan Africa remains by far the most affected region of the world: An estimated 22.5 million people there are living with HIV, over two-thirds of the global population of persons who are HIV-positive, and the region suffered more than three quarters of all AIDS deaths in 2007. In six countries in southern Africa (Botswana, Lesotho, South Africa, Swaziland, Zambia, and Zimbabwe), estimated prevalence rates continue to exceed 15 percent. Women and girls make up over 60 percent of persons in sub-Saharan Africa who are HIV infected, and the disparities along gender lines are even more striking among younger age cohorts. Africa is most affected but not alone. Rates of HIV incidence (the number of new infections in a population in a given year) are rising in East Asia. The Caribbean has the second highest regional prevalence rate at 1.0 percent (with Haiti and the Dominican Republic accounting for three quarters of the 230,000 people living with HIV in the Caribbean), while Eastern Europe and Central Asia are experiencing prevalence rates of 0.9 percent with an estimated 1.6 million people living with HIV. Illicit injection drug use continues to be a major driver of the epidemic; unsafe sex among men who have sex with men and the commercial sex trade are also significant means of transmission in many areas. These basic demographic realities must continue to shape the U.S. strategy on HIV/AIDS, as should the economic need of recipient countries, as these programs enter a new phase of operations.

The U.S. global HIV/AIDS initiative, like the Marshall Plan, represents American foreign policy at its best. It demonstrates the efficacy of U.S. assistance and the generosity of the American people. It has also demonstrated the ability to adapt both to changing conditions on the ground and to more accurate data as it has become available. This Reauthorization Act seeks to enhance that flexibility and to reflect the progress that has been made and the lessons learned. As this program continues to grow and potentially expands to other poor countries, it will face new challenges. As treatment rosters grow, so does the responsibility to maintain them—a patient on ARV treatment must, for now at least, continue taking the medication for the rest of his or her life. This fact, and its clear economic and moral implications, reinforces the need to improve and expand prevention efforts. While treatment must remain a key component of our strategy, without greater emphasis on prevention, HIV/AIDS will never be successfully controlled or contained. Countries currently receiving our assistance are eager to assume greater leadership but lack much of the capacity,

[7] Data on global and regional prevalence and incidence rates are from the report of the United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO), "AIDS epidemic update" (December 2007). The December UNAIDS 2007 report significantly reduced prevalence estimates from previous years and included a revised estimate of approximately 32 million persons living with HIV, down from the 2006 estimate of 38.6 million. These revised estimates stemmed most directly from improved data in countries such as India, rather than changes in the epidemic, but they also reflected notable reductions in prevalence rates in several countries, including Kenya and Zimbabwe.

healthcare workforce, and delivery systems to do so. Improved harmonization of U.S. programs with one another and with other international actors is necessary to maximize impact; and a clearer roadmap is needed of how global HIV/AIDS programs fit into the broader U.S. health and development agenda.

S. 2731 recognizes the lethal impact of tuberculosis and malaria and authorizes a substantial increase in resources to address these deadly diseases. Together, TB and malaria claim over 2.6 million lives a year, and they have a devastating effect on economic development in many countries. The Act, building on the initial inclusion of these diseases in the 2003 Leadership Act, seeks to strengthen these efforts and to promote improved coordination across prevention and care programs for HIV/AIDS, TB, and malaria and between these programs and other U.S. assistance efforts.

III. REAUTHORIZATION ACT OF 2008

The reauthorization of the 2003 Leadership Act for FY 2009–2013 is designed to respond to these challenges. It sets ambitious targets for treatment, care, prevention, pediatric treatment, care for orphans and vulnerable children, and the prevention of mother-to-child transmission, and for helping countries to train and retain healthcare workers. Among these goals, the Act explicitly prioritizes prevention as critical to saving lives in recognition of both the progress made in initiating path-breaking treatment programs and the fact that we must do more to break the cycle of new infections. It underscores the value of the ABC approach to preventing the sexual transmission of HIV and requires a balanced approach to prevention. The Reauthorization Act recognizes that the drivers of the epidemic vary from country to country and that our public health professionals and their partners should be given the means to respond to these variances as well. The legislation emphasizes capacity-building, coordination, and evaluation and oversight and calls for an increased focus on the needs and vulnerabilities of women and girls. It addresses the grave threats posed by malaria and tuberculosis, including the increasing dangers of drug-resistant TB. Finally, it supports a transition from a U.S.-led emergency approach to a more sustainable, country-driven public health strategy toward HIV/AIDS, including increased technical assistance to improve the capabilities of partner governments to play such a role. To accomplish these goals, the Reauthorization Act increases U.S. funding for bilateral and multilateral HIV/AIDS, tuberculosis, and malaria programs to $50 billion over the next 5 fiscal years.

Estimates of Funding

The $50 billion, 5-year authorization will provide a total of $41 billion for bilateral HIV/AIDS programs and the Global Fund, $5 billion for malaria programs, and $4 billion for tuberculosis programs. The committee chose not to assign annual spending for the $50 billion in order to allow for these programs to be increased over time as services are expanded and to accommodate absorptive capacities. The Reauthorization Act authorizes up to $2 billion for the Global Fund for fiscal year 2009 and such sums as are necessary for the following 4 fiscal years.

The Global Stop TB Partnership, of which the United States is a member, has estimated that total country needs to achieve the

goals of the Global Plan to Stop TB will require $24.9 billion over the 2009 to 2013 period. The plan calls for 57 percent of funds to go toward the expansion of Daily Observed Treatment Short-course (DOTS) therapy, with the remainder directed primarily toward TB/HIV programs; DOTS-Plus programs that supplement the standard DOTS strategy in areas with significant drug resistance; TB drugs; and vaccine research and development.

The WHO's current best estimate of global need for malaria programs as outlined in the Global Malaria Business Plan of the Roll Back Malaria partnership is $4.1 billion per year (which the WHO breaks down to $3.2 billion for implementation and $0.9 billion for research and development). The Reauthorization Act authorizes up to $5 billion as the U.S. Government's contribution to this global effort over 5 years.

HIV Prevention Policy

A growing body of evidence led the committee to reform the approach to budgetary allocations or earmarks within U.S. global HIV/AIDS programs. Simply put, current earmarks have constrained the ability of the U.S. Government and its partners to combat the local epidemics that they are facing in individual countries. They also undercut efforts to promote harmonization with other national and international efforts. This conclusion was highlighted in the Institute of Medicine's report, "PEPFAR Implementation: Progress and Promise," which was mandated under the 2003 Leadership Act and which stated that the short-term targets manifested in the budget allocations have "adversely affected implementation of the U.S. Global AIDS Initiative."[8] Other types of activities, such as the prevention of mother to child transmission (PMTCT), as well as more comprehensive approaches to the prevention of the sexual transmission of HIV that combine abstince, fidelity, and condom programming (A, B, and C), have sometimes directly suffered as a result of budget allocations, according to reports by the Government Accountability Office (GAO).[9] Additionally, an independent comparative analysis of PEPFAR, the Global Fund, and the World Bank concluded that, of the three, "PEPFAR funding is least conducive to allowing recipients to implement comprehensive approaches that combine elements of treatment, prevention, and care."[10]

The committee believes that goals rather than numerical percentages should guide programming. By setting a goal of preventing 12 million new infections through a balanced approach and strengthening evaluations of prevention programs, the committee hopes to make a greater impact in stemming the epidemic.

In order to increase flexibility and allow for the more effective allocation of resources in response to local conditions, S. 2731 removes the one-third "abstinence until marriage" funding directive from the 2003 Leadership Act, along with all other numerical ear-

[8] Institute of Medicine, "PEPFAR Implementation: Progress and Promise," Washington, D.C.: National Academies Press, 2007, p. 10.

[9] Government Accountability Office, "Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief," GAO–06–395 (April 4, 2006).

[10] Nandini Oomman, et al. "Following the Funding for HIV/AIDS: A Comparative Analysis of the Funding Practices of PEPFAR, the Global Fund and World Bank MAP in Mozambique, Uganda and Zambia," Center for Global Development (October 10, 2007), p. xii.

marks within HIV/AIDS funding, except for the 10-percent allocation for orphans and vulnerable children. The Reauthorization Act explicitly prioritizes prevention and continues support for a balanced approach in which behavior change programs that are aimed at promoting abstinence and fidelity, reducing numbers of concurrent partners, and delaying sexual debut, which may collectively be termed "AB," are to be funded in a meaningful and equitable way, in tandem with "C" prevention tools promoting the correct and consistent use of condoms. Because the committee believes that both the "AB" behavior change elements and the "C" elements of the ABC approach are crucial to stopping the spread of HIV/AIDS, language in the Reauthorization Act explicitly requires the Global AIDS Coordinator to report to Congress if the funding ratio for these "AB" behavior change programs and for "C" (condom) programs falls below one to one (AB:C). Additional means of prevention including programs to empower women and others, medical male circumcision, the safeguarding of blood supplies, and the potential development of new mechanisms or approaches are also addressed, separately from this one to one ratio.

S. 2731 strengthens an existing provision in the 2003 Leadership Act to ensure that no organization shall be required to endorse, participate in, or make a referral to any program to which that organization has a moral or religious objection, nor shall they be required to endorse or participate in a multisectoral or comprehensive approach to HIV/AIDS. Such organizations cannot be discriminated against in grants or other agreements as a result of electing not to endorse, participate in, or refer patients to such programmatic activities.

As noted, the Reauthorization Act requires a prevention strategy for each country in which the United States maintains an HIV/AIDS program; if, in that strategy, less than 50 percent of the prevention programs aimed at the sexual transmission of HIV are directed toward behavior change programs aimed at reducing or delaying sexual activity or reducing numbers of sexual partners as outlined above, then the Global AIDS Coordinator must provide a justification to Congress. The objective epidemiological evidence to be used for the Coordinator's determination should be primarily partner country Demographic and Health Surveys, the AIDS Information Service (AIS), and other United States Government supported surveys and data, including surveys requested by the Congress; other independent, scientifically sound studies may also be taken into account. The modification of the previous abstinence spending requirement should not be interpreted to imply that abstinence and be faithful programs are no longer considered by the committee to be a priority for prevention funding. Modifications in the directive and the required country strategies are intended to promote locally guided approaches to prevention that respond to changes in patterns of incidence (new HIV infections) and to specific drivers of the epidemic. Any program to change cultural norms should be led by the partner countries, with the U.S. Government providing financial and technical assistance when appropriate; one of the clear lessons of Uganda's early success in reducing HIV prevalence rates is that national and local leadership matters.

The prevention of the transmission of HIV from mother to child represents an important component of the overall prevention strat-

egy. S. 2731 establishes a goal of helping partner countries to achieve 80 percent access to counseling, testing, and treatment to prevent mother-to-child transmission and emphasizes the importance of maintaining a continuum of care before and after birth and of promoting provider-initiated or "opt-out" HIV testing.[11] The committee also recognizes new and promising developments regarding the use of ARVs to reduce the transmission of HIV through breast milk and supports expansion of these interventions as appropriate.

HIV/AIDS Treatment and Care Policy

S. 2731 maintains treatment and care as core priorities of U.S. HIV/AIDS programs and sets a target of supporting treatment for 3 million people by 2013, an increase of 1 million people to be added to treatment rosters, and additional access to treatment through contributions to the Global Fund. The bill also sets a target of supporting care for 12 million people, including 5 million orphans and vulnerable children.[12] In order to measure progress toward the treatment objective, the Reauthorization Act requires a timetable with yearly global treatment targets and subsequent reporting, including country-level explanations if the timetable's goals are not on track to be achieved. As with most of the other HIV/AIDS budget directives, S. 2731 removes the allocation requiring that 55 percent of funding go toward treatment, again reflecting the committee's preference that goals to guide planning and resources rather than numerical directives. The 55 percent earmark was seen as necessary 5 years ago when treatment was almost nonexistent in resource-poor settings such as Africa, and some claimed it was not even possible, but current data demonstrate that this directive is no longer needed or appropriate. The President's Emergency Plan for AIDS Relief has proven the skeptics wrong: Today, due to the combined efforts of PEPFAR and the Global Fund, nearly 2 million people are on treatment, mostly in Africa. Additionally, with the availability of less expensive generic drugs and better supply chain management in place, the cost of ARV supply and distribution has decreased, while other public and private partners have increased their role in supporting treatment programs. The 55 percent earmark for treatment was also set at a time when the infrastructure to deliver treatment was almost completely absent in many areas and the costs were considered by some to be prohibitively expensive. This 55 percent figure has never correlated with actual treatment costs in pursuit of the targets of the 2003 Leadership Act, and the goal of supporting 3 million people on treatment by 2013 does not require such a budgetary directive.

Some have suggested that a target of 3 million people on treatment is insufficient. While the committee would prefer that all who need treatment receive it, the committee shares the view of the

[11] For PMTCT in developing countries, 80 percent is often defined as "universal access" because 100 percent access is not realistically achievable. "Opt out" testing refers to a protocol in which all clients in a medical facility are asked if they would be willing to take an HIV test, rather than waiting for clients to request testing. All voluntary counseling and testing should follow WHO guidelines.

[12] In his 2003 State of the Union Address, President Bush established targets of treating 2 million people, preventing 7 million new infections and providing care for millions more. Currently, over 1.4 million people are enrolled in ARV treatment programs through U.S. bilateral assistance programs. The direct impact of prevention programs is more difficult to measure.

Global AIDS Coordinator, Ambassador Mark Dybul, that "we cannot treat our way out of this epidemic." For every person put on ARVs last year, six more became newly infected with HIV; prevention efforts, capacity building, and other programs are critical to establishing a more sustainable approach. Treatment targets should be and are ambitious, but the committee believes it is neither advisable nor financially feasible for the United States to be the sole supplier of ARVs. In a number of communities, U.S. bilateral programs now focus on providing the more complex "second line drugs" (for patients whose initial treatments have failed), while the Global Fund, private foundations, or others provide many of the "first line" drugs). The committee encourages such shared efforts. The U.S. commitment to support treatment for 3 million people in this Act would constitute well over half of the commitment made to date by the entire Group of Eight (G–8). The world, not just the United States, needs to confront this crisis, and members of the G–8 and others need to do more, particularly because treatment, as noted previously, is a long-term commitment—at this time, it must be life-long for every person who begins taking ARVs.

Furthermore, the committee believes that in seeking to provide treatment for at least 3 million people, the United States, and its implementing partners, must also do more to ensure that its programs achieve the desired outcome, namely the long-term survival of people on treatment and their return to productive lives. In some PEPFAR-supported programs, as many as a quarter or more of those who begin treatment are subsequently "lost to followup" and disappear from rosters. Some of these patients will have died; others may have dropped out or enrolled elsewhere. Poor adherence to ARV regimes is extremely dangerous for the individual and has larger ramifications as it may contribute to the spread of drug resistant strains of HIV/AIDS, which are more difficult and costly to treat. Through enhanced oversight and analysis, along with strengthened coordination with nutrition programs and other support, the Reauthorization Act seeks to save more lives through improved as well as expanded treatment and care.

In terms of care, S. 2731 recognizes the impact of opportunistic infections such as tuberculosis, bacterial pneumonia, toxoplasmosis, viral and fungal diseases, and HIV/AIDS-associated malignancies such as Kaposi's sarcoma on many persons with HIV/AIDS and includes a provision calling for free or readily affordable prophylaxis and treatment for these infections as part of care and treatment. Palliative assistance and pain management are also important components of HIV/AIDS care and treatment programs, as noted in the Reauthorization Act. Additionally, the committee strongly supports expanded access to voluntary counseling and testing, particularly the adoption of provider-initiated or "opt-out" testing, expanded mobile services, and the use of rapid testing to reduce waiting times for patients and facilitate the delivery of test results.

Pediatric participation in care and treatment programs has been underrepresented to date, in part because many HIV infected children die without ever being tested, particularly in countries with low rates of access to Prevention of Mother to Child Transmission (PMTCT) programs. Drawing on S. 2472, the Global Pediatric HIV/AIDS Prevention and Treatment Act, the Reauthorization Act establishes a target for participation in treatment and care programs

for children in proportion to their percentage within the HIV-infected population of a given country as a policy objective of U.S. global HIV/AIDS programs.

The Role of HIV/AIDS, Tuberculosis, and Malaria Programs Within the United States Health and Development Agenda

A core objective of this Act is to encourage the President to situate programs to combat HIV/AIDS, tuberculosis, and malaria more clearly within the United States health and development agenda, particularly because HIV/AIDS programs have come to dominate U.S. assistance in many countries in sub-Saharan Africa and elsewhere. To address this issue, S. 2731 requires strategic planning for HIV/AIDS programs within this broader context as well as long-range planning for the initiative. The Reauthorization Act also seeks to improve coordination between HIV/AIDS programs and other development activities; to address the needs and heightened vulnerabilities of girls and women to HIV; and to build capacity in the health sectors of partner countries and promote a shift toward more sustainable approaches grounded in national strategies. The Act also calls for closer coordination between HIV/AIDS, TB, and malaria programs. In approaching the question of how these health programs fit into the broader U.S. development agenda, the committee explicitly builds upon the 2003 Leadership Act; with the insights gained from 5 years of programs, it seeks to strengthen these activities in order to maximize the positive impact of taxpayer dollars and to achieve improved outcomes in saving lives and helping people resume productive activities.

Nutrition and Food Support for Persons With HIV/AIDS and Their Families

The Reauthorization Act strengthens linkages between HIV/AIDS and nutritional and food support. The 2003 Leadership Act recognized the importance of nutritional support, but persons living with AIDS, clinicians, and other implementers working to treat and support them through PEPFAR programs have repeatedly identified inadequate access to food or nutrition as a major problem in combating the effects of HIV/AIDS. Adequate nutrition is important clinically in terms of improved health outcomes and better adherence to regimes, in part because lack of food can make it very difficult to tolerate ARVs, and many malnourished patients will simply stop taking their ARVs because the side effects are too severe.[13] Current efforts to address this issue through "wraparound" programs with the World Food Program and other agencies cannot completely bridge this gap. In wraparound programs, another agency provides a service such as nutritional support for persons with HIV/AIDS. These wraparound programs often lack the resources to provide sufficient services to the individuals receiving PEPFAR support and are frequently based in rural areas, while PEPFAR programs tend to be more urban. S. 2731 directs the Global AIDS Coordinator to integrate nutrition programs more fully with HIV/AIDS activities and to establish services where referrals are inadequate. The Reauthorization Act identifies nutritional and food

[13] PEPFAR Implementation: Progress and Promise, p. 157.

support as a basic component of care and treatment for those persons with HIV/AIDS who meet established criteria of need.

Providing food assistance only or preferentially to persons who are HIV-infected also poses clear ethical and policy difficulties, both within any given community and in terms of the overall distribution of resources. This community concern may be offset somewhat by the grim economic impact of long-term illness: Families whose breadwinner has been stricken by AIDS have often been forced to sell off what assets they possess. Therefore, even in a community where food insecurity is widespread, these families may have fewer resources on which to draw. Nonetheless, this matter remains an issue of concern. In communities where HIV/AIDS and food insecurity are both highly prevalent, the Reauthorization Act supports community-based assistance programs, with an emphasis on sustainable approaches such as community gardens.

Women and Girls and HIV/AIDS

Women and girls are biologically more vulnerable to the sexual transmission of HIV, and sociological and economic factors add to this heightened peril. Young women in much of sub-Saharan Africa, where HIV/AIDS rates are the highest in the world, are three times as likely as their male counterparts to be infected with HIV; globally, two-thirds of all new infections among young people aged 15 to 24 are among women.[14] S. 2731 emphasizes the issue of gender as a risk factor for HIV on a number of levels, with the goal of strengthening U.S. efforts to help partner countries address the underlying issues that heighten vulnerabilities for girls and women and to improve the quality and enhance the impact of gender-based programming. Gender elements are central to the required 5-year strategy and report and subsequent evaluations, and the committee emphasizes the importance of programs to reach men, women, and youth to reduce gender-based vulnerabilities to, and the disparate impacts of, HIV/AIDS. Gender-based programs must also be a core element of any future compacts or framework agreements. Consistent with the underlying 2003 Leadership Act, programmatic components to address gender issues within the Reauthorization Act include support for property and inheritance rights for women and children as well as assistance to promote broader legal equality and legal protection; support for civic organizations run by and for women; life skills training for adolescents; recognition and prevention of gender-based violence and strengthened legal and support responses to violence; and improved coordination with antitrafficking efforts. The committee recommends that additional staff training and development of expertise on gender-related issues be included in planning for HIV/AIDS programs and country operational plans, along with expanded local input from women, including women living with HIV/AIDS. Similarly, additional technical assistance may be needed to help encourage the participation and involvement of women in drafting, coordinating, and implementing the national HIV/AIDS strategic plans of their countries.

The committee believes it is important to monitor and evaluate progress on outcomes and impacts linked to goals and targets and

[14] Office of the Global AIDS Coordinator, "The President's Emergency Plan for AIDS Relief Report on Gender-Based Violence and HIV/AIDS" (November 2006), p. 4.

to ensure that data are disaggregated by risk factors, including sex, age, marital status, and other factors relevant to local epidemics. The Global AIDS Coordinator should provide clear guidance to field missions to integrate gender across all prevention, care, and treatment programs; adopt specific targets for reaching women and girls within the country's prevention, care, and treatment targets; and undertake gender analysis in order to identify priority interventions. Gender-specific indicators are critical to measure program outreach and effectiveness. Operations research and evaluations of gender-responsive interventions, as required under the Reauthorization Act, will help identify and encourage replication or adaptation of effective models, and provide both positive and negative lessons learned for dissemination among programs supported by U.S. assistance in different countries or regions.

The Reauthorization Act authorizes structural HIV prevention efforts intended to help alter social, political, and economic factors in the environment so that people may be empowered to engage in safer behaviors. These efforts help countries to address factors within the environment, such as gender inequities or migration patterns that can create conditions conducive to the spread of HIV, and begin to remedy them, for example by supporting microcredit opportunities for women or providing off-hours activities or housing options for migrant men or transport workers. Such prevention approaches also offer important opportunities for increased linkage across development lines, through the promotion of livelihoods and small enterprise development, job training, basic health services, and education. These activities are particularly relevant in terms of the needs of women and girls and continue programs that were authorized under the 2003 Leadership Act.

Gender-based violence plays a significant role in the transmission of HIV in many areas, and efforts to assist countries in the development and enforcement of laws and policies to prevent and respond to gender-based violence and to promote screening and appropriate counseling, testing, and treatment in both HIV/AIDS and gender-based violence programs are important components of prevention, care, and treatment programs as authorized under this Reauthorization Act. Violence against women and girls in humanitarian relief, conflict, and post-conflict operations is an issue of particular concern. Domestic violence is widespread in some regions, including areas of high HIV prevalence, but this situation can change. Strengthening laws and enforcement mechanisms; publicizing laws and penalties and expanding awareness of victims' services through national media campaigns; expanding youth education efforts; and promoting communication across gender lines, along with efforts to address alcohol abuse, can help to change social norms contributing to tolerance of violence. Increased access to economic opportunities is also an important component in the prevention of and response to domestic and sexual violence. Recognizing the importance of these programs in the fight against HIV/AIDS, microcredit activities continue to be authorized under this legislation. Finally, the committee notes that currently many women and girls are unable to rely on the ABC strategy to protect themselves because they lack the power to abstain, cannot control or depend on their partners' faithfulness, and cannot impose the use of condoms within their relationships. That fact makes efforts

to strengthen women's rights an important component of HIV/AIDS and national development strategies and underscores the need for support for programs such as those outlined above as well as new advances in prevention methods that women themselves can control.

Children and HIV/AIDS

According to UNAIDS, an estimated 2.5 million children are living with HIV; nearly 9 out of 10 live in sub-Saharan Africa. Over 300,000 children under the age of 15 died of AIDS-related causes in 2007. Over 14 million children in the world have lost one or both parents to AIDS. Millions of more children are affected by or vulnerable to HIV/AIDS. S. 2731 seeks to address these issues confronting children on multiple levels, from increasing emphasis on PMTCT programs and expanding access to pediatric HIV/AIDS testing, treatment, and care, to supporting assistance for orphans and other children directly affected by the disease and expanding our understanding of what it means to be vulnerable to HIV/AIDS.

The prevention of mother to child transmission (PMTCT) represents an area where scientific certainty—we know how to prevent transmission during pregnancy and childbirth—meets the limitations of maternal healthcare access and infrastructure in much of sub-Saharan Africa and elsewhere. Around the world, approximately a thousand infants a day are infected with HIV, most in sub-Saharan Africa. S. 2731 underscores the importance of expanding access to PMTCT services and achieving delivery targets and of supporting a continuum of care to connect prenatal and antenatal services with health services for mother and child after delivery.

To date, children with HIV/AIDS have been underserved within global HIV/AIDS assistance programs. Barriers to enrollment for children in treatment programs include limited access to reliable HIV testing for the youngest children; a shortage of providers trained in delivering pediatric care; weak linkages between services to prevent mother-to-child transmission and HIV/AIDS care and treatment and child health programs; and the need for additional, low-cost pediatric formulations of HIV/AIDS medications—pediatric treatment is far more complex and expensive than that for adults. The Reauthorization Act identifies treatment of children in proportion to their percentage within the HIV infected population of a given country as a policy objective and seeks to help countries surmount these treatment barriers. The committee strongly supports expanded treatment and care for children not only through ARVs but also through increased access to additional medications such as cotrimoxazole prophylactic, for example, which at a cost of three cents a day has been shown to cut childhood HIV/AIDS mortality rates dramatically.

The one numerical budgetary allocation for HIV/AIDS retained in this legislation is the 10-percent earmark for orphans and vulnerable children. This directive continues to receive broad support from implementers and U.S. Government officials alike. It is important to retain this allocation, and to maintain it separately from pediatric treatment, in order to ensure that orphans and vulnerable children remain a priority within U.S. HIV/AIDS country programs and to signal their importance to partner countries, many of

whom have not sufficiently emphasized programs for children. S. 2731 also recognizes that, particularly in areas with high HIV prevalence rates, definitions of what it means to be vulnerable to HIV/AIDS or its socioeconomic effects should be expanded. For this reason, the legislation amends the original budget directive on orphans and vulnerable children from "orphans and vulnerable children affected by HIV/AIDS" to "orphans and other children affected by, or vulnerable to" HIV/AIDS. The committee encourages the Global AIDS Coordinator to provide clear guidance to the field on this subject.

Capacity Building and Sustainability

Lack of health personnel, inadequate infrastructure and health systems, and poor management represent formidable roadblocks to progress in the battle against HIV/AIDS and other infectious diseases and medical conditions, particularly in sub-Saharan Africa. The HIV/AIDS pandemic has aggravated the existing shortage of health workers through loss of life and illness among medical staff, unsafe working conditions for medical personnel, and increased workloads for diminished staff. The shortage of health personnel in turn undermines efforts to prevent infection and provide care and treatment for those with HIV/AIDS and to address other health challenges. Migration of health workers—often termed the "brain drain"—adds to these losses; the committee supports codes of conduct and other measures to promote ethical practices in the international recruiting of healthcare workers, as well as steps to reduce "push factors" such as unsafe working conditions that also fuel this brain drain. According to the 2003 United Nations Development Programme, Human Development Report, approximately 3 out of 4 countries in sub-Saharan Africa have fewer than 20 physicians per 100,000 people, the minimum ratio recommended by the World Health Organization, and 14 countries have 5 or fewer physicians per 100,000 people.[15] Numbers of nurses and other health professionals are also critically low across much of the continent. The concentration of professionals in cities further limits the delivery of health services in rural areas. Capacity building is critical to making progress against HIV/AIDS, tuberculosis, and malaria and to shifting from a donor-led emergency line of attack to a more sustainable, country-driven public health approach.

The PEPFAR program has made real progress in training personnel, increasing laboratory capacity, and improving infrastructure. The Reauthorization Act seeks to build on that progress and elevate the objective of capacity-building within U.S. programs. Additional health professionals, paraprofessionals, and compensated community health workers are all needed in this effort. The Reauthorization Act draws on S. 805, the African Health Capacity Investment Act of 2007 (which the committee approved in September 2007), to address the need for health workers, infrastructure, and management development.

In order to help achieve needed staffing levels, S. 2731 sets a target of training and retaining 140,000 professionals and paraprofes-

[15] According to the United Nations Development Program, Tanzania, Malawi, Niger, Burundi, Ethiopia, Mozambique, Sierra Leone, Togo, Benin, Chad, Lesotho, Eritrea, Rwanda, and Burkina Faso all have 5 or fewer physicians per 100,000 people. The only other nations in the world with such a small number of physicians per capita are Bhutan and Papua New Guinea.

sionals with the objective of helping countries to achieve World Health Organization recommended minimum staffing levels for doctors, nurses, and midwives. Doctors, nurses, and other health professionals must be trained, but also effectively deployed, under safe working conditions and with additional incentives to support retention. Skilled paraprofessionals, such as laboratory technicians, are needed, as are community health workers who often serve on the front lines of health services. The bulk of community health workers in many PEPFAR programs are volunteers; the committee recognizes the value of their service, but has concerns about the sustainability of a volunteer-based model and relying upon the poorest participants in the health workforce as volunteers.

Older orphans, vulnerable children, and at risk youth are in need of educational and employment opportunities, while virtually all countries receiving significant U.S. assistance programs are in need of an expanded healthcare workforce. Public-private partnerships and other mechanisms should be pursued to help address this nexus through training of these individuals as entry level health workers and as paraprofessionals and through expanded support for higher education, with appropriate measures to promote in-country service following graduation.

In addition to training more individuals (and retaining them in-country), systemic reforms and improvements are needed to combat HIV/AIDS and other diseases and health challenges. Task-shifting—in which lower-level health workers are authorized to assume some duties formerly reserved for physicians or other highly trained professionals—will help address imbalances in service delivery, but is only a partial solution and raises potential concerns that nurses and other healthcare workers might be diverted from primary healthcare duties for HIV/AIDS care.[16] More diversified training is also needed, including instruction in the detection of opportunistic infections, pediatrics, gender-based violence assessments, TB/HIV coinfection, prevention education, and counseling and testing, to help achieve a work force with sufficient skills. The Reauthorization Act supports such training efforts as well as health and financial management reforms and infrastructural development to allocate resources more effectively. In undertaking such efforts, the potential benefit for the health system as a whole should help guide decisionmaking, and every precaution should be taken to ensure that HIV/AIDS programs do not diminish access to, or quality of, broader health services.

Partner countries themselves must also invest more heavily in their health and education sectors, and S. 2731 urges them to do so, as set forth in the Abuja Declaration.[17] The Reauthorization Act underscores the importance of the national HIV/AIDS and health strategies of partner countries in U.S. planning and allows for additional technical assistance to strengthen such instruments where needed. The legislation authorizes the Secretary of the Treasury to provide assistance to country health and finance ministries to at-

[16] The World Health Organization has issued guidelines on task-shifting in WHO, "Treat, Train, Retain: Task Shifting: Rational Redistribution of Tasks among Health Workforce Teams" (December 2007).

[17] In the Abuja Declaration of 2001, heads of state of the Organization of African Unity [the predecessor of the African Union] pledged to place the fight against HIV/AIDS at the forefront in national development plans and committed to set a target of allocating 15 percent of annual budgets to the improvement of the health sector.

tract and manage international assistance more effectively. The committee also emphasizes the importance of supply chain management and equipment maintenance to ensure the effective use of purchased and donated goods. Sustainability of global HIV/AIDS programs cannot be achieved in the next 5 years, but it should ultimately be one of the longer term objectives of U.S. programs.[18]

Promoting country ownership of HIV/AIDS programs and methodologies represents one of the underlying goals of this legislation. Compacts or framework agreements between the United States and regional or national governments may be one way to achieve this objective. As part of his announcement regarding the reauthorization of PEPFAR on May 30, 2007, President Bush expressed his desire to establish partnership compacts with participating nations. S. 2731 includes language providing for the development of compacts or framework agreements. Compacts would constitute partnership agreements, with mutual obligations commensurate with national resources and capabilities. For countries with greater resources, U.S. contributions might be limited largely to technical assistance. Compacts could be reached either with one or more individual countries or with regions, such as the Caribbean Community (CARICOM). Key components of prospective compacts include health capacity-building; country investments; elements to strengthen the legal, economic, educational, and social status of women, girls, and vulnerable children and youth; civic participation; the promotion of policies, regulations, and law conducive to enhancing HIV/AIDS prevention, treatment, and care; evaluation, research, and information-sharing; and improved coordination of efforts to combat HIV/AIDS, TB, and malaria with national health and development strategies. Benchmarks, targets, and intended methodology to achieve them should be included within such framework agreements.

Oversight and Evaluation of HIV/AIDS Programs

The scope of the U.S. global HIV/AIDS initiative and the speed with which it has been developed and implemented under the leadership of the Global AIDS Coordinator are extremely impressive; this scope and speed, however, also contribute to challenges of sustainability and accountability. As indicated in reports by the offices of the Inspectors General for the Department of State and USAID, PEPFAR country teams have tended to be understaffed for the workload, budget, and responsibilities associated with the programs that they manage.[19] Oversight, monitoring, and evaluation will almost inevitably suffer if staffing is inadequate. To facilitate smoother coordination and improve oversight and management of programs, S. 2731 recommends the appointment of full-time, experienced country coordinators for all U.S. missions with significant

[18] The term sustainability is widely used but more rarely defined. Dr. Helene Gayle of CARE, in testifying before the House Foreign Affairs Committee on September 25, 2007, stated that "sustainability relates to a set of activities continuing, even after their initiator exits. Another type refers to the durability of a certain impact: For example, a vaccine that provides immunity to a disease. A deeper form of sustainability is reflected in the ability of societies to maintain processes of economic, social and cultural transformation."

[19] USAID Office of Inspector General reports on Zimbabwe (October 2007), Malawi (September 2007), and Tanzania (May 2006) reported respectively that staff shortages adversely affected basic monitoring activities of partners; data collection and management; and reduced site visits, which "could jeopardize the achievement of future outputs and targets, and impact the quality of the program data reported by the partners to the Mission, and the target information reported to the U.S. Government by USAID/Tanzania."

HIV/AIDS programs, supports adequate staffing of all country teams, and acknowledges the important contributions of Foreign Service Nationals to these efforts.

The committee has included several provisions in the legislation to maintain and strengthen oversight and program review of U.S. global HIV/AIDS efforts.

First, the bill calls for a report, including a preliminary design plan and budget, by the Institute of Medicine of the National Academies that assesses the performance of U.S. global HIV/AIDS programs and an evaluation of the impact of these programs on prevention, treatment, and care. The Institute conducted a similar study during the first 5 years of the global HIV/AIDS effort under the Leadership Act. That study, released in 2007, helped inform the committee's work on the Reauthorization Act, particularly in regard to whether to retain certain funding allocations, or earmarks. The Institute of Medicine study under the Reauthorization Act is intended to address progress toward prevention, treatment, and care targets and evaluate the impact of treatment and care programs (e.g., mortality, adherence, and resistance rates) and of programs directed toward women and orphans and vulnerable children, as well as seeking to assess the impact of these efforts on health systems and service delivery in countries with significant programs.

Second, the bill requires a review by the Government Accountability Office (GAO) no later than 3 years after enactment of this Act that will examine monitoring and evaluation practices, interagency coordination, procurement practices, and harmonization of the U.S. effort with national and international strategies. It will also assess the effect of HIV/AIDS investments on U.S. global health programming, and provide recommendations for improving global HIV/AIDS programs.

Third, the Reauthorization Act emphasizes operations research, in order to evaluate policies and program outcomes.[20] To promote the dissemination of information, the bill requires the Global AIDS Coordinator to publish a "best practices" report annually to highlight those programs with potential for replication or adaptation, particularly those programs that may be replicated or adapted at a low cost in other settings. In this manner, U.S. programs can make an indirect but important contribution to HIV/AIDS efforts where the United States is not directly involved. The committee regards it as important for OGAC to communicate information on adverse outcomes or unsuccessful approaches as well.

Finally, the bill requires the Inspectors General (IGs) of the three largest U.S. Government agencies involved in the global HIV/AIDS efforts—the Department of State, the Department of Health and Human Services, and the U.S. Agency for International Development—to coordinate on an annual oversight plan of bilateral programs. The provision also requires the Global AIDS Coordinator to make available not more than $10 million to fund the oversight by the Inspectors General. The committee is aware that the Offices of Inspector General at State and USAID have received only modest budgetary increases in recent appropriations, and are often asked

[20] Regarding operations research, S. 2731 draws on S. 2584, the PEPFAR Accountability and Transparency Act.

to do more with less. This financing mechanism—just .0002 percent of the $50 billion authorized in this bill—will strengthen the ability of those Offices to conduct regular audits, inspections, and performance reviews of bilateral HIV/AIDS programs. Oversight and monitoring and evaluation should be seen as components of effective prevention, treatment, and care programs rather than as competitors with them for resources.

The Global Fund to Fight HIV/AIDS, Tuberculosis, and Malaria

S. 2731 authorizes up to $2 billion for the Global Fund for fiscal year 2009 and such sums as necessary for the subsequent 4 fiscal years; this structure parallels section 202(d)(1) of the 2003 Act, which authorized $1 billion for fiscal year 2004 and such sums as necessary for the remaining fiscal years. The Global Fund represents the primary multilateral component of the Reauthorization Act. The legislation recognizes the increasingly effective coordination between the Global Fund and bilateral U.S. assistance programs. The committee commends this development, recognizes that the bilateral and multilateral efforts each possess comparative advantages in certain areas, and notes that the Global Fund model may have the potential for greater capacity-building and sustainability in the long term. The committee also regards the Global Fund as having made significant progress toward addressing concerns raised by the Government Accountability Office about transparency and accountability and anticipates further progress as the newly appointed Inspector General for the Global Fund attains full staffing levels and undertakes monitoring activities.

In order to promote greater transparency, accountability, and public availability of information, the Reauthorization Act includes a provision to withhold 20 percent of the U.S. contribution beginning in FY 2010 if certain benchmarks are not met. Benchmarks include: The evaluation of Local Fund Agents; the disclosure of information, performance data, and funding levels for principal and subrecipients; the activities of the Inspector General; reporting on standard indicators and distribution of resources; the establishment of a tariff policy and pursuit of steps to prevent the imposition of taxes on Global Fund services; the Global Fund's continuation as a financing institution focused on the three diseases; and progress in sustaining a multisectoral approach with resources allocated to different sectors, including governments, civil society, and faith-and community-based programs.

Table 1.—Global Fund Contributions

(in U.S. dollars)

	2001–02	2003	2004	2005	2006	2007	2008 est.
Total Global Contributions	947M	937M	1.5B	1.5B	2.2B	2.5B	3.5B
U.S. Appropriations	300M	348M	547M	435M	545M	724M	841M
U.S. Share of Contributions (as a percentage)	32	33	32	31	24	28	28

M = million.
B = billion.

Tuberculosis

Tuberculosis claims an estimated 1.6 million lives a year, and drug resistant strains of the disease are becoming increasingly

common and more dangerous. This airborne disease, including its drug-resistant variants, is becoming a more generalized epidemic in many countries of the world. While there are an estimated 9 million new tuberculosis cases per year, only one-third of those with the disease currently receive treatment. The World Health Organization recently reported that 5 percent of new cases of TB are multidrug resistant (MDR–TB), and that at least 40,000 persons are thought to have extensively drug resistant TB (XDR–TB); this number could be considerably higher as many countries lack the capacity to test for resistance.[21] Drug resistance emerges most commonly when TB patients fail to complete their course of treatment; mutations in the bacterium may then develop, and drug-resistant strains can subsequently be transmitted to others. Tuberculosis normally requires a 6-month course of treatment with costs as low as $20 per patient; treatment for MDR–TB may take 2 years and cost thousands of dollars. XDR–TB is even more difficult to treat and often fatal. Persons with HIV/AIDS are particularly vulnerable to TB, and coinfection rates within the HIV infected population top 50 percent in some countries.

Drawing upon S. 968, the Stop Tuberculosis (TB) Now Act of 2007, which was favorably reported by the committee in October 2007, S. 2731 recognizes the global threat posed by tuberculosis, and particularly MDR– and XDR–TB, and authorizes $4 billion to combat the disease over 5 years. The World Health Organization's "Stop TB" Strategy offers a roadmap for combating tuberculosis and reducing the threats of increasing drug resistance and for the resources necessary for this effort. Directly Observed Treatment Short-course (DOTS) treatment for TB is one of the most cost-effective health interventions available today. The committee emphasizes the importance of both ensuring maximum on the ground impact of resources to combat TB and of maintaining the quality of programs and services delivered, not least because of the extraordinary public health costs associated with poor adherence to standard treatment for TB. Patient services, training for health workers and the maintenance of safe working conditions, laboratory capacity, and drugs and diagnostics should be prioritized. The committee recognizes and supports funding for the global TB work of the Centers for Disease Control and Prevention. The committee also supports robust funding for the Global Tuberculosis Drug Facility and recommends significantly increased annual U.S. contributions, building on recent appropriations.

Coinfection between HIV/AIDS and TB represents a significant public health problem in many countries, making increased coordination between HIV/AIDS and TB programs a continuing priority; TB remains the leading cause of death among persons with AIDS. Diagnosis can be difficult particularly because TB symptoms may manifest themselves differently in HIV positive persons, often as sputum smear-negative pulmonary and extra-pulmonary forms of TB that are more difficult to detect and that are associated with higher mortality rates. In order to help achieve the objectives set forth in the Stop TB Strategy and the Millennium Development Goals, expanded diagnostic and treatment capacity for all forms of

[21] MDR–TB is defined as TB demonstrating resistance to the two most commonly used drug treatments, rifamin and isoniazid; XDR–TB is resistant to those two first-line drugs and at least two other major drug treatments.

TB is necessary, as is expanded laboratory capacity to detect drug resistance.

Malaria

Over 1 million people a year die of malaria, most of them children under the age of 5 or pregnant women. The President's Malaria Initiative, launched in 2005, is already beginning to make an impact in the fight against this deadly and preventable disease. S. 2731 authorizes $5 billion for fiscal years 2009 to 2013 in order to build on this early progress by expanding the resources and reach of U.S antimalarial programs. In order to advance these efforts and improve the operations of antimalarial programs and coordination across U.S. agencies and with other multilateral, national, and private actors, the Reauthorization Act codifies a position within USAID of a Coordinator of United States Government Activities to Combat Malaria Globally [hereafter, the Malaria Coordinator].

This legislation supports numerous primary interventions, including long-lasting insecticide-treated bednets; indoor residual spraying with insecticides; intermittent presumptive treatment of pregnant women in areas of high malaria transmission; community-based symptoms detection, management and care; artemisinin-based combination therapies (ACTs); and other measures to promote treatment, care, and prevention. As with other health interventions, capacity-building is a critical element in the fight against malaria. The Reauthorization Act also supports research activities to develop and evaluate new diagnostics, treatment regimens, and prevention and control measures. Artemisinin-based drugs and insecticides are potentially subject to increasing resistance over time. The spread of counterfeit drugs may hasten the emergence of more widespread drug resistance, signs of which are already appearing in the Mekong Delta region. The World Health Organization also indicates that malaria-carrying mosquitoes have developed resistance to some of the 12 approved insecticides in the Amazon Basin, the Mekong Delta, and particular regions of Africa, thus reducing the efficacy of insecticide-treated bednets and indoor spraying programs. S. 2731 requires the monitoring of global malaria trends and the assessment of the environmental and health impact of malarial vector control efforts, including the use and production of insecticides for bednets and residential spraying. The committee also underscores the importance of adherence to World Health Organization and other relevant standards in the use and control of these products.

IV. Committee Action

Last year, the committee held two hearings directly related to the subject matter of the bill. On October 24, 2007, the committee held a hearing on "The Next Phase of the Global Fight against HIV/AIDS," at which Ambassador Mark Dybul, the Global AIDS Coordinator, testified. On December 13, 2007, it held a hearing with outside witnesses on "Perspectives on the Next Phase of the Global Fight against HIV/AIDS, Tuberculosis, and Malaria."

On March 7, 2008, Senators Biden, Lugar, Kennedy, and Sununu introduced S. 2731, a bill to authorize appropriations for fiscal years 2009 through 2013 to provide assistance to foreign countries

to combat HIV/AIDS, tuberculosis, and malaria, and for other purposes.

On March 13, 2008, the committee held a business meeting to consider S. 2731. The committee approved a series of amendments by voice vote. The amendments were as follows:

- An amendment by Senator Biden making technical amendments to section 101(f) on Inspectors General.
- An amendment by Senators Biden and Lugar to alter the conscience clause provision to conform to the House bill.
- An amendment by Senator Biden to change "healthcare workers and professionals" to "healthcare paraprofessionals and professionals" in section 301 and adding definition of paraprofessionals.
- An amendment by Senator DeMint regarding the Global Fund.
- An amendment by Senators Biden and Lugar to eliminate the phrase "behavior change" in several places in the bill to conform to the House bill and clarify its meaning.
- An amendment by Senators Biden and Dodd to make adjustments to the provisions on pediatric treatment.
- An amendment by Senator Biden to define "structural prevention."
- An amendment by Senator Dodd to create a panel to review Prevention of Mother-to-Child Transmission.
- An amendment by Senator Kerry to promote vaccine development.
- An amendment by Senator Obama to promote microbicide development.
- An amendment by Senator DeMint to ensure that CDC surveillance activities on malaria do not duplicate the work of the World Health Organization.
- An amendment by Senators Nelson and Menendez to highlight the Caribbean region as a potential partner for regional approaches to HIV/AIDS.
- An amendment by Senators Biden and Lugar to add a new section 401(b) on the scaleup of the spending over the course of the five fiscal years.
- An amendment by Senator Cardin to promote preservice training for health capacity.
- An amendment by Senators Biden and Lugar to make a technical change to insert section 307 and to renumber the rest of Title III accordingly.

The committee then voted to order the bill, as amended, reported favorably by a vote of 18 to 3. Voting in favor of the bill were Senators Biden, Dodd, Kerry, Feingold, Boxer, Nelson, Obama, Menendez, Cardin, Casey, Webb, Lugar, Hagel, Coleman, Corker, Voinovich, Murkowski, and Isakson. Voting against the bill were Senators DeMint, Vitter, and Barrasso.

V. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

The short title is the "Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008."

Sec. 2. Findings

This section amends the findings in the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 ("the 2003 Leadership Act") by adding to that Act additional findings with updated data on human immunodeficiency virus (HIV) and the acquired immunodeficiency syndrome (AIDS) (hereafter referred to as "HIV/AIDS"), tuberculosis (TB), and malaria around the world and the impact of U.S. assistance in combating these diseases since the 2003 Leadership Act was enacted. The findings also identify ongoing and growing challenges in meeting the needs for treatment, care, prevention, cure and research of and related to these diseases.

Sec. 3. Definitions

This section amends the 2003 Leadership Act by adding additional definitions of terms.

Sec. 4. Purpose

This section amends the purpose section of the 2003 Leadership Act and sets out the overall goals and objectives of this bill. It refers to the mandate for a new 5-year coordinated strategy to combat HIV/AIDS, tuberculosis, and malaria as part of the overall United States global health and development agenda; calls for increased resources for bilateral and multilateral efforts to combat these diseases; intensifies prevention, treatment, and care efforts and seeks to enhance program effectiveness including addressing the particular vulnerabilities of girls and women; encourages public-private partnerships; reinforces vaccine development and other research, including operations research; and helps partner countries to strengthen health systems and improve capacity.

Sec. 5. Authority to consolidate and combine reports

This section maintains a provision in current law allowing the executive branch to consolidate and combine reports, with a minor technical amendment.

TITLE I—POLICY PLANNING AND COORDINATION

Sec. 101. Development of a comprehensive, 5-year, global strategy

This section amends section 101 of the 2003 Leadership Act by providing additional guidance to the President on the development of the second 5-year plan to combat HIV/AIDS globally and a subsequent report to Congress.

It instructs the President to seek to situate United States efforts to combat HIV/AIDS, tuberculosis, and malaria within the broader health and development agenda; to provide a plan to be carried out over the next 5 years to prevent 12 million new HIV infections, support care for 12 million adults and children with HIV/AIDS (including 5 million orphans and other children affected by HIV/AIDS), and to support treatment for 3 million persons with HIV/AIDS through bilateral efforts as well as additional persons through multilateral programs.

It also establishes targets to promote universal access (defined as 80 percent) to services to prevent mother-to-child transmission, to treat children in proportion to their numbers within a country's

population of persons with HIV/AIDS, and to strengthen health workforces. The strategy prioritizes the importance of HIV prevention, including programs to promote abstinence, fidelity, and the use of condoms, as well as other prevention tools. To ensure that treatment is not neglected, it requires a timetable for achieving treatment targets. It instructs the President to strengthen health capacity in, and to enhance attention to the national HIV/AIDS strategies of partner countries, and to promote coordination in United States responses to HIV/AIDS, tuberculosis, and malaria.

This section calls for a plan for regional priorities for resource distribution and a structure for potential new compacts or framework agreements. It underscores the importance of addressing the needs and vulnerabilities of women and girls. Finally, it calls for a long-range estimate of projected resource needs and progress toward sustainability.

This section also instructs the Global AIDS Coordinator to commission a study by the Institute of Medicine (with prior design plan and budget) to assess progress and outcomes of United States global HIV/AIDS programs and provides for a Government Accountability Office report on monitoring and evaluation, coordination, and impact of HIV/AIDS funding and programs on United States global health programs as a whole. It requires annual publication of a "Best Practices" report based on operations research. To enhance oversight, it requires joint, coordinated plans by the Inspectors General (IGs) of the three largest U.S. Government agencies carrying out this program (State Department, HHS, and USAID) and authorizes the transfer of up to $10 million to the IGs to support financial audits, inspections, and performance reviews.

Sec. 102. Interagency working group

This section amends current law to strengthen and expand the duties of the Global AIDS Coordinator, including enhancing the role of the Coordinator in consulting and coordinating with foreign governments, nongovernmental organizations, and other U.S. Government agencies. It expands the duties of the AIDS Coordinator to include establishing and heading a working group consisting of representatives from the United States Agency for International Development (USAID) and the Department of Health and Human Services.

Sec. 103. Sense of Congress

This section provides a sense of Congress about the importance of country coordinators, foreign service nationals, and staffing levels for country teams.

TITLE II—SUPPORT FOR MULTILATERAL FUNDS, PROGRAMS, AND PUBLIC-PRIVATE PARTNERSHIPS

Sec. 201. Voluntary contributions to International vaccine funds

This section reauthorizes the existing programs under section 302 of the Foreign Assistance Act for fiscal years 2009–2013, specifically the vaccine fund, the International AIDS Vaccine Initiative, and the malaria vaccine development program. This section also provides a new authorization for a U.S. contribution to tuberculosis vaccine development programs.

Sec. 202. Participation in the Global Fund to Fight AIDS, Tuberculosis and Malaria

This section amends section 202 of the 2003 Leadership Act relating to U.S. contributions to the Global Fund. Subsection (a) updates findings in the Act and expresses the sense of Congress regarding transparency, accountability, and coordination. Subsection (b) increases the annual authorization for the U.S. contribution to the Global Fund from $1 billion to up to $2 billion for fiscal years 2009, and such sums as necessary for fiscal years 2010–2013.

The subsection includes new benchmarks designed to improve the accountability and transparency of the Global Fund's activities, including a provision, beginning in fiscal year 2010, that would withhold 20 percent of appropriated funds until the Secretary of State certifies achievement of certain benchmarks.

Sec. 203. Microbicide research

Subsection (a) expresses the sense of Congress recognizing the need and urgency to expand the range of interventions for preventing the transmission of HIV, including nonvaccine prevention methods that can be controlled by women.

Subsection (b) amends the Public Health Service Act (42 U.S.C. 300cc-40 et seq.) by directing the Director of the National Institutes of Health Office of AIDS Research to develop and implement Federal strategic plans for microbicide research and to review and update such plans annually, prioritizing funding and activities relative to scientific urgency and potential market readiness of microbicide products as appropriate. The subsection also directs the Director to consult with representatives of other relevant Federal agencies, the microbicide research community, and health advocates. The subsection includes authorization of such sums as necessary.

Subsection (c) amends the Public Health Service Act by directing the Director of the National Institute of Allergy and Infectious Diseases (NIAID) to conduct research and development of microbicides for use in developing countries to prevent HIV transmission. The Director shall ensure adequate staffing and structure to carry out such activities, such as through a dedicated microbicide research and development branch.

Subsection (d) directs the Director of the Centers for Disease Control and Prevention (CDC) to fully implement the CDC's microbicide agenda to support research and development of microbicides. It authorizes as such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out these activities.

Subsection (e) authorizes the Administrator of USAID, in coordination with the Coordinator of U.S. Government Activities to Combat HIV/AIDS Globally, to develop and implement a program to facilitate wide scale availability of microbicides that prevent the transmission of HIV if such microbicides are proven safe and effective. It authorizes such sums as may be necessary for fiscal years 2009 through 2013 to carry out this section.

Sec. 204. Combating HIV/AIDS, tuberculosis, and malaria by strengthening health policies and health systems of partner countries

This section amends title II of the 2003 Leadership Act by adding a new section 204 relating to strengthening health policies and health systems of host countries. Subsection (a) provides a statement of policy regarding the need for strengthening of such health policies and systems. Subsection (b) authorizes the appropriation of funds authorized under section 401 of the Act to the Department of Treasury to provide technical assistance to host countries to improve the public finance management systems of such countries to enable them to receive HIV/AIDS assistance, collect revenue, and manage their own programs.

Sec. 205. Facilitating effective operations of the Centers for Disease Control and Prevention

This section amends the Public Health Service Act by authorizing the Secretary of Health and Human Services to participate with other countries in cooperative endeavors in research, healthcare services, and other activities authorized under the Reauthorization Act. The section also strikes a provision prohibiting the Secretary from providing financial assistance for the construction of any facility in any foreign country. It authorizes the provision of funds by advance or reimbursement to the Secretary of State, as may be necessary, to pay for the acquisition, lease, construction alteration, equipping, or managing of facilities outside the United States and authorizes grants or cooperative agreements relating to such activities, in consultation with the Secretary of State.

Section 206. Facilitating vaccine development

Subsection (a) authorizes the USAID Administrator to strengthen the capacity of developing countries' governments to conduct proper protocols for the introduction of new vaccines, if such vaccines are proven safe and effective, to review protocols for clinical trials and impact studies and improve implementation, and to ensure adequate supply chain and delivery systems.

Subsection (b) directs the Secretary of the Treasury to enter into negotiations with appropriate entities including the World Bank and GAVI Alliance to establish advanced market commitments to purchase vaccines to combat HIV/AIDS, tuberculosis, malaria, and other related infectious diseases. In such negotiations, the Secretary is directed to take into account factors regarding pricing, transparency, safety, dispute settlement, and needed flexibility. Not later than 1 year after enactment, the Secretary shall provide the appropriate congressional committees with a report on negotiations and the President shall produce a report by a study group of qualified professionals setting forth a strategy for vaccine development.

TITLE III—BILATERAL EFFORTS

Subtitle A—General Assistance and Programs

Sec. 301. Assistance to combat HIV/AIDS

This section amends section 104A of the Foreign Assistance Act of 1961 and section 301 of the 2003 Leadership Act, both of which relate to bilateral U.S. HIV/AIDS assistance.

Subsection (a) modifies the findings of the 2003 Leadership Act and identifies that it is a policy objective of the United States for FY 2009–2013 to assist countries in:

- Preventing 12 million new HIV infections;
- Supporting treatment of at least 3 million people with HIV/AIDS as well as additional support through multilateral efforts;
- Supporting care for 12 million people including care and support for 5 million children affected by HIV/AIDS;
- Providing access to counseling and services for prevention of mother-to-child transmission to 80 percent of the target population (80 percent is the level most often defined as "universal access");
- Providing care and treatment services to children with HIV/AIDS in proportion to their percentage within the population of persons who are infected within a given country; and
- Training 140,000 new paraprofessionals and professionals.

The subsection further amends section 104A by supporting a coordinated global strategy to confront HIV/AIDS in sub-Saharan Africa, the Caribbean, Central Asia, Eastern Europe, Latin America, and other countries and regions to help address generalized and concentrated HIV/AIDS epidemics, highlighting the importance of prevention.

Section 301 also notes the activities for which U.S. HIV/AIDS assistance can be used for prevention, including an increased focus on counseling, delay of sexual debut, abstinence, fidelity, life skills, prevention of mother-to-child HIV transmission, and medical male circumcision. It also provides for a more coordinated approach to HIV/AIDS by supporting access to treatment for opportunistic infections and development programs that can improve the effectiveness of HIV/AIDS efforts, such as nutrition, education, and programs that improve the livelihood of individuals with HIV/AIDS as well as programs to address the needs and vulnerabilities of girls and women. It promotes the use of provider-initiated or "opt out" voluntary counseling and testing as well as rapid testing.

The section underscores the importance of operations research as a component of HIV/AIDS activities, and amends the 2003 Leadership Act to create an enhanced focus on food and nutrition assistance as critical to an integrated approach to treatment of individuals with HIV/AIDS. Section 301 authorizes, though does not mandate, compacts or framework agreements in order to promote a more sustainable, country-driven approach. The section includes necessary components of such compacts. It also expands the annual report to address a number of the new approaches described in this Act and to emphasize outcomes of programs.

Section 301 also amends section 301 of the 2003 Leadership Act to extend the authorization to fiscal years 2009 through 2013.

Subsection (h) clarifies that not only are groups receiving funds under the Act not required to endorse or utilize any activities or programs to which they have a moral or religious objection, they are also not required to integrate with, or refer to programs to which they have a moral or religious objections.

Sec. 302. Assistance to combat tuberculosis

Subsections (a) and (b) amend section 104B of the Foreign Assistance Act of 1961 relating to assistance to combat tuberculosis, drawing from S. 968, the Stop Tuberculosis (TB) Now Act of 2007, which the committee approved on September 11, 2007. These amendments include a revised statement of policy; a requirement to provide assistance to combat tuberculosis and a list of activities to be carried out, including diagnostic testing and counseling, treatment, and implementation of protocols to address drug resistance.

Subsection (c) authorizes the provision of increased resources to the World Health Organization.

Subsection (d) offers definitions of additional terms.

Subsection (e) amends section 302 of the 2003 Leadership Act to authorize up to a total of $4 billion for fiscal years 2009 to 2013 from the overall amounts authorized by section 401 of the 2003 Leadership Act (as amended by this Act) for assistance to combat tuberculosis.

Sec. 303. Assistance to combat malaria

Subsection (a) amends section 104C of the Foreign Assistance Act of 1961 to ensure that treatment is part of U.S. efforts to combat malaria.

Subsection (b) amends section 303 of the 2003 Leadership Act to authorize up to a total of $5 billion for fiscal years 2009 to 2013 from the overall amounts authorized by section 401 of the 2003 Leadership Act (as amended by this Act) for assistance to combat malaria.

Subsection (c) provides a statement of policy regarding malaria.

Subsection (d) requires the President to provide a comprehensive 5-year strategy to combat malaria.

Sec. 304. Malaria Response Coordinator

Section 304 amends section 304 of the 2003 Leadership Act by adding a requirement for a comprehensive strategy to combat malaria and to establish within USAID a malaria coordinator. It also authorizes contributions to the Roll Back Malaria Partnership and the World Health Organization; research by relevant U.S. agencies to address prevention, treatment, and care of malaria; and requires an annual report on the prevention, treatment, control and elimination of malaria.

Sec. 305. Amendment to the Immigration and Nationality Act

Section 305 amends section 212(a)(1)(A) of the Immigration and Nationality Act by removing the statutory prohibition on persons with HIV entering the country. Under section 212, should this provision be enacted, aliens remain inadmissible if they have a "communicable disease of public health significance" under regulations issued by the Secretary for Health and Human Services.

Sec. 306. Clerical amendment

This provides a technical amendment to a subtitle heading in the 2003 Act.

Sec. 307. Requirements

This section amends section 312 of the 2003 Leadership Act to provide for additional policy and other requirements, including the establishment of targets for reaching 80 percent of the target population for prevention of mother-to-child transmission (PMTCT) of HIV and to ensure that the proportion of children receiving care and treatment for HIV/AIDS is proportionate to their numbers within the population. The section also calls for integrating care and treatment with PMTCT programs; expanding programs for orphans and for children who are affected by or vulnerable to HIV/AIDS; increasing access of women in PMTCT programs to maternal and child health services; and establishing a timeline for expanding access to PMTCT regimes.

Sec. 308. Annual reports on prevention of mother-to-child transmission of the HIV infection

This section amends section 313 of the 2003 Leadership Act by extending the duration of the annual PMTCT report required by such subsection and requires that such report include additional information on the number of women who receive various types of assistance related to PMTCT.

Section 309. Prevention of mother-to-child transmission expert panel

This section amends section 312 of the 2003 Leadership Act by directing the Global AIDS Coordinator to establish a panel of experts on the prevention of mother-to-child transmission of HIV to review PMTCT activities and make recommendations to the Global AIDS Coordinator and the appropriate congressional committees. The panel shall terminate 60 days after said report is submitted.

TITLE IV—FUNDING ALLOCATIONS

Sec. 401. Authorization of appropriations

Subsection (a) increases the authorization under section 401(a) of the 2003 Leadership Act to $50 billion for fiscal years 2009 to 2013. Unlike the House bill, which provides an authorization of $10 billion per fiscal year, this allows for a gradual expansion of the program.

Subsection (b) expresses the sense of the Congress that these funds should be gradually increased over the 5 fiscal years covered by the bill and in a manner consistent with program requirements, absorptive capacity, and priorities set forth in the Act. The committee does not expect the President to request or the Congress to fund these programs all in 1 year. For fiscal year 2008, Congress appropriated $6.327 billion for these programs, according to the Congressional Research Service.

Sec. 402. Sense of Congress

This section amends the "sense of Congress" language included in section 402(b) of the 2003 Leadership Act to eliminate specific spending directives in the legislation expressed as a sense of Con-

gress for percentage allocations for treatment and for the use of prevention funds for abstinence programs.

Sec. 403. Allocation of funds

This section amends section 403(a) of the 2003 Leadership Act to maintain focus on balanced prevention programming. This section includes a requirement that the Coordinator provide balanced funding for prevention activities for sexual transmission of HIV/AIDS and ensure that abstinence, delay sexual debut, monogamy, fidelity and partner reduction programs are implemented and funded in a meaningful and equitable way in the strategy for each host country, based on objective epidemiological evidence as to the source of infection and in consultation with the government of each host country involved in HIV/AIDS prevention activities.

The new subsection also provides that the Coordinator shall establish an HIV sexual transmission prevention strategy governing the expenditure of funds authorized by the Act used to prevent the sexual transmission of HIV in any host country with a generalized epidemic. In each such host country, if this strategy provides less than 50 percent of such funds for behavior change programs including abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction activities, the Coordinator shall, within 30 days of the issuance of this strategy, report to the appropriate congressional committees on the justification for this decision. The subsection excludes new prevention technologies or modalities such as medical male circumcision or microbicides as well as PMTCT activities, blood safety measures, and other prevention tools unrelated to the sexual transmission of HIV from calculations to determine compliance with the balanced funding reporting requirement.

Finally, this section maintains the 10-percent earmark for orphans and vulnerable children, and modifies the focus of this effort to include children who are vulnerable to, as well as affected by, HIV/AIDS to allow greater flexibility in providing services to at-risk children, especially in communities with high prevalence rates.

VI. COST ESTIMATE

In accordance with rule XXVI, paragraph 11(a) of the Standing Rules of the Senate, the committee provides this estimate of the costs of this legislation prepared by the Congressional Budget Office.

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 11, 2008.

Hon. JOSEPH R. BIDEN, Jr.,
Chairman, Committee on Foreign Relations,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 2731, the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Michelle S. Patterson.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

S. 2731—Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008

Summary: S. 2731 would reauthorize several assistance programs aimed at preventing and treating HIV/AIDS, tuberculosis, and malaria in other countries. For those programs, the bill would authorize the appropriation of $50 billion over the next 5 years. Other provisions of the bill would authorize funding for U.S. contributions to international vaccine funds and for research on the development of substances that can be applied topically to limit the transmission of HIV. CBO estimates that implementing S. 2731 would cost $35 billion over the 2009–2013 period, assuming appropriation of the authorized amounts. (Additional amounts would be spent after 2013.)

In addition, enacting S. 2731 would increase direct spending. The bill would allow immigrants with HIV/AIDS to enter the United States. CBO estimates that providing certain benefits to those immigrants and their children would increase direct spending by less than $500,000 in 2010 and by $83 million over the 2010–2018 period. Enacting S. 2731 would have no effect on revenues.

S. 2731 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that state spending for Medicaid would increase by $53 million over the 2010–2018 period as a result of the bill's immigration provisions, but such spending would not result from intergovernmental mandates.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 2731 is shown in Table 1. The costs of this legislation fall within budget functions 150 (international affairs), 550 (health), and 600 (income security).

TABLE 1.—ESTIMATED BUDGETARY IMPACT OF S. 2731

	By fiscal year, in millions of dollars—					
	2009	2010	2011	2012	2013	2009–2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
HIV/AIDS, Tuberculosis, and Malaria Programs:						
Estimated Authorization Level	10,000	10,000	10,000	10,000	10,000	50,000
Estimated Outlays	1,392	6,392	8,262	9,082	9,482	34,610
Contributions to Vaccine Funds:						
Estimated Authorization Level	108	108	108	158	158	640
Estimated Outlays	108	108	108	158	158	640
Microbicide Research:						
Estimated Authorization Level	10	11	13	12	12	58
Estimated Outlays	4	9	11	12	12	48
Total Changes:						
Estimated Authorization	10,118	10,119	10,121	10,170	10,170	50,698
Level Estimated Outlays	1,504	6,509	8,381	9,252	9,652	35,298

TABLE 1.—ESTIMATED BUDGETARY IMPACT OF S. 2731—Continued

	By fiscal year, in millions of dollars—					
	2009	2010	2011	2012	2013	2009–2013
CHANGES IN DIRECT SPENDING [1]						
Estimated Budget Authority	0	*	*	1	2	3
Estimated Outlays	0	*	*	1	2	3

[1] In addition to the direct spending effects shown here, enacting S. 2731 would have effects on direct spending after 2013 (see Table 2). The estimated increase in direct spending sums to $3 million over the 2010–2013 period and $83 million over the 2010–2018 period.

Note: * = less than $500,000.

Basis of estimate: For this estimate, CBO assumes that the bill will be enacted by September 30, 2008, that the authorized amounts will be appropriated, and that outlays will follow historical spending patterns for existing programs.

Spending subject to appropriation

S. 2731 would reauthorize several assistance programs and increase the funding levels for those programs. It also would require research into various vaccines and microbicides. In total, implementing the bill would have discretionary costs of $1.5 billion in 2009 and $35 billion over the 2009–2013 period.

HIV/AIDS, Tuberculosis, and Malaria Programs. Section 401 would authorize the appropriation of $50 billion over the 2009–2013 period. For this estimate, CBO assumes that $10 billion would be appropriated for each of the 5 years, though the allocation of the $50 billion authorization could vary from that assumption. The funds would be used to operate and expand the existing assistance programs that provide grants and contributions to organizations and global funds devoted to treating the effects of HIV/AIDS, tuberculosis, and malaria, and to preventing the transmission of those diseases. Those programs, which received a total of $6 billion for 2008, are run by the Department of State, the U.S. Agency for International Development (USAID), and the Department of Health and Human Services.

Based on information from the Department of State, CBO estimates that the authorized 5-year total of $50 billion is sufficient to fund the expanded requirements. CBO estimates that implementing section 401 would cost about $35 billion over the 2009–2013 period. Most of the additional amounts from the authorized funding would be spent by 2018.

Contribution to Vaccine Funds. Section 201 would authorize the appropriation of such sums as may be necessary to make contributions for research and development of various vaccines. Based on information from USAID on the current amount of contributions to those funds (about $100 million in 2008) and, after 2011, the amount needed to fund the final stages of development for a tuberculosis vaccine, CBO estimates that implementing section 201 would cost $640 million over the 2009–2013 period.

Microbicide Research. Section 203 would direct the Centers for Disease Control and Prevention (CDC) to conduct research with the goal of developing topical mircobicides that could be used to limit the transmission of HIV. For that purpose, it would authorize the appropriation of such sums as necessary.

Based on information from the CDC, CBO estimates that such research would require $10 million in 2009 and $58 million over the 2009–2013 period. Assuming appropriation of those amounts, and that spending for those activities would follow historical spending patterns, CBO estimates that implementing section 203 would cost $48 million over the 2009–2013 period.

AIDS Drug Assistance Programs. The Ryan White Care Act provides grants to states to run the AIDS Drug Assistance Program (ADAP). ADAP provides prescription drug benefits to certain low-income individuals with HIV/AIDS. Implementing S. 2731 would increase the number of individuals eligible for ADAP benefits. CBO estimates that the number of people newly eligible for ADAP benefits would reach about 1,000 in 2011.

The Ryan White Care Act authorizes the appropriation of specific amounts for ADAP through 2011. Absent a change in the specific authorization or appropriation for ADAP, no new Federal funding would be available to meet this increased demand. If additional funding were provided for the ADAP program, CBO estimates it would cost about $20 million in 2010 and 2011 to provide ADAP benefits to individuals affected by section 305. (This section would have direct spending costs, as explained below.)

Direct spending

Section 305 would amend the Immigration and Nationality Act by removing language that explicitly identified HIV infection—and consequently AIDS—as one of the communicable diseases of public-health significance that render aliens ineligible for visas or admission to the United States. Based on information from the CDC, CBO expects that the agency would amend the regulations concerning communicable diseases to allow aliens with HIV or AIDS into the United States if section 305 were enacted. CBO expects that the amended regulations would take effect at the beginning of fiscal year 2010.

Enacting section 305 would enable additional immigrants to receive visas to enter the United States, primarily in the visa program for immediate family members. (For some visa programs, the number of immigrants with HIV/AIDS would increase, but the total number of immigrants admitted would not change.) Based on information from the CDC, the World Health Organization, and the Department of Homeland Security, CBO estimates the annual number of additional immigrants with HIV/AIDS would total about 900 in 2010 and grow to approximately 4,300 in fiscal year 2013. Thereafter, the number of additional immigrants would grow in line with overall immigration, totaling roughly 5,600 in 2018. Additionally, CBO estimates that about 800 citizen-children would be born to those immigrants between 2010 and 2018, a markedly lower birth rate than that for non-HIV/AIDS immigrants.

CBO estimates that a small percentage of the immigrants who would enter the United States under section 305 would receive Federal disability, health, and nutrition benefits. In total, CBO estimates that providing benefits to those immigrants and their children would increase spending by less than $500,000 in 2010 and $83 million over the 2010–2018 period, as shown in Table 2. (Through 2017, the end of the Senate's enforcement period for di-

rect spending under the current budget resolution, the bill would increase direct spending by $46 million.)

TABLE 2.—COMPONENTS OF DIRECT SPENDING UNDER S. 2731

	By fiscal year, in millions of dollars—											
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2009-2013	2009-2018
CHANGES IN DIRECT SPENDING												
Medicaid:												
Estimated Budget Authority	0	*	*	1	2	3	5	10	18	31	3	70
Estimated Outlays	0	*	*	1	2	3	5	10	18	31	3	70
Food and Nutrition Programs:												
Estimated Budget Authority	0	*	*	*	*	1	1	1	3	3	*	9
Estimated Outlays	0	*	*	*	*	1	1	1	3	3	*	9
Supplemental Security Income:												
Estimated Budget Authority	0	*	*	*	*	*	*	*	1	3	*	4
Estimated Outlays	0	*	*	*	*	*	*	*	1	3	*	4
Total Changes:												
Estimated Budget Authority	0	*	*	1	2	4	6	11	22	37	3	83
Estimated Outlays	0	*	*	1	2	4	6	11	22	37	3	83

Note: * = less than $500,000.

Medicaid. Under the Medicaid eligibility rules for noncitizens, immigrants entering under section 305 who meet Medicaid's income and categorical eligibility criteria would have to wait 5 years before they could receive full Medicaid benefits. However, those individuals would be eligible for emergency Medicaid services before the end of the 5-year waiting period.

CBO estimates that enacting section 305 would increase direct spending for the Federal share of the Medicaid program by $3 million over the 2010–2013 period and $70 million over the 2010–2018 period. The increase in estimated costs after 2014 reflects individuals becoming eligible for full Medicaid benefits after completing the 5-year waiting period.

Food and Nutrition Programs. By 2018, CBO estimates that about 1,300 newly admitted immigrants would qualify for Food Stamps with an average benefit of about $130 a month. In addition, about 4,000 children of the additional immigrants would be eligible for child nutrition programs in 2018, with an average monthly cost of about $30 (in 2018 dollars). In total, CBO estimates that direct spending for the Food Stamp and Child Nutrition programs would increase by less than $500,000 in 2010 and $9 million over the 2010–2018 period.

Supplemental Security Income (SSI). CBO estimates that direct spending for the Supplemental Security Income program would increase by less than $500,000 in 2010 and $4 million over the 2010–2018 period. Under current law, immigrants generally have to wait until they became naturalized citizens before they can receive SSI. Based on data from the CDC, the Social Security Administration, and private researchers, CBO estimates that nearly 400 of the additional immigrants under section 305 would enter the rolls by 2018. Over that period, CBO projects average monthly benefits would grow from $500 to $590.

Social Security Disability Insurance. CBO estimates that, under section 305, off-budget direct spending for the Social Security Disability Insurance (DI) program would increase by less than $500,000 over the 10-year budget window. Based on the age and

health profile of immigrants, CBO estimates that few people would qualify for DI over that period.

Medicare. Noncitizens can become eligible for Medicare if they are over the age of 65 and are residents of the United States for five consecutive years, or after receiving DI for 2 years. CBO assumes that few of the new entrants under section 305 would meet either of these eligibility criteria. Therefore, CBO estimates that direct spending for Medicare would increase by less than $500,000 over the 2010–2018 period.

Estimated impact on state, local, and tribal governments: S. 2731 contains no intergovernmental mandates as defined in UMRA, but changes to immigration law would result in an increased number of individuals eligible for Medicaid, SSI, and ADAP. State spending for those programs would increase, but that additional spending would not result from intergovernmental mandates.

CBO estimates state spending for Medicaid would increase by $53 million over the 2010–2018 period, while state spending for supplemental SSI payments would increase only slightly. ADAP benefits are state-controlled, voluntary, and federally funded through grants. Any additional costs to state, local, or tribal governments might incur in that program, including matching funds, would result from complying with conditions of aid.

Estimated impact on the private sector: S. 2731 contains no new private-sector mandates as defined in UMRA.

Previous CBO estimate: On March 5, 2008, CBO transmitted a cost estimate for H.R. 5501, the Tom Lantos and Henry J. Hyde U.S. Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, as ordered reported by the House Committee on Foreign Affairs on February 28, 2008. While the two pieces of legislation have many provisions in common, S. 2731 contains two provisions that are not included in H.R. 5501. Section 305 of S. 2731 would allow immigrants with HIV to enter the United States, which CBO estimates would increase direct spending. In addition, section 203 of S. 2731 would require the CDC to conduct additional research. Differences in the estimated costs of S. 2731 and H.R. 5501 reflect those differences in the legislation.

Estimate prepared by: Federal Costs: Foreign Aid—Michelle S. Patterson; Centers for Disease Control and Prevention—Tim Gronniger; Supplemental Security Income—David Rafferty; Medicaid—Andrea Kastin Noda; Food and Nutrition Programs—Jonathan Morancy.

Impact on State, Local, and Tribal Governments: Neil Hood; Impact on the Private Sector: MarDestinee C. Perez.

Estimate approved by: Peter H. Fontaine, Assistant Director for Budget Analysis.

VII. MINORITY VIEWS

We strongly dissent from the committee's report of S. 2731 to the full Senate. We are gravely concerned that the President's Emergency Plan for AIDS Relief (PEPFAR) program is under serious threat of dramatic policy reversals that endanger the lives of millions around the world suffering from and at risk of contracting HIV/AIDS. First authorized in 2003, PEPFAR was a historic new approach to combating HIV/AIDS. The elements of the program were unprecedented:

- Saving the lives of people with AIDS: For the first time, the U.S. would fund antiretroviral treatment for millions.
- Evidence-based prevention: The U.S. would implement the African-grown "ABC" model of abstinence, "be faithful" and condoms that had led to such dramatic reductions in HIV incidence in Uganda.
- Concentration of effort: Targeted funding for the poorest countries in sub-Saharan Africa and the Caribbean with the worst AIDS epidemics.

As the bill to authorize this new initiative moved through the Congress, its sponsors and supporters fought hard to keep off the many worthy, but competing initiatives that would have diluted the impact of the PEPFAR program. Unfortunately, S. 2731 fails to protect the program from similar efforts; and we are gravely concerned that the noble impact and long-term legacy of the program are being threatened. Specifically, we believe that S. 2731 has the following serious flaws:

Politics Trump Proven Prevention Policy

We object to the bill's elimination of the protected funding for abstinence-until-marriage programs required under current law and replaces it with watered-down, ill-defined language that would permit a prevention program to operate without measurable, significant support for abstinence and fidelity programs. Prior to the implementation of PEPFAR, the only country to ever demonstrate a nationwide reduction in HIV incidence was Uganda. The success was driven by the African-grown, grassroots, low-tech, low-cost "ABC" model of HIV prevention, based on three commonsense messages, each targeted to a different population: (1) The promotion of abstinence until marriage or delay of sexual debut for youth and unmarried adults, (2) the promotion of fidelity within marriage and partner reduction for sexually active unmarried adults, and (3) the promotion of the consistent and correct use of condoms for especially high-risk subpopulations, such as prostitutes and their customers, substance abusers and their equipment-sharing and sexual partners, and HIV-serodiscordant married couples. The evidence is clear: ABC works to prevent sexual transmission of HIV/AIDS in a generalized epidemic such as you find in sub-Saharan Africa.

Nothing else ever has. As a result of this sound approach, Uganda now has company: Several PEPFAR focus countries have started to see reductions, including Kenya, Côte D'Ivoire, and Ethiopia.

No Conscience Protections for Organizations Providing HIV/AIDS Care

The bill removes most references to faith-based organizations contained in current law, causing us to question whether the bill authors intend PEPFAR to retreat from its important recognition of the indispensable role of such organizations in reaching communities affected by HIV/AIDS in the developing world that might never be successfully reached using U.S.-based USAID contractors. Of even more concern, however, is the bill's elimination of conscience protections for organizations providing the critical third element of the HIV treatment, prevention, and care combination. The bill protects organizations participating in HIV/AIDS treatment, prevention, and monitoring programs from being required to support or provide services to which they have a moral or religious objection. However, no such protection is provided for organizations providing HIV "care" programs, which include all programs for orphans and vulnerable children, hospice and palliative care services, support groups and psychosocial services and many other services.

Support for Morally Dubious Activities

The bill contains many references to activities "demonstrated to be effective in reducing the transmission of HIV infection among injection drug users without increasing illicit drug use." Given the claim by some that programs to distribute clean needles to injection drug users are effective at reducing transmission and do not lead to more drug use, these provisions could be interpreted to support needle exchange programs, a practice not currently supported domestically or abroad using U.S. funds. Americans should not be forced to subsidize the distribution of paraphernalia for illicit drug use, when the best HIV prevention for injection drug use would be treatment of the underlying addiction.

The Global Fund Takes Cues from the U.N.

When the 108th Congress authorized the first contribution to the Global Fund to Fight HIV/AIDS, Tuberculosis, we were assured that the Fund would not be like the U.N. and that the Fund would guarantee full transparency and accountability. The current law contains some important provisions to protect the taxpayer investment in this multilateral disease-fighting organization. However, we have seen during the first few years of the Fund's operation that these provisions have not been sufficient to ensure full accountability and transparency by the scandal-ridden Fund. What's more, the Fund has failed to provide Congress with all documents requested, including reports of the so-called "independent" Inspector General. The Fund has lost money by relying on the U.N. Development Program (UNDP) in Burma, and failed to recoup funds from terminated grants there. Burma is not the only country where the Fund relies on UNDP, but actually uses the U.N. agency as a "safer" alternative to directly funding rogue regimes such as Zimbabwe and Sudan. UNDP is under investigation by the U.S.

Senate Permanent Subcommittee on Investigations for using donor money to finance North Korea illicit weapons sales; laundering untold millions from terrorist regimes through U.N. bank accounts; using donor money to help Zimbabwe officials purchase "blood diamonds"; and a variety of other crimes.

Further, the Fund has failed to adequately safeguard the quality of medicines procured using its funding. While we support the bill's provision conditioning 20 percent of the U.S. contribution to the Fund to the achievement of certain accountability measures, the bill also contains a variety of important transparency measures in a nonbinding "Sense of Congress" provision. We believe that these provisions should be made binding, as well.

Fiscal Irresponsibility

Before PEPFAR was authorized, the U.S. spent less than $200 million annually on global AIDS. Compared to past levels, PEPFAR's initial authorization of $15 billion over 5 years was a dramatic increase. Indeed, the administration has ramped up to an annual spending level that grossly exceeds the statutory limit in current law. Even if Congress agreed to extend funding at these unauthorized levels, we would "only" need to pass a reauthorization bill to provide between $25–$30 billion over the next 5 years. S. 2731, however, authorizes $50 billion over 5 years in addition to numerous, "such sums" authorizations.

What's more, the current targeted, effective HIV/AIDS program is under assault in this bill by "mission creep" that threatens to dilute the impact of the program and violate all pretentions of fiscal restraint by prioritizing seemingly every activity except HIV treatment, prevention, and care. The bill's HIV programs are crowded out by every possible development program imaginable, including schools, poverty alleviation, microcredit, legal aid, government advocacy, women's "empowerment," "stigma reduction," nutrition, U.S.-based university agricultural research, biomedical vaccine development, and health workforce development. In addition to squeezing-out the higher priority HIV programs, the inclusion of all these additional development programs will only guarantee that the pressure to exceed the authorization caps in the bill will be irresistible in the out years as the development needs of the world can never be fully met.

CONCLUSION

The PEPFAR program has been one of the few success stories of U.S. foreign assistance policy. The scientific policy has been sound, the fiscal priorities appropriate, and the results astounding. As a means of building diplomatic good will, PEPFAR has been an unquestioned success in strengthening bilateral relationships in the important emerging governments and economies in Africa. Simply put, the program isn't "broken." The best approach to reauthorization would be to simply extend current authorities at a fiscally responsible level. S. 2731 is a radical departure from current policy, and will serve to reverse the many gains the program has achieved

to date. We dissent from the committee's report of the bill to the Senate for full consideration.

Sincerely,

DAVID VITTER,
U.S. Senator.
JIM DEMINT,
U.S. Senator.

VIII. CHANGES IN EXISTING LAW

In compliance with Rule XXVI, paragraph 12 of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman).

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003

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SEC. 2. FINDINGS.

Congress makes the following findings:

(1) * * *

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(28) * * *

(29) On May 27, 2003, the President signed this Act into law, launching the largest international public health program of its kind ever created.

(30) Between 2003 and 2008, the United States, through the President"s Emergency Plan for AIDS Relief (PEPFAR) and in conjunction with other bilateral programs and the multilateral Global Fund has helped to—

(A) provide antiretroviral therapy for over 1,900,000 people;

(B) ensure that over 150,000 infants, most of whom would have likely been infected with HIV during pregnancy or childbirth, were not infected; and

(C) provide palliative care and HIV prevention assistance to millions of other people.

(31) While United States leadership in the battles against HIV/AIDS, tuberculosis, and malaria has had an enormous impact, these diseases continue to take a terrible toll on the human race.

(32) According to the 2007 AIDS Epidemic Update of the Joint United Nations Programme on HIV/AIDS (UNAIDS)—

(A) an estimated 2,100,000 people died of AIDS-related causes in 2007; and

(B) an estimated 2,500,000 people were newly infected with HIV during that year.

(33) According to the World Health Organization, malaria kills more than 1,000,000 people per year, 70 percent of whom are children under 5 years of age.

(34) According to the World Health Organization, 1/3 of the world"s population is infected with the tuberculosis bacterium, and tuberculosis is 1 of the greatest infectious causes of death of adults worldwide, killing 1,600,000 people per year.

(35) Efforts to promote abstinence, fidelity, the correct and consistent use of condoms, the delay of sexual debut, and the reduction of concurrent sexual partners represent important elements of strategies to prevent the transmission of HIV/AIDS.

(36) According to UNAIDS—

(A) women and girls make up nearly 60 percent of persons in sub-Saharan Africa who are HIV positive;

(B) women and girls are more biologically, economically, and socially vulnerable to HIV infection; and

(C) gender issues are critical components in the effort to prevent HIV/AIDS and to care for those affected by the disease.

(37) Children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence may be vulnerable to the disease or its socioeconomic effects.

(38) Lack of health capacity, including insufficient personnel and inadequate infrastructure, in sub-Saharan Africa and other regions of the world is a critical barrier that limits the effectiveness of efforts to combat HIV/AIDS, tuberculosis, and malaria, and to achieve other global health goals.

(39) On March 30, 2007, the Institute of Medicine of the National Academies released a report entitled "PEPFAR Implementation: Progress and Promise", which found that budget allocations setting percentage levels for spending on prevention, care, and treatment and for certain subsets of activities within the prevention category—

(A) have "adversely affected implementation of the U.S. Global AIDS Initiative";

(B) have inhibited comprehensive, integrated, evidence based approaches;

(C) "have been counterproductive";

(D) "may have been helpful initially in ensuring a balance of attention to activities within the 4 categories of prevention, treatment, care, and orphans and vulnerable children";

(E) "have also limited PEPFAR"s ability to tailor its activities in each country to the local epidemic and to coordinate with the level of activities in the countries" national plans"; and

(F) should be removed by Congress and replaced with more appropriate mechanisms that—

(i) "ensure accountability for results from Country Teams to the U.S. Global AIDS Coordinator and to Congress"; and

(ii) "ensure that spending is directly linked to and commensurate with necessary efforts to achieve both country and overall performance targets for prevention, treatment, care, and orphans and vulnerable children".

(40) The United States Government has endorsed the principles of harmonization in coordinating efforts to combat HIV/AIDS commonly referred to as the "Three Ones", which includes—

(A) 1 agreed HIV/AIDS action framework that provides the basis for coordination of the work of all partners;

(B) 1 national HIV/AIDS coordinating authority, with a broadbased multisectoral mandate; and

(C) 1 agreed HIV/AIDS country-level monitoring and evaluating system.

(41) In the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases, of April 26–27, 2001 (referred to in this Act as the "Abuja Declaration"), the Heads of State and Government of the Organization of African Unity (OAU)—

(A) declared that they would "place the fight against HIV/AIDS at the forefront and as the highest priority issue in our respective national development plans";

(B) committed "TO TAKE PERSONAL RESPONSIBILITY AND PROVIDE LEADERSHIP for the activities of the National AIDS Commissions/Councils";

(C) resolved "to lead from the front the battle against HIV/AIDS, Tuberculosis and Other Related Infectious Diseases by personally ensuring that such bodies were properly convened in mobilizing our societies as a whole and providing focus for unified national policymaking and programme implementation, ensuring coordination of all sectors at all levels with a gender perspective and respect for human rights, particularly to ensure equal rights for people living with HIV/AIDS"; and

(D) pledged "to set a target of allocating at least 15% of our annual budget to the improvement of the health sector".

* * * * * * *

SEC. 3. DEFINITIONS.

In this Act:

(1) AIDS.—The term "AIDS" means the acquired immune deficiency syndrome.

(2) APPROPRIATE CONGRESSIONAL COMMITTEES.—The term "appropriate congressional committees" means the Committee on Foreign Relations of the Senate and the ⟦Committee on International Relations⟧ *Committee on Foreign Affairs of the House of Representatives, the Committee on Appropriations of the Senate, and the Committee on Appropriations* of the House of Representatives.

(3) GLOBAL AIDS COORDINATOR.—The term "Global AIDS Coordinator" means the Coordinator of United States Government Activities to Combat HIV/AIDS Globally.

⟦(3)⟧ *(4)* GLOBAL FUND.—The term "Global Fund" means the public-private partnership known as the Global Fund to Fight AIDS, Tuberculosis and Malaria established pursuant to Article 80 of the Swiss Civil Code.

⟦(4)⟧ *(5)* HIV.—The term "HIV" means the human immunodeficiency virus, the pathogen that causes AIDS.

⟦(5)⟧ *(6)* HIV/AIDS.—The term "HIV/AIDS" means, with respect to an individual, an individual who is infected with HIV or living with AIDS.

(7) IMPACT EVALUATION RESEARCH.—The term "impact evaluation research" means the application of research methods and statistical analysis to measure the extent to which change in a population-based outcome can be attributed to program intervention instead of other environmental factors.

(8) OPERATIONS RESEARCH.—The term "operations research" means the application of social science research methods and statistical analysis to judge, compare, and improve policies and program outcomes, from the earliest stages of defining and designing programs through their development and implementation, with the objective of the rapid dissemination of conclusions and concrete impact on programming.

(9) PARAPROFESSIONAL.—The term "paraprofessional" means an individual who is trained and employed as a health agent for the provision of basic assistance in the identification, prevention, or treatment of illness or disability.

(10) PARTNER GOVERNMENT.—The term "partner government" means a government with which the United States is working to provide assistance to combat HIV/AIDS, tuberculosis, or malaria on behalf of people living within the jurisdiction of such government.

(11) PROGRAM MONITORING.—The term "program monitoring" means the collection, analysis, and use of routine program data to determine—

(A) how well a program is carried out; and

(B) how much the program costs.

(12) STRUCTURAL HIV PREVENTION.—The term "structural HIV prevention" means activities or programs designed to—

(A) address environmental factors that could create conditions conducive to the spread of HIV; and

(B) determine the best ways to remedy such factors by enhancing life skills and promoting changes in laws, policies, and social norms.

[(6)**]** *(13)* RELEVANT EXECUTIVE BRANCH AGENCIES.—The term "relevant executive branch agencies" means the Department of State, the United States Agency for International Development, and any other department or agency of the United States that participates in international HIV/AIDS activities pursuant to the authorities of such department or agency or the Foreign Assistance Act of 1961.

[SEC. 4. PURPOSE.

[The purpose of this Act is to strengthen United States leadership and the effectiveness of the United States response to certain global infectious diseases by—

[(1) establishing a comprehensive, integrated five-year, global strategy to fight HIV/AIDS that encompasses a plan for phased expansion of critical programs and improved coordination among relevant executive branch agencies and between the United States and foreign governments and international organizations;

[(2) providing increased resources for multilateral efforts to fight HIV/AIDS;

[(3) providing increased resources for United States bilateral efforts, particularly for technical assistance and training, to combat HIV/AIDS, tuberculosis, and malaria;

[(4) encouraging the expansion of private sector efforts and expanding public-private sector partnerships to combat HIV/AIDS; and

[(5) intensifying efforts to support the development of vaccines and treatment for HIV/AIDS, tuberculosis, and malaria.]

SEC. 4. PURPOSE.

The purpose of this Act is to strengthen and enhance United States leadership and the effectiveness of the United States response to the HIV/AIDS, tuberculosis, and malaria pandemics and other related and preventable infectious diseases as part of the overall United States health and development agenda by—

(1) establishing comprehensive, coordinated, and integrated 5-year, global strategies to combat HIV/AIDS, tuberculosis, and malaria by—

(A) building on progress and successes to date;

(B) improving harmonization of United States efforts with national strategies of partner governments and other public and private entities; and

(C) emphasizing capacity building initiatives in order to promote a transition toward greater sustainability through the support of country-driven efforts;

(2) providing increased resources for bilateral and multilateral efforts to fight HIV/AIDS, tuberculosis, and malaria as integrated components of United States development assistance;

(3) intensifying efforts to—

(A) prevent HIV infection;

(B) ensure the continued support for, and expanded access to, treatment and care programs;

(C) enhance the effectiveness of prevention, treatment, and care programs; and

(D) address the particular vulnerabilities of girls and women;

(4) encouraging the expansion of private sector efforts and expanding public-private sector partnerships to combat HIV/AIDS, tuberculosis, and malaria;

(5) reinforcing efforts to—

(A) develop safe and effective vaccines, microbicides, and other prevention and treatment technologies; and

(B) improve diagnostics capabilities for HIV/AIDS, tuberculosis, and malaria; and

(6) helping partner countries to—

(A) strengthen health systems;

(B) improve human health capacity; and

(C) address infrastructural weaknesses.

SEC. 5. AUTHORITY TO CONSOLIDATE AND COMBINE REPORTS.

With respect to the reports required by this Act to be submitted by the President, to ensure an efficient use of resources, the President may, in his discretion and notwithstanding any other provision of this Act, consolidate or combine any of these reports, except for the report required by section 101 of this Act, so long as the

required elements of each report are addressed and reported within a 90-day period from the original deadline date for submission of the report specified in this Act. The President may also enter into contracts with organizations with relevant expertise to develop, originate, or contribute to any of the reports required by this Act to be submitted by the President*, with the exception of the 5-year strategy*.

TITLE I—POLICY PLANNING AND COORDINATION

SEC. 101. DEVELOPMENT OF A COMPREHENSIVE, FIVE-YEAR, GLOBAL STRATEGY.

[(a) STRATEGY.—The President shall establish a comprehensive, integrated, five-year strategy to combat global HIV/AIDS that strengthens the capacity of the United States to be an effective leader of the international campaign against HIV/AIDS. Such strategy shall maintain sufficient flexibility and remain responsive to the ever-changing nature of the HIV/AIDS pandemic and shall—

[(1) include specific objectives, multisectoral approaches, and specific strategies to treat individuals infected with HIV/AIDS and to prevent the further spread of HIV infections, with a particular focus on the needs of families with children (including the prevention of mother-to-child transmission), women, young people, and children (such as unaccompanied minor children and orphans);

[(2) as part of the strategy, implement a tiered approach to direct delivery of care and treatment through a system based on central facilities augmented by expanding circles of local delivery of care and treatment through local systems and capacity;

[(3) assign priorities for relevant executive branch agencies;

[(4) provide that the reduction of HIV/AIDS behavioral risks shall be a priority of all prevention efforts in terms of funding, educational messages, and activities by promoting abstinence from sexual activity and substance abuse, encouraging monogamy and faithfulness, promoting the effective use of condoms, and eradicating prostitution, the sex trade, rape, sexual assault and sexual exploitation of women and children;

[(5) improve coordination and reduce duplication among relevant executive branch agencies, foreign governments, and international organizations;

[(6) project general levels of resources needed to achieve the stated objectives;

[(7) expand public-private partnerships and the leveraging of resources;

[(8) maximize United States capabilities in the areas of technical assistance and training and research, including vaccine research;

[(9) establish priorities for the distribution of resources based on factors such as the size and demographics of the population with HIV/AIDS, tuberculosis, and malaria and the needs of that population and the existing infrastructure or funding levels that may exist to cure, treat, and prevent HIV/AIDS, tuberculosis, and malaria; and

[(10) include initiatives describing how the President will maximize the leverage of private sector dollars in reduction and treatment of HIV/AIDS, tuberculosis, and malaria.]

(a) STRATEGY.—The President shall establish a comprehensive, integrated, 5-year strategy to expand and improve efforts to combat global HIV/AIDS. This strategy shall—

(1) further strengthen the capability of the United States to be an effective leader of the international campaign against this disease and strengthen the capacities of nations experiencing HIV/AIDS epidemics to combat this disease;

(2) maintain sufficient flexibility and remain responsive to—

(A) changes in the epidemic;

(B) challenges facing partner countries in developing and implementing an effective national response; and

(C) evidence-based improvements and innovations in the prevention, care, and treatment of HIV/AIDS;

(3) situate United States efforts to combat HIV/AIDS, tuberculosis, and malaria within the broader United States global health and development agenda, establishing a roadmap to link investments in specific disease programs to the broader goals of strengthening health systems and infrastructure and to integrate and coordinate HIV/AIDS, tuberculosis, or malaria programs with other health or development programs, as appropriate;

(4) provide a plan to—

(A) prevent 12,000,000 new HIV infections worldwide;

(B) support treatment of at least 3,000,000 individuals with HIV/AIDS and support additional treatment through coordinated multilateral efforts;

(C) support care for 12,000,000 individuals with HIV/AIDS, including 5,000,000 orphans and vulnerable children affected by HIV/AIDS, with an emphasis on promoting a comprehensive, coordinated system of services to be integrated throughout the continuum of care;

(D) help partner countries in the effort to achieve goals of 80 percent access to counseling, testing, and treatment to prevent the transmission of HIV from mother to child, emphasizing a continuum of care model;

(E) help partner countries to provide care and treatment services to children with HIV in proportion to their percentage within the HIV-infected population in each country;

(F) promote preservice training for health professionals designed to strengthen the capacity of institutions to develop and implement policies for training health workers to combat HIV/AIDS, tuberculosis, and malaria;

(G) equip teachers with skills needed for HIV/AIDS prevention, treatment, and care;

(H) provide and share best practices for combating HIV/AIDS with health professionals; and

(I) help partner countries to train and support retention of healthcare professionals and paraprofessionals, with the target of training and retaining at least 140,000 new healthcare professionals and paraprofessionals and to strengthen capacities in developing countries, especially in

sub-Saharan Africa, to deliver primary healthcare with the objective of helping countries achieve staffing levels of at least 2.3 doctors, nurses, and midwives per 1,000 population, as called for by the World Health Organization;

(5) include multisectoral approaches and specific strategies to treat individuals infected with HIV/AIDS and to prevent the further transmission of HIV infections, with a particular focus on the needs of families with children (including the prevention of mother-to-child transmission), women, young people, orphans, and vulnerable children;

(6) establish a timetable with annual global treatment targets;

(7) expand the integration of timely and relevant research within the prevention, care, and treatment of HIV/AIDS;

(8) include a plan for program monitoring, operations research, and impact evaluation and for the dissemination of a best practices report to highlight findings;

(9) provide for consultation with local leaders and officials to develop prevention strategies and programs that are tailored to the unique needs of each country and community and targeted particularly toward those most at risk of acquiring HIV infection;

(10) make the reduction of HIV/AIDS behavioral risks a priority of all prevention efforts by—

(A) promoting abstinence from sexual activity and encouraging monogamy and faithfulness;

(B) encouraging the correct and consistent use of male and female condoms and increasing the availability of, and access to, these commodities;

(C) promoting the delay of sexual debut and the reduction of multiple concurrent sexual partners;

(D) promoting education for discordant couples (where an individual is infected with HIV and the other individual is uninfected or whose status is unknown) about safer sex practices;

(E) promoting voluntary counseling and testing, addiction therapy, and other prevention and treatment tools for illicit injection drug users and other substance abusers;

(F) educating men and boys about the risks of procuring sex commercially and about the need to end violent behavior toward women and girls;

(G) supporting comprehensive programs to promote alternative livelihoods, safety, and social reintegration strategies for commercial sex workers and their families;

(H) promoting cooperation with law enforcement to prosecute offenders of trafficking, rape, and sexual assault crimes with the goal of eliminating such crimes; and

(I) working to eliminate rape, gender-based violence, sexual assault, and the sexual exploitation of women and children;

(11) include programs to reduce the transmission of HIV through structural prevention efforts, particularly addressing the heightened vulnerabilities of women and girls to HIV in many countries; and

(12) support other important means of preventing or reducing the transmission of HIV, including—

(A) medical male circumcision;

(B) the maintenance of a safe blood supply; and

(C) other mechanisms to reduce the transmission of HIV;

(13) increase support for prevention of mother-to-child transmission;

(14) build capacity within the public health sector of developing countries by improving health systems and public health infrastructure and developing indicators to measure changes in broader public health sector capabilities;

(15) increase the coordination of HIV/AIDS programs with development programs;

(16) provide a framework for expanding or developing existing or new country or regional programs, including—

(A) drafting compacts or other agreements, as appropriate;

(B) establishing criteria and objectives for such compacts and agreements; and

(C) promoting sustainability;

(17) provide a plan for national and regional priorities for resource distribution and a global investment plan by region;

(18) provide a plan to address the immediate and ongoing needs of women and girls, which—

(A) addresses the vulnerabilities that contribute to their elevated risk of infection;

(B) includes specific goals and targets to address these factors;

(C) provides clear guidance to field missions to integrate gender across prevention, care, and treatment programs;

(D) sets forth gender-specific indicators to monitor progress on outcomes and impacts of gender programs;

(E) supports efforts in countries in which women or orphans lack inheritance rights and other fundamental protections to promote the passage, implementation, and enforcement of such laws;

(F) supports life skills training and other structural prevention activities, especially among women and girls, with the goal of reducing vulnerabilities to HIV/AIDS;

(G) addresses and prevents gender-based violence; and

(H) addresses the posttraumatic and psychosocial consequences and provides postexposure prophylaxis protecting against HIV infection to victims of gender-based violence and rape;

(19) provide a plan to address the vulnerabilities and needs of orphans and children who are vulnerable to, or affected by, HIV/AIDS;

(20) provide a framework to work with international actors and partner countries toward universal access to HIV/AIDS prevention, treatment, and care programs, recognizing that prevention is of particular importance in terms of sequencing;

(21) enhance the coordination of United States bilateral efforts to combat global HIV/AIDS with other major public and private entities;

(22) enhance the attention given to the national strategic HIV/AIDS plans of countries receiving United States assistance by—

(A) reviewing the planning and programmatic decisions associated with that assistance; and

(B) helping to strengthen such national strategies, if necessary;

(23) support activities described in the Global Plan to Stop TB, including—

(A) expanding and enhancing the coverage of the Directly Observed Treatment Short-course (DOTS) in order to treat individuals infected with tuberculosis and HIV, including multi-drug resistant or extensively drug resistant tuberculosis; and

(B) improving coordination and integration of HIV/AIDS and tuberculosis programming;

(24) ensure coordination between the Global AIDS Coordinator and the Malaria Coordinator and address issues of comorbidity between HIV/AIDS and malaria; and

(25) include a longer term estimate of the projected resource needs, progress toward greater sustainability and country ownership of HIV/AIDS programs, and the anticipated role of the United States in the global effort to combat HIV/AIDS during the 10-year period beginning on October 1, 2013.

[(b) REPORT.—

[(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the President shall submit to the appropriate congressional committees a report setting forth the strategy described in subsection (a).

[(2) REPORT CONTENTS.—The report required by paragraph (1) shall include a discussion of the elements described in paragraph (3) and may include a discussion of additional elements relevant to the strategy described in subsection (a). Such discussion may include an explanation as to why a particular element described in paragraph (3) is not relevant to such strategy.

[(3) REPORT ELEMENTS.—The elements referred to in paragraph (2) are the following:

[(A) The objectives, general and specific, of the strategy.

[(B) A description of the criteria for determining success of the strategy.

[(C) A description of the manner in which the strategy will address the fundamental elements of prevention and education, care, and treatment (including increasing access to pharmaceuticals and to vaccines), the promotion of abstinence, monogamy, avoidance of substance abuse, and use of condoms, research (including incentives for vaccine development and new protocols), training of healthcare workers, the development of healthcare infrastructure and delivery systems, and avoidance of substance abuse.

[(D) A description of the manner in which the strategy will promote the development and implementation of national and community-based multisectoral strategies and

programs, including those designed to enhance leadership capacity particularly at the community level.

[(E) A description of the specific strategies developed to meet the unique needs of women, including the empowerment of women in interpersonal situations, young people and children, including those orphaned by HIV/AIDS and those who are victims of the sex trade, rape, sexual abuse, assault, and exploitation.

[(F) A description of the specific strategies developed to encourage men to be responsible in their sexual behavior, child rearing and to respect women including the reduction of sexual violence and coercion.

[(G) A description of the specific strategies developed to increase women's access to employment opportunities, income, productive resources, and microfinance programs.

[(H) A description of the programs to be undertaken to maximize United States contributions in the areas of technical assistance, training (particularly of healthcare workers and community-based leaders in affected sectors), and research, including the promotion of research on vaccines and microbicides.

[(I) An identification of the relevant executive branch agencies that will be involved and the assignment of priorities to those agencies.

[(J) A description of the role of each relevant executive branch agency and the types of programs that the agency will be undertaking.

[(K) A description of the mechanisms that will be utilized to coordinate the efforts of the relevant executive branch agencies, to avoid duplication of efforts, to enhance on-site coordination efforts, and to ensure that each agency undertakes programs primarily in those areas where the agency has the greatest expertise, technical capabilities, and potential for success.

[(L) A description of the mechanisms that will be utilized to ensure greater coordination between the United States and foreign governments and international organizations including the Global Fund, UNAIDS, international financial institutions, and private sector organizations.

[(M) The level of resources that will be needed on an annual basis and the manner in which those resources would generally be allocated among the relevant executive branch agencies.

[(N) A description of the mechanisms to be established for monitoring and evaluating programs, promoting successful models, and for terminating unsuccessful programs.

[(O) A description of the manner in which private, nongovernmental entities will factor into the United States Government-led effort and a description of the type of partnerships that will be created to maximize the capabilities of these private sector entities and to leverage resources.

[(P) A description of the ways in which United States leadership will be used to enhance the overall inter-

national response to the HIV/AIDS pandemic and particularly to heighten the engagement of the member states of the G–8 and to strengthen key financial and coordination mechanisms such as the Global Fund and UNAIDS.

[(Q) A description of the manner in which the United States strategy for combating HIV/AIDS relates to and supports other United States assistance strategies in developing countries.

[(R) A description of the programs to be carried out under the strategy that are specifically targeted at women and girls to educate them about the spread of HIV/AIDS.

[(S) A description of efforts being made to address the unique needs of families with children with respect to HIV/AIDS, including efforts to preserve the family unit.

[(T) An analysis of the emigration of critically important medical and public health personnel, including physicians, nurses, and supervisors from sub-Saharan African countries that are acutely impacted by HIV/AIDS, including a description of the causes, effects, and the impact on the stability of health infrastructures, as well as a summary of incentives and programs that the United States could provide, in concert with other private and public sector partners and international organizations, to stabilize health institutions by encouraging critical personnel to remain in their home countries.

[(U) A description of the specific strategies developed to promote sustainability of HIV/AIDS pharmaceuticals (including antiretrovirals) and the effects of drug resistance on HIV/AIDS patients.

[(V) A description of the specific strategies to ensure that the extraordinary benefit of HIV/AIDS pharmaceuticals (especially antiretrovirals) are not diminished through the illegal counterfeiting of pharmaceuticals and black market sales of such pharmaceuticals.

[(W) An analysis of the prevalence of Human Papilloma Virus (HPV) in sub-Saharan Africa and the impact that condom usage has upon the spread of HPV in sub-Saharan Africa.]

(b) REPORT.—

(1) IN GENERAL.—Not later than October 1, 2009, the President shall submit a report to the appropriate congressional committees that sets forth the strategy described in subsection (a).

(2) CONTENTS.—The report required under paragraph (1) shall include a discussion of the following elements:

(A) The purpose, scope, methodology, and general and specific objectives of the strategy.

(B) The problems, risks, and threats to the successful pursuit of the strategy.

(C) The desired goals, objectives, activities, and outcome-related performance measures of the strategy.

(D) A description of future costs and resources needed to carry out the strategy.

(E) A delineation of United States Government roles, responsibility, and coordination mechanisms of the strategy.

(F) A description of the strategy—

(i) to promote harmonization of United States assistance with that of other international, national, and private actors as elucidated in the "Three Ones"; and

(ii) to address existing challenges in harmonization and alignment.

(G) A description of the manner in which the strategy will—

(i) further the development and implementation of the national multisectoral strategic HIV/AIDS frameworks of partner governments; and

(ii) enhance the centrality, effectiveness, and sustainability of those national plans.

(H) A description of how the strategy will seek to achieve the specific targets described in subsection (a) and other targets, as appropriate.

(I) A description of, and rationale for, the timetable for annual global treatment targets.

(J) A description of how operations research is addressed in the strategy and how such research can most effectively be integrated into care, treatment, and prevention activities in order to—

(i) improve program quality and efficiency;

(ii) ascertain cost effectiveness;

(iii) ensure transparency and accountability;

(iv) assess population-based impact;

(v) disseminate findings and best practices; and

(vi) optimize delivery of services.

(K) An analysis of United States-assisted strategies to prevent the transmission of HIV/AIDS, including methodologies to promote abstinence, monogamy, faithfulness, the correct and consistent use of male and female condoms, reductions in concurrent sexual partners, and delay of sexual debut, and of intended monitoring and evaluation approaches to measure the effectiveness of prevention programs and ensure that they are targeted to appropriate audiences.

(L) Within the analysis required under subparagraph (J), an examination of additional planned means of preventing the transmission of HIV including medical male circumcision, maintenance of a safe blood supply, and other tools.

(M) A description of the specific targets, goals, and strategies developed to address the needs and vulnerabilities of women and girls to HIV/AIDS, including—

(i) structural prevention activities;

(ii) activities directed toward men and boys;

(iii) activities to enhance educational, microfinance, and livelihood opportunities for women and girls;

(iv) activities to promote and protect the legal empowerment of women, girls, and orphans and vulnerable children;

(v) programs targeted toward gender-based violence and sexual coercion;

(vi) strategies to meet the particular needs of adolescents;

(vii) assistance for victims of rape, sexual abuse, assault, exploitation, and trafficking; and

(viii) programs to prevent alcohol abuse.

(N) A description of strategies—

(i) to address the needs of orphans and vulnerable children, including an analysis of—

(I) factors contributing to children's vulnerability to HIV/AIDS; and

(II) vulnerabilities caused by the impact of HIV/AIDS on children and their families; and

(ii) in areas of higher HIV/AIDS prevalence, to promote a community-based approach to vulnerability, maximizing community input into determining which children participate.

(O) A description of capacity-building efforts undertaken by countries themselves, including adherents of the Abuja Declaration and an assessment of the impact of International Monetary Fund macroeconomic and fiscal policies on national and donor investments in health.

(P) A description of the strategy to—

(i) strengthen capacity building within the public health sector;

(ii) improve healthcare in those countries;

(iii) help countries to develop and implement national health workforce strategies;

(iv) strive to achieve goals in training, retaining, and effectively deploying health staff;

(v) promote ethical recruiting practices for healthcare workers; and

(vi) increase the sustainability of health programs.

(Q) A description of the criteria for selection, objectives, methodology, and structure of compacts or other framework agreements with countries or regional organizations, including—

(i) the role of civil society;

(ii) the degree of transparency;

(iii) benchmarks for success of such compacts or agreements; and

(iv) the relationship between such compacts or agreements and the national HIV/AIDS and public health strategies and commitments of partner countries.

(R) A strategy to better coordinate HIV/AIDS assistance with nutrition and food assistance programs.

(S) A description of transnational or regional initiatives to combat regionalized epidemics in highly affected areas such as the Caribbean.

(T) A description of planned resource distribution and global investment by region.

(U) A description of coordination efforts in order to better implement the Stop TB Strategy and to address the prob-

lem of coinfection of HIV/AIDS and tuberculosis and of projected challenges or barriers to successful implementation.

(V) A description of coordination efforts to address malaria and comorbidity with malaria and HIV/AIDS.

[(c) STUDY; DISTRIBUTION OF RESOURCES.—

[(1) STUDY.—Not later than 3 years after the date of the enactment of this Act, the Institute of Medicine shall publish findings comparing the success rates of the various programs and methods used under the strategy described in subsection (a) to reduce, prevent, and treat HIV/AIDS, tuberculosis, and malaria.

[(2) DISTRIBUTION OF RESOURCES.— In prioritizing the distribution of resources under the strategy described in subsection (a), the President shall consider the findings published by the Institute of Medicine under this subsection.]

(c) STUDY OF PROGRESS TOWARD ACHIEVEMENT OF POLICY OBJECTIVES.—

(1) DESIGN AND BUDGET PLAN FOR DATA EVALUATION.—The Global AIDS Coordinator shall enter into a contract with the Institute of Medicine of the National Academies that provides that not later than 18 months after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, the Institute, in consultation with the Global AIDS Coordinator and other relevant parties representing the public and private sector, shall provide the Global AIDS Coordinator with a design plan and budget for the evaluation and collection of baseline and subsequent data to address the elements set forth in paragraph (2)(B). The Global AIDS Coordinator shall submit the budget and design plan to the appropriate congressional committees.

(2) STUDY.—

(A) IN GENERAL.—Not later than 4 years after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, the Institute of Medicine of the National Academies shall publish a study that includes—

(i) an assessment of the performance of United States-assisted global HIV/AIDS programs; and

(ii) an evaluation of the impact on health of prevention, treatment, and care efforts that are supported by United States funding, including multilateral and bilateral programs involving joint operations.

(B) CONTENT.—The study conducted under this paragraph shall include—

(i) an assessment of progress toward prevention, treatment, and care targets;

(ii) an assessment of the effects on health systems, including on the financing and management of health systems and the quality of service delivery and staffing;

(iii) an assessment of efforts to address gender-specific aspects of HIV/AIDS, including gender related

constraints to accessing services and addressing underlying social and economic vulnerabilities of women and men;

(iv) an evaluation of the impact of treatment and care programs on 5-year survival rates, drug adherence, and the emergence of drug resistance;

(v) an evaluation of the impact of prevention programs on HIV incidence in relevant population groups;

(vi) an evaluation of the impact on child health and welfare of interventions authorized under this Act on behalf of orphans and vulnerable children;

(vii) an evaluation of the impact of programs and activities authorized in this Act on child mortality; and

(viii) recommendations for improving the programs referred to in subparagraph (A)(i).

(C) METHODOLOGIES.—Assessments and impact evaluations conducted under the study shall utilize sound statistical methods and techniques for the behavioral sciences, including random assignment methodologies as feasible. Qualitative data on process variables should be used for assessments and impact evaluations, wherever possible.

(3) CONTRACT AUTHORITY.—The Institute of Medicine may enter into contracts or cooperative agreements or award grants to conduct the study under paragraph (2).

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out the study under this subsection.

(d) COMPTROLLER GENERAL REPORT.—

(1) REPORT REQUIRED.—Not later than 3 years after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, the Comptroller General of the United States shall submit a report on the global HIV/AIDS programs of the United States to the appropriate congressional committees.

(2) CONTENTS.—The report required under paragraph (1) shall include—

(A) a description and assessment of the monitoring and evaluation practices and policies in place for these programs;

(B) an assessment of coordination within Federal agencies involved in these programs, examining both internal coordination within these programs and integration with the larger global health and development agenda of the United States;

(C) an assessment of procurement policies and practices within these programs;

(D) an assessment of harmonization with national government HIV/AIDS and public health strategies as well as other international efforts;

(E) an assessment of the impact of global HIV/AIDS funding and programs on other United States global health programming; and

(F) recommendations for improving the global HIV/AIDS programs of the United States.

(e) BEST PRACTICES REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and annually thereafter, the Global AIDS Coordinator shall publish a best practices report that highlights the programs receiving financial assistance from the United States that have the potential for replication or adaption, particularly at a low cost, across global AIDS programs, including those that focus on both generalized and localized epidemics.

(2) DISSEMINATION OF FINDINGS.—

(A) PUBLICATION ON INTERNET WEBSITE.—The Global AIDS Coordinator shall disseminate the full findings of the annual best practices report on the Internet website of the Office of the Global AIDS Coordinator.

(B) DISSEMINATION GUIDANCE.—The Global AIDS Coordinator shall develop guidance to ensure timely submission and dissemination of significant information regarding best practices with respect to global AIDS programs.

(f) INSPECTORS GENERAL.—

(1) OVERSIGHT PLAN.—

(A) DEVELOPMENT.—The Inspectors General of the Department of State and Broadcasting Board of Governors, the Department of Health and Human Services, and the United States Agency for International Development shall jointly develop 5 coordinated annual plans for oversight activity in each of the fiscal years 2009 through 2013, with regard to the programs authorized under this Act and sections 104A, 104B, and 104C of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–2, 2151b–3, and 2151b–4).

(B) CONTENTS.—The plans developed under subparagraph (A) shall include a schedule for financial audits, inspections, and performance reviews, as appropriate.

(C) DEADLINE.—

(i) INITIAL PLAN.—The first plan developed under subparagraph (A) shall be completed not later than the later of—

(I) September 1, 2008; or

(II) 60 days after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(ii) SUBSEQUENT PLANS.—Each of the last four plans developed under subparagraph (A) shall be completed not later than 30 days before each of the fiscal years 2010 through 2013, respectively.

(2) COORDINATION.—In order to avoid duplication and maximize efficiency, the Inspectors General described in paragraph (1) shall coordinate their activities with—

(A) the Government Accountability Office; and

(B) the Inspectors General of the Department of Commerce, the Department of Defense, the Department of Labor, and the Peace Corps, as appropriate, pursuant to the 2004 Memorandum of Agreement Coordinating Audit Coverage of Programs and Activities Implementing the President's Emergency Plan for AIDS Relief, or any successor agreement.

(3) FUNDING.—The Global AIDS Coordinator and the Coordinator of the United States Government Activities to Combat Malaria Globally shall make available necessary funds not exceeding $10,000,000 during the 5-year period beginning on October 1, 2008 to the Inspectors General described in paragraph (1) for the audits, inspections, and reviews described in that paragraph.

SEC. 102. HIV/AIDS RESPONSE COORDINATOR.

(a) ESTABLISHMENT OF POSITION.—* * *

* * * * * * *

(d) SENSE OF CONGRESS.—It is the sense of Congress that—

(1) full-time country level coordinators, preferably with management experience, should head each HIV/AIDS country team for United States missions overseeing significant HIV/AIDS programs;

(2) foreign service nationals provide critically important services in the design and implementation of United States country-level HIV/AIDS programs and their skills and experience as public health professionals should be recognized within hiring and compensation practices; and

(3) staffing levels for United States country-level HIV/AIDS teams should be adequately maintained to fulfill oversight and other obligations of the positions.

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TITLE II—SUPPORT FOR MULTILATERAL FUNDS, PROGRAMS, AND PUBLIC-PRIVATE PARTNERSHIPS

SEC. 201. SENSE OF CONGRESS ON PUBLIC-PRIVATE PARTNERSHIPS.

* * * * * * *

SEC. 202. PARTICIPATION IN THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA.

[(a) FINDINGS.—The Congress finds as follows:

[(1) The establishment of the Global Fund in January 2002 is consistent with the general principles for an international AIDS trust fund first outlined by the Congress in the Global AIDS and Tuberculosis Relief Act of 2000 (Public Law 106–264).

[(2) Section 2, Article 5 of the bylaws of the Global Fund provides for the International Bank for Reconstruction and Development to serve as the initial collection trustee for the Global Fund.

[(3) The trustee agreement signed between the Global Fund and the International Bank for Reconstruction and Development narrows the range of duties to include receiving and in-

vesting funds from donors, disbursing the funds upon the instruction of the Global Fund, reporting on trust fund resources to donors and the Global Fund, and providing an annual external audit report to the Global Fund.]

(a) FINDINGS; SENSE OF CONGRESS.—

(1) FINDINGS.—Congress makes the following findings:

(A) The establishment of the Global Fund in January 2002 is consistent with the general principles for an international AIDS trust fund first outlined by Congress in the Global AIDS and Tuberculosis Relief Act of 2000 (Public Law 106–264).

(B) The Global Fund is an innovative financing mechanism which—

(i) has made progress in many areas in combating HIV/AIDS, tuberculosis, and malaria; and

(ii) represents the multilateral component of this Act, extending United States efforts to more than 130 countries around the world.

(C) The Global Fund and United States bilateral assistance programs—

(i) are demonstrating increasingly effective coordination, with each possessing certain comparative advantages in the fight against HIV/AIDS, tuberculosis, and malaria; and

(ii) often work most effectively in concert with each other.

(D) The United States Government—

(i) is the largest supporter of the Global Fund in terms of resources and technical support;

(ii) made the founding contribution to the Global Fund; and

(iii) is fully committed to the success of the Global Fund as a multilateral public-private partnership.

(2) SENSE OF CONGRESS.—It is the sense of Congress that—

(A) transparency and accountability are crucial to the long-term success and viability of the Global Fund;

(B) the Global Fund has made significant progress toward addressing concerns raised by the Government Accountability Office by—

(i) improving risk assessment and risk management capabilities;

(ii) providing clearer guidance for and oversight of Local Fund Agents; and

(iii) strengthening the Office of the Inspector General for the Global Fund;

(C) the provision of sufficient resources and authority to the Office of the Inspector General for the Global Fund to ensure that office has the staff and independence necessary to carry out its mandate will be a measure of the commitment of the Global Fund to transparency and accountability;

(D) regular, publicly published financial, programmatic, and reporting audits of the Fund, its grantees, and Local

Fund Agents are also important benchmarks of transparency;

(E) the Global Fund should establish and maintain a system to track—

(i) the amount of funds disbursed to each subrecipient on the grant's fiscal cycle; and

(ii) the distribution of resources, by grant and principal recipient, for prevention, care, treatment, drug and commodity purchases, and other purposes;

(F) relevant national authorities in recipient countries should exempt from duties and taxes all products financed by Global Fund grants and procured by any principal recipient or subrecipient for the purpose of carrying out such grants;

(G) the Global Fund, UNAIDS, and the Global AIDS Coordinator should work together to standardize program indicators wherever possible; and

(H) for purposes of evaluating total amounts of funds contributed to the Global Fund under subsection (d)(4)(A)(i), the timetable for evaluations of contributions from sources other than the United States should take into account the fiscal calendars of other major contributors.

* * * * * * *

(d) UNITED STATES FINANCIAL PARTICIPATION.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to any other funds authorized to be appropriated for bilateral or multilateral HIV/AIDS, tuberculosis, or malaria programs, of the amounts authorized to be appropriated under section 401, there are authorized to be appropriated to the President up to **[**$1,000,000,000 for the period of fiscal year 2004 beginning on January 1, 2004,**]** *$2,000,000,000 for fiscal year 2009,* and such sums as may be necessary for **[**the fiscal years 2005–2008**]** *each of the fiscal years 2010 through 2013*, for contributions to the Global Fund.

(2) AVAILABILITY OF FUNDS.—Amounts appropriated under paragraph (1) are authorized to remain available until expended.

(3) REPROGRAMMING OF FISCAL YEAR 2001 FUNDS.—Funds made available for fiscal year 2001 under section 141 of the Global AIDS and Tuberculosis Relief Act of 2000—

(A) are authorized to remain available until expended; and

(B) shall be transferred to, merged with, and made available for the same purposes as, funds made available for fiscal years 2004 through 2008 under paragraph (1).

(4) LIMITATION.—

(A)(i) At any time during **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013*, no United States contribution to the Global Fund may cause the total amount of United States Government contributions to the Global Fund to exceed 33 percent of the total amount of funds contributed to the Global Fund from all sources. Contributions to the Global Fund from the International Bank for Reconstruction and Development and the Inter-

national Monetary Fund shall not be considered in determining compliance with this paragraph.

(ii) If, at any time [during any of the fiscal years 2004 through 2008] *during any of the fiscal years 2009 through 2013*, the President determines that the Global Fund has provided assistance to a country, the government of which the Secretary of State has determined, for purposes of section 6(j)(1) of the Export Administration Act of 1979 (50 U.S.C. App. 2405(j)(1)), has repeatedly provided support for acts of international terrorism, then the United States shall withhold from its contribution for the next fiscal year an amount equal to the amount expended by the Fund to the government of each such country.

(iii) If at any time the President determines that the expenses of the Governing, Administrative, and Advisory Bodies (including the Partnership Forum, the Foundation Board, the Secretariat, and the Technical Review Board) of the Global Fund exceed 10 percent of the total expenditures of the Fund for any 2-year period, the United States shall withhold from its contribution for the next fiscal year an amount equal the to the average annual amount expended by the Fund for such 2-year period for the expenses of the Governing, Administrative, and Advisory Bodies in excess of 10 percent of the total expenditures of the Fund.

(iv) The President may waive the application of clause (iii) if the President determines that extraordinary circumstances warrant such a waiver. No waiver under this clause may be for any period that exceeds 1 year.

(v) If, at any time during any of the fiscal years 2004 through 2008, the President determines that the salary of any individual employed by the Global Fund exceeds the salary of the Vice President of the United States (as determined under section 104 of title 3, United States Code) for that fiscal year, then the United States shall withhold from its contribution for the next fiscal year an amount equal to the aggregate amount by which the salary of each such individual exceeds the salary of the Vice President of the United States.

(vi) [for the purposes] *For the purposes* of clause (i), "funds contributed to the Global Fund from all sources" means funds contributed to the Global Fund at any time during [fiscal years 2004 through 2008] *fiscal years 2009 through 2013* that are not contributed to fulfill a commitment made for a fiscal year [prior to fiscal year 2004] *before fiscal year 2009*.

(B)(i) Any amount made available under this subsection that is withheld by reason of subparagraph (A)(i) shall be contributed to the Global Fund as soon as practicable, subject to subparagraph (A)(i), after additional contributions to the Global Fund are made from other sources.

(ii) Any amount made available under this subsection that is withheld by reason of subparagraph (A)(iii) shall be transferred to the Activities to Combat HIV/AIDS Globally

Fund and shall remain available under the same terms and conditions as funds appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance.

(iii) Any amount made available under this subsection that is withheld by reason of clause (ii) or (iii) of subparagraph (A) is authorized to be made available to carry out section 104A of the Foreign Assistance Act of 1961 (as added by section 301 of this Act). Amounts made available under the preceding sentence are in addition to amounts appropriated pursuant to the authorization of appropriations under section 401 of this Act for HIV/AIDS assistance.

(iv) Notwithstanding clause (i), after July 31 of each of the ⟦fiscal years 2004 through 2008⟧ *fiscal years 2009 through 2013*, any amount made available under this subsection that is withheld by reason of subparagraph(A)(i) is authorized to be made available to carry out sections 104A, 104B, and 104C of the Foreign Assistance Act of 1961 (as added by title III of this Act).

(C)(i) The President may suspend the application of subparagraph (A) with respect to a fiscal year if the President determines that an international health emergency threatens the national security interests of the United States.

(ii) The President shall notify the ⟦Committee on International Relations⟧ *Committee on Foreign Affairs* of the House of Representatives and the Committee on Foreign Relations of the Senate not less than 5 days before making a determination under clause (i) with respect to the application of subparagraph (A)(i) and shall include in the notification—

(I) a justification as to why increased United States Government contributions to the Global Fund is preferable to increased United States assistance to combat HIV/AIDS, tuberculosis, and malaria on a bilateral basis; and

(II) an explanation as to why other government donors to the Global Fund are unable to provide adequate contributions to the Fund.

(5) WITHHOLDING FUNDS.—Notwithstanding any other provision of this Act, 20 percent of the amounts appropriated pursuant to this Act for a contribution to support the Global Fund for each of the fiscal years 2010 through 2013 shall be withheld from obligation to the Global Fund until the Secretary of State certifies to the appropriate congressional committees that the Global Fund—

(A) has established an evaluation framework for the performance of Local Fund Agents (referred to in this paragraph as "LFAs");

(B) is undertaking a systematic assessment of the performance of LFAs;

(C) is making available for public review, according to the Fund Board's policies and practices on disclosure of information, a regular collection and analysis of performance

data of Fund grants, which shall cover principal recipients and subrecipients;

(D) is maintaining an independent, well-staffed Office of the Inspector General that—

(i) reports directly to the Board of the Global Fund; and

(ii) is responsible for regular, publicly published audits of financial, programmatic, and reporting aspects of the Global Fund, its grantees, and LFAs;

(E) has established, and is reporting publicly on, standard indicators for all program areas;

(F) has established a methodology to track and is reporting on—

(i) all subrecipients and the amount of funds disbursed to each subrecipient on the grant's fiscal cycle; and

(ii) the distribution of resources, by grant and principal recipient, for prevention, care, treatment, drugs and commodities purchase, and other purposes;

(G) has established a policy on tariffs imposed by national governments on all goods and services financed by the Global Fund;

(H) through its Secretariat, has taken meaningful steps to prevent national authorities in recipient countries from imposing taxes or tariffs on goods or services provided by the Fund;

(I) is maintaining its status as a financing institution focused on programs directly related to HIV/AIDS, malaria, and tuberculosis; and

(J) is maintaining and making progress on—

(i) sustaining its multisectoral approach, through country coordinating mechanisms; and

(ii) the implementation of grants, as reflected in the proportion of resources allocated to different sectors, including governments, civil society, and faith- and community-based organizations.

SEC. 204. COMBATING HIV/AIDS, TUBERCULOSIS, AND MALARIA BY STRENGTHENING HEALTH POLICIES AND HEALTH SYSTEMS OF PARTNER COUNTRIES.

(a) STATEMENT OF POLICY.—It shall be the policy of the United States Government—

(1) to invest appropriate resources authorized under this Act—

(A) to carry out activities to strengthen HIV/AIDS, tuberculosis, and malaria health policies and health systems; and

(B) to provide workforce training and capacity-building consistent with the goals and objectives of this Act; and

(2) to support the development of a sound policy environment in partner countries to increase the ability of such countries—

(A) to maximize utilization of healthcare resources from donor countries;

(B) to increase national investments in health and education and maximize the effectiveness of such investments;

(C) to improve national HIV/AIDS, tuberculosis, and malaria strategies;

(D) to deliver evidence-based services in an effective and efficient manner; and

(E) to reduce barriers that prevent recipients of services from achieving maximum benefit from such services.

(b) ASSISTANCE TO IMPROVE PUBLIC FINANCE MANAGEMENT SYSTEMS.—

(1) IN GENERAL.—Consistent with the authority under section 129 of the Foreign Assistance Act of 1961 (22 U.S.C. 2152), the Secretary of the Treasury, acting through the head of the Office of Technical Assistance, is authorized to provide assistance for advisors and partner country finance, health, and other relevant ministries to improve the effectiveness of public finance management systems in partner countries to enable such countries to receive funding to carry out programs to combat HIV/AIDS, tuberculosis, and malaria and to manage such programs.

(2) AUTHORIZATION OF APPROPRIATIONS.—Of the amounts authorized to be appropriated under section 401 for HIV/AIDS assistance, there are authorized to be appropriated to the Secretary of the Treasury such sums as may be necessary for each of the fiscal years 2009 through 2013 to carry out this subsection.

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TITLE III—BILATERAL EFFORTS

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SEC. 301. ASSISTANCE TO COMBAT HIV/AIDS.

(a) AMENDMENT OF THE FOREIGN ASSISTANCE ACT OF 1961.—* * *

* * * * * * *

(b) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, such sums as may be necessary for each of the **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013* to carry out section 104A of the Foreign Assistance Act of 1961, as added by subsection (a).

(2) AVAILABILITY OF FUNDS.—Amounts appropriated pursuant to paragraph (1) are authorized to remain available until expended.

(3) ALLOCATION OF FUNDS.—Of the amount authorized to be appropriated by paragraph (1) for the **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013*, such sums as may be necessary are authorized to be appropriated to carry out section 104A(d)(4) of the Foreign Assistance Act of 1961 (as added by subsection (a)), relating to the procurement and distribution of HIV/AIDS pharmaceuticals.

[(c) RELATIONSHIP TO ASSISTANCE PROGRAMS TO ENHANCE NUTRITION.—In recognition of the fact that malnutrition may hasten the progression of HIV to AIDS and may exacerbate the decline among AIDS patients leading to a shorter life span, the Administrator of the United States Agency for International Development shall, as appropriate—

[(1) integrate nutrition programs with HIV/AIDS activities, generally;

[(2) provide, as a component of an anti-retroviral therapy program, support for food and nutrition to individuals infected with and affected by HIV/AIDS; and

[(3) provide support for food and nutrition for children affected by HIV/AIDS and to communities and households caring for children affected by HIV/AIDS.]

(c) FOOD AND NUTRITIONAL SUPPORT.—

(1) IN GENERAL.—As indicated in the report produced by the Institute of Medicine, entitled "PEPFAR Implementation: Progress and Promise", inadequate caloric intake has been clearly identified as a principal reason for failure of clinical response to antiretroviral therapy. In recognition of the impact of malnutrition as a clinical health issue for many persons living with HIV/AIDS that is often associated with health and economic impacts on these individuals and their families, the Global AIDS Coordinator and the Administrator of the United States Agency for International Development shall—

(A) follow World Health Organization guidelines for HIV/AIDS food and nutrition services;

(B) integrate nutrition programs with HIV/AIDS activities through effective linkages among the health, agricultural, and livelihood sectors and establish additional services in circumstances in which referrals are inadequate or impossible;

(C) provide, as a component of care and treatment programs for persons with HIV/AIDS, food and nutritional support to individuals infected with, and affected by, HIV/AIDS who meet established criteria for nutritional support (including clinically malnourished children and adults, and pregnant and lactating women in programs in need of supplemental support), including—

(i) anthropometric and dietary assessment;

(ii) counseling; and

(iii) therapeutic and supplementary feeding;

(D) provide food and nutritional support for children affected by HIV/AIDS and to communities and households caring for children affected by HIV/AIDS; and

(E) in communities where HIV/AIDS and food insecurity are highly prevalent, support programs to address these often intersecting health problems through community-based assistance programs, with an emphasis on sustainable approaches.

(2) AUTHORIZATION OF APPROPRIATIONS.—Of the amounts authorized to be appropriated under section 401, there are authorized to be appropriated to the President such sums as may be

necessary for each of the fiscal years 2009 through 2013 to carry out this subsection.

SEC. 302. ASSISTANCE TO COMBAT TUBERCULOSIS.

* * * * * * *

(b) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, ⟦such sums as may be necessary for each of the fiscal years 2004 through 2008⟧ *a total of $4,000,000,000 for the 5-year period beginning on October 1, 2008* to carry out section 104B of the Foreign Assistance Act of 1961, as added by subsection (a).

(2) AVAILABILITY OF FUNDS.—Amounts appropriated pursuant to the authorization of appropriations under paragraph (1) are authorized to remain available until expended.

(3) TRANSFER OF PRIOR YEAR FUNDS.—Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c)(7) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)(7) (as in effect immediately before the date of enactment of this Act) shall be transferred to, merged with, and made available for the same purposes as funds made available for ⟦fiscal years 2004 through 2008⟧ *fiscal years 2009 through 2013* under paragraph (1).

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SEC. 303. ASSISTANCE TO COMBAT MALARIA.

* * * * * * *

(b) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, ⟦such sums as may be necessary for fiscal years 2004 through 2008⟧ *$5,000,000,000 during the 5-year period beginning on October 1, 2008* to carry out section 104C of the Foreign Assistance Act of 1961, as added by subsection (a), including for the development of anti-malarial pharmaceuticals by theMedicines for Malaria Venture.

(2) AVAILABILITY OF FUNDS.—Amounts appropriated pursuant to paragraph (1) are authorized to remain available until expended.

(3) TRANSFER OF PRIOR YEAR FUNDS.—Unobligated balances of funds made available for fiscal year 2001, 2002, or 2003 under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c) (as in effect immediately before the date of enactment of this Act) and made available for the control of malaria shall be transferred to, merged with, and made available for the same purposes as funds made available for ⟦fiscal years 2004 through 2008⟧ *fiscal years 2009 through 2013* under paragraph (1).

(c) CONFORMING AMENDMENT.—Section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)), as amended by section 301 of this Act, is further amended by adding after paragraph (3) the following: * * *

(c) STATEMENT OF POLICY.—Providing assistance for the prevention, control, treatment, and the ultimate eradication of malaria is—

(1) a major objective of the foreign assistance program of the United States; and

(2) 1 component of a comprehensive United States global health strategy to reduce disease burdens and strengthen communities around the world.

(d) DEVELOPMENT OF A COMPREHENSIVE 5-YEAR STRATEGY.—The President shall establish a comprehensive, 5-year strategy to combat global malaria that—

(1) strengthens the capacity of the United States to be an effective leader of international efforts to reduce malaria burden;

(2) maintains sufficient flexibility and remains responsive to the ever-changing nature of the global malaria challenge;

(3) includes specific objectives and multisectoral approaches and strategies to reduce the prevalence, mortality, incidence, and spread of malaria;

(4) describes how this strategy would contribute to the United States' overall global health and development goals;

(5) clearly explains how outlined activities will interact with other United States Government global health activities, including the 5-year global AIDS strategy required under this Act;

(6) expands public-private partnerships and leverage of resources;

(7) coordinates among relevant Federal agencies to maximize human and financial resources and to reduce duplication among these agencies, foreign governments, and international organizations;

(8) coordinates with other international entities, including the Global Fund;

(9) maximizes United States capabilities in the areas of technical assistance and training and research, including vaccine research; and

(10) establishes priorities and selection criteria for the distribution of resources based on factors such as—

(A) the size and demographics of the population with malaria;

(B) the needs of that population;

(C) the country's existing infrastructure; and

(D) the ability to closely coordinate United States Government efforts with national malaria control plans of partner countries.

SEC. 304. PILOT PROGRAM FOR THE PLACEMENT OF healthcare PROFESSIONALS IN OVERSEAS AREAS SEVERELY AFFECTED BY HIV/AIDS, TUBERCULOSIS, AND MALARIA.

[(a) IN GENERAL.—The President should establish a program to demonstrate the feasibility of facilitating the service of United States healthcare professionals in those areas of sub-Saharan Afri-

ca and other parts of the world severely affected by HIV/AIDS, tuberculosis, and malaria.

[(b) REQUIREMENTS.—Participants in the program shall—

[(1) provide basic healthcare services for those infected and affected by HIV/AIDS, tuberculosis, and malaria in the area in which they are serving;

[(2) provide on-the-job training to medical and other personnel in the area in which they are serving to strengthen the basic healthcare system of the affected countries;

[(3) provide healthcare educational training for residents of the area in which they are serving;

[(4) serve for a period of up to 3 years; and

[(5) meet the eligibility requirements in subsection (d).

[(c) ELIGIBILITY REQUIREMENTS.—To be eligible to participate in the program, a candidate shall—

[(1) be a national of the United States who is a trained healthcare professional and who meets the educational and licensure requirements necessary to be such a professional such as a physician, nurse, physician assistant, nurse practitioner, pharmacist, other type of healthcare professional, or other individual determined to be appropriate by the President; or

[(2) be a retired commissioned officer of the Public Health Service Corps.

[(d) RECRUITMENT.—The President shall ensure that information on the program is widely distributed, including the distribution of information to schools for health professionals, hospitals, clinics, and nongovernmental organizations working in the areas of international health and aid.

[(e) PLACEMENT OF PARTICIPANTS.—

[(1) IN GENERAL.—To the maximum extent practicable, participants in the program shall serve in the poorest areas of the affected countries, where healthcare needs are likely to be the greatest. The decision on the placement of a participant should be made in consultation with relevant officials of the affected country at both the national and local level as well as with local community leaders and organizations.

[(2) COORDINATION.—Placement of participants in the program shall be coordinated with the United States Agency for International Development in countries in which that Agency is conducting HIV/AIDS, tuberculosis, or malaria programs. Overall coordination of placement of participants in the program shall be made by the Coordinator of United States Government Activities to Combat HIV/AIDS Globally (as described in section 1(f) of the State Department Basic Authorities Act of 1956 (as added by section 102(a) of this Act)).

[(f) INCENTIVES.—The President may offer such incentives as the President determines to be necessary to encourage individuals to participate in the program, such as partial payment of principal, interest, and related expenses on government and commercial loans for educational expenses relating to professional health training and, where possible, deferment of repayments on such loans, the provision of retirement benefits that would otherwise be jeopardized by participation in the program, and other incentives.

[(g) REPORT.—Not later than 18 months after the date of enactment of this Act, the President shall submit to the appropriate congressional committees a report on steps taken to establish the program, including—

[(1) the process of recruitment, including the venues for recruitment, the number of candidates recruited, the incentives offered, if any, and the cost of those incentives;

[(2) the process, including the criteria used, for the selection of participants;

[(3) the number of participants placed, the countries in which they were placed, and why those countries were selected; and

[(4) the potential for expansion of the program.

[(h) AUTHORIZATION OF APPROPRIATIONS.—

[(1) IN GENERAL.—In addition to amounts otherwise available for such purpose, there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 401, such sums as may be necessary for each of the fiscal years 2004 through 2008 to carry out the program.

[(2) AVAILABILITY OF FUNDS.—Amounts appropriated pursuant to the authorization of appropriations under paragraph (1) are authorized to remain available until expended.]

SEC. 304. MALARIA RESPONSE COORDINATOR.

(a) IN GENERAL.—There is established within the United States Agency for International Development a Coordinator of United States Government Activities to Combat Malaria Globally (referred to in this section as the "Malaria Coordinator"), who shall be appointed by the President.

(b) AUTHORITIES.—The Malaria Coordinator, acting through nongovernmental organizations (including faith-based and community-based organizations), partner country finance, health, and other relevant ministries, and relevant executive branch agencies as may be necessary and appropriate to carry out this section, is authorized to—

(1) operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities to reduce the prevalence, mortality, and incidence of malaria;

(2) provide grants to, and enter into contracts and cooperative agreements with, nongovernmental organizations (including faith-based organizations) to carry out this section; and

(3) transfer and allocate executive branch agency funds that have been appropriated for the purposes described in paragraphs (1) and (2).

(c) DUTIES.—

(1) IN GENERAL.—The Malaria Coordinator has primary responsibility for the oversight and coordination of all resources and international activities of the United States Government relating to efforts to combat malaria.

(2) SPECIFIC DUTIES.—The Malaria Coordinator shall—

(A) facilitate program and policy coordination of antimalaria efforts among relevant executive branch agencies and nongovernmental organizations by auditing, monitoring, and evaluating such programs;

(B) ensure that each relevant executive branch agency undertakes antimalarial programs primarily in those areas in which the agency has the greatest expertise, technical capability, and potential for success;

(C) coordinate relevant executive branch agency activities in the field of malaria prevention and treatment;

(D) coordinate planning, implementation, and evaluation with the Global AIDS Coordinator in countries in which both programs have a significant presence;

(E) coordinate with national governments, international agencies, civil society, and the private sector; and

(F) establish due diligence criteria for all recipients of funds appropriated by the Federal Government for malaria assistance.

(d) ASSISTANCE FOR THE WORLD HEALTH ORGANIZATION.—In carrying out this section, the President may provide financial assistance to the Roll Back Malaria Partnership of the World Health Organization to improve the capacity of countries with high rates of malaria and other affected countries to implement comprehensive malaria control programs.

(e) COORDINATION OF ASSISTANCE EFFORTS.—In carrying out this section and in accordance with section 104C of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b–4), the Malaria Coordinator shall coordinate the provision of assistance by working with—

(1) relevant executive branch agencies, including—

(A) the Department of State (including the Office of the Global AIDS Coordinator);

(B) the Department of Health and Human Services;

(C) the Department of Defense; and

(D) the Office of the United States Trade Representative;

(2) relevant multilateral institutions, including—

(A) the World Health Organization;

(B) the United Nations Children's Fund;

(C) the United Nations Development Programme;

(D) the Global Fund;

(E) the World Bank; and

(F) the Roll Back Malaria Partnership;

(3) program delivery and efforts to lift barriers that would impede effective and comprehensive malaria control programs; and

(4) partner or recipient country governments and national entities including universities and civil society organizations (including faith- and community-based organizations).

(f) RESEARCH.—To carry out this section and in accordance with section 104C of the Foreign Assistance Act of 1961 (22 U.S.C. 1151d–4), the Secretary of Health and Human Services, through the Centers for Disease Control and Prevention and the National Institutes of Health, shall conduct appropriate programmatically relevant clinical and operational research to identify and evaluate new diagnostics, treatment regimens, and interventions to prevent and control malaria.

(g) MONITORING.—To ensure that adequate malaria controls are established and implemented, the Centers for Disease Control and Prevention shall carry out appropriate surveillance and evaluation

activities to monitor global malaria trends and assess environmental and health impacts of malarial control efforts. Such activities shall complement the work of the World Health Organization, rather than duplicate such work.

(h) ANNUAL REPORT.—

(1) SUBMISSION.—Not later than 1 year after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and annually thereafter, the President shall submit a report to the appropriate congressional committees that describes United States assistance for the prevention, treatment, control, and elimination of malaria.

(2) CONTENTS.—The report required under paragraph (1) shall describe—

(A) the countries and activities to which malaria resources have been allocated;

(B) the number of people reached through malaria assistance programs, including data on children and pregnant women;

(C) research efforts to develop new tools to combat malaria, including drugs and vaccines;

(D) the collaboration and coordination of United States antimalarial efforts with the World Health Organization, the Global Fund, the World Bank, other donor governments, major private efforts, and relevant executive agencies;

(E) the coordination of United States antimalarial efforts with the national malarial strategies of other donor or partner governments and major private initiatives;

(F) the estimated impact of United States assistance on childhood mortality and morbidity from malaria;

(G) the coordination of antimalarial efforts with broader health and development programs; and

(H) the constraints on implementation of programs posed by health workforce shortages or capacities; and

(I) the number of personnel trained as health workers and the training levels achieved.

[Subtitle B—Assistance for Children and Families]

Subtitle B—Assistance for Women, Children, and Families

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SEC. 312. POLICY AND REQUIREMENTS.

(a) POLICY.—The United States Government's response to the global HIV/AIDS pandemic should place high priority on the prevention of mother-to-child transmission, the care and treatment of family members and caregivers, and the care of children orphaned by AIDS. To the maximum extent possible, the United States Government should seek to leverage its funds by seeking matching contributions from the private sector, other national governments, and international organizations.

(b) REQUIREMENTS.—The 5-year United States Government strategy required by section 101 of this Act shall—

[(1) provide for meeting or exceeding the goal to reduce the rate of mother-to-child transmission of HIV by 20 percent by 2005 and by 50 percent by 2010;

[(2) include programs to make available testing and treatment to HIV-positive women and their family members, including drug treatment and therapies to prevent mother-to-child transmission; and

[(3) expand programs designed to care for children orphaned by AIDS.]

(1) establish a target for the prevention and treatment of mother-to-child transmission of HIV that, by 2013, will reach at least 80 percent of pregnant women in those countries most affected by HIV/AIDS in which the United States has HIV/AIDS programs;

(2) establish a target that, by 2013, the proportion of children receiving care and treatment under this Act is proportionate to their numbers within the population of HIV infected individuals in each country;

(3) integrate care and treatment with prevention of mother-to-child transmission of HIV programs to improve outcomes for HIV-affected women and families as soon as is feasible and support strategies that promote successful follow-up and continuity of care of mother and child;

(4) expand programs designed to care for children orphaned by, affected by, or vulnerable to HIV/AIDS;

(5) ensure that women in prevention of mother-to-child transmission of HIV programs are provided with, or referred to, appropriate maternal and child services; and

(6) develop a timeline for expanding access to more effective regimes to prevent mother-to-child transmission of HIV, consistent with the national policies of countries in which programs are administered under this Act and the goal of achieving universal use of such regimes as soon as possible.

(c) PREVENTION OF MOTHER-TO-CHILD TRANSMISSION EXPERT PANEL.—

(1) ESTABLISHMENT.—The Global AIDS Coordinator shall establish a panel of experts to be known as the Prevention of Mother-to-Child Transmission Panel (referred to in this subsection as the "Panel") to—

(A) provide an objective review of activities to prevent mother-to-child transmission of HIV; and

(B) provide recommendations to the Global AIDS Coordinator and to the appropriate committees of Congress for scale-up of mother-to-child transmission prevention services under this Act in order to achieve the target established in subsection (b)(1).

(2) MEMBERSHIP.—The Panel shall be convened and chaired by the Global AIDS Coordinator, who shall serve as a nonvoting member. The Panel shall consist of not more than 15 members (excluding the Global AIDS Coordinator), to be appointed by the Global AIDS Coordinator not later than 1 year after the date of the enactment of this Act, including—

(A) 2 members from the Department of Health and Human Services with expertise relating to the prevention of mother-to-child transmission activities;

(B) 2 members from the United States Agency for International Development with expertise relating to the prevention of mother-to-child transmission activities;

(C) 2 representatives from among health ministers of national governments of foreign countries in which programs under this Act are administered;

(D) 3 members representing organizations implementing prevention of mother-to-child transmission activities under this Act;

(E) 2 healthcare researchers with expertise relating to global HIV/AIDS activities; and

(F) representatives from among patient advocate groups, healthcare professionals, persons living with HIV/AIDS, and non-governmental organizations with expertise relating to the prevention of mother-to-child transmission activities, giving priority to individuals in foreign countries in which programs under this Act are administered.

(3) DUTIES OF PANEL.—The Panel shall—

(A) assess the effectiveness of current activities in reaching the target described in subsection (b)(1);

(B) review scientific evidence related to the provision of mother-to-child transmission prevention services, including programmatic data and data from clinical trials;

(C) review and assess ways in which the Office of the United States Global AIDS Coordinator collaborates with international and multilateral entities on efforts to prevent mother-to-child transmission of HIV in affected countries;

(D) identify barriers and challenges to increasing access to mother-to-child transmission prevention services and evaluate potential mechanisms to alleviate those barriers and challenges;

(E) identify the extent to which stigma has hindered pregnant women from obtaining HIV counseling and testing or returning for results, and provide recommendations to address such stigma and its effects;

(F) identify opportunities to improve linkages between mother-to-child transmission prevention services and care and treatment programs; and

(G) recommend specific activities to facilitate reaching the target described in subsection (b)(1).

(4) REPORT.—

(A) IN GENERAL.—Not later than 1 year after the date on which the Panel is first convened, the Panel shall submit a report containing a detailed statement of the recommendations, findings, and conclusions of the Panel to the appropriate congressional committees.

(B) AVAILABILITY.—The report submitted under subparagraph (A) shall be made available to the public.

(C) CONSIDERATION BY COORDINATOR.—The Coordinator shall—

(i) consider any recommendations contained in the report submitted under subparagraph (A); and

(ii) include in the annual report required under section 104A(f) of the Foreign Assistance Act of 1961 a description of the activities conducted in response to the recommendations made by the Panel and an explanation of any recommendations not implemented at the time of the report.

(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Panel such sums as may be necessary for each of the fiscal years 2009 through 2011 to carry out this section.

(6) TERMINATION.—The Panel shall terminate on the date that is 60 days after the date on which the Panel submits the report to the appropriate congressional committees under paragraph (4).

SEC. 313. ANNUAL REPORTS ON PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF THE HIV INFECTION.

(a) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, and annually thereafter for a period of [5 years] *10 years*, the President shall submit to appropriate congressional committees a report on the activities of relevant executive branch agencies during the reporting period to assist in the prevention of mother-to-child transmission of the HIV infection.

(b) REPORT ELEMENTS.—Each report shall include—

(1) a statement of whether or not all relevant executive branch agencies have met the goal described in section 312(b)(1); and

(2) a description of efforts made by the relevant executive branch agencies to expand those activities, including—

(A) information on the number of sites supported for the prevention of mother-to-child transmission of the HIV infection;

(B) the specific activities supported;

(C) the number of women tested and counseled; and

(D) the number of women receiving preventative drug therapies.

(c) REPORTING PERIOD DEFINED.—In this section, the term "reporting period" means, in the case of the initial report, the period since the date of enactment of this Act and, in the case of any subsequent report, the period since the date of submission of the most recent report.

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TITLE IV—AUTHORIZATION OF APPROPRIATIONS

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—There are authorized to be appropriated to the President to carry out this Act and the amendments made by this Act [$3,000,000,000 for each of the fiscal years 2004 through 2008] *$50,000,000,000 for the 5-year period beginning on October 1, 2008*.

(b) AVAILABILITY.—Amounts appropriated pursuant to the authorization of appropriations in subsection (a) are authorized to remain available until expended.

(c) AVAILABILITY OF AUTHORIZATIONS.—Authorizations of appropriations under subsection (a) shall remain available until the appropriations are made.

SEC. 402. SENSE OF CONGRESS.

(a) INCREASE IN HIV/AIDS ANTIRETROVIRAL TREATMENT.—It is a sense of the Congress that an urgent priority of United States assistance programs to fight HIV/AIDS should be the rapid increase in distribution of antiretroviral treatment so that—

(1) by the end of fiscal year 2004, at least 500,000 individuals with HIV/AIDS are receiving antiretroviral treatment through United States assistance programs;

(2) by the end of fiscal year 2005, at least 1,000,000 such individuals are receiving such treatment; and

(3) by the end of fiscal year 2006, at least 2,000,000 such individuals are receiving such treatment.

(b) EFFECTIVE DISTRIBUTION OF HIV/AIDS FUNDS.—It is the sense of Congress that, of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance, [an effective distribution of such amounts would be—

[(1) 55 percent of such amounts for treatment of individuals with HIV/AIDS;

[(2) 15 percent of such amounts for palliative care of individuals with HIV/AIDS;

[(3) 20 percent of such amounts for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act), of which such amount at least 33 percent should be expended for abstinence-until-marriage programs; and

[(4) 10 percent of such amounts] *10 percent should be used* for orphans and vulnerable children.

SEC. 403. ALLOCATION OF FUNDS.

[(a) THERAPEUTIC MEDICAL CARE.—For fiscal years 2006 through 2008, not less than 55 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for therapeutic medical care of individuals infected with HIV, of which such amount at least 75 percent should be expended for the purchase and distribution of antiretroviral pharmaceuticals and at least 25 percent should be expended for related care. For fiscal years 2006 through 2008, not less than 33 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS prevention consistent with section 104A(d) of the Foreign Assistance Act of 1961 (as added by section 301 of this Act) for each such fiscal year shall be expended for abstinence-until-marriage programs.]

(a) BALANCED FUNDING REQUIREMENT.—

(1) IN GENERAL.—The Global AIDS Coordinator shall—

(A) provide balanced funding for prevention activities for sexual transmission of HIV/AIDS; and

(B) ensure that behavioral change programs, including abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, are implemented and funded in a meaningful and equitable way in the strategy for each host coun-

try based on objective epidemiological evidence as to the source of infections and in consultation with the government of each host county involved in HIV/AIDS prevention activities.

(2) PREVENTION STRATEGY.—

(A) ESTABLISHMENT.—In carrying out paragraph (1), the Global AIDS Coordinator shall establish a HIV sexual transmission prevention strategy governing the expenditure of funds authorized under this Act to prevent the sexual transmission of HIV in any host country with a generalized epidemic.

(B) REPORT.—In each host country described in subparagraph (A), if the strategy established under subparagraph (A) provides less than 50 percent of the funds described in subparagraph (A) for behavioral change programs, including abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, the Global AIDS Coordinator shall, not later than 30 days after the issuance of this strategy, report to the appropriate congressional committees on the justification for this decision.

(3) EXCLUSION.—Programs and activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision, pre-exposure pharmaceutical prophylaxis to prevent transmission of HIV, or microbicides and programs and activities that provide counseling and testing for HIV or prevent mother-to-child prevention of HIV, shall not be included in determining compliance with paragraph (2).

(4) REPORT.—Not later than 1 year after the date of the enactment of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and annually thereafter as part of the annual report required under section 104A(e) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b-2(e)), the President shall—

(A) submit a report on the implementation of paragraph (2) for the most recently concluded fiscal year to the appropriate congressional committees; and

(B) make the report described in subparagraph (A) available to the public.

(b) ORPHANS AND VULNERABLE CHILDREN.—For **[**fiscal years 2006 through 2008**]** *fiscal years 2009 through 2013*, not less than 10 percent of the amounts appropriated pursuant to the authorization of appropriations under section 401 for HIV/AIDS assistance for each such fiscal year shall be expended for assistance for orphans and **[**vulnerable children affected by**]** *other children affected by, or vulnerable to,* HIV/AIDS, of which such amount at least 50 percent shall be provided through non-profit, nongovernmental organizations, including faith-based organizations, that implement programs on the community level.

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The Foreign Assistance Act of 1961

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PART I

Chapter 1—Policy; Development Assistance Authorizations

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SEC. 104A. ASSISTANCE TO COMBAT HIV/AIDS.

(a) FINDING.—Congress recognizes that the alarming spread of HIV/AIDS in countries in sub-Saharan Africa, the Caribbean, *Central Asia, Eastern Europe, Latin America*, and other developing countries is a major global health, national security, development, and humanitarian crisis.

[(b) POLICY.—It is a major objective of the foreign assistance program of the United States to provide assistance for the prevention, treatment, and control of HIV/AIDS. The United States and other developed countries should provide assistance to countries in sub-Saharan Africa, the Caribbean, and other countries and areas to control this crisis through HIV/AIDS prevention, treatment, monitoring, and related activities, particularly activities focused on women and youth, including strategies to protect women and prevent mother-to-child transmission of the HIV infection.]

(b) POLICY.—

(1) OBJECTIVES.—It is a major objective of the foreign assistance program of the United States to provide assistance for the prevention and treatment of HIV/AIDS and the care of those affected by the disease. It is the policy objective of the United States, by 2013, to—

(A) assist partner countries to—

(i) prevent 12,000,000 new HIV infections worldwide;

(ii) support treatment of at least 3,000,000 individuals with HIV/AIDS;

(iii) support additional treatment through coordinated multilateral efforts;

(iv) support care for 12,000,000 individuals with HIV/AIDS, including 5,000,000 orphans and vulnerable children affected by HIV/AIDS, with an emphasis on promoting a comprehensive, coordinated system of services to be integrated throughout the continuum of care;

(v) provide at least 80 percent of the target population with access to counseling, testing, and treatment to prevent the transmission of HIV from mother-to-child;

(vi) provide care and treatment services to children with HIV in proportion to their percentage within the HIV-infected population of a given partner country; and

(vii) train and support retention of healthcare professionals, paraprofessionals, and community health workers in HIV/AIDS prevention, treatment, and care, with the target of providing such training to at least 140,000 new healthcare professionals and paraprofessionals;

(B) strengthen the capacity to deliver primary healthcare in developing countries, especially in sub-Saharan Africa; and

(C) help countries achieve staffing levels of at least 2.3 doctors, nurses, and midwives per 1,000 population, as called for by the World Health Organization.

(2) COORDINATED GLOBAL STRATEGY.—The United States and other countries with the sufficient capacity should provide assistance to countries in sub-Saharan Africa, the Caribbean, Central Asia, Eastern Europe, and Latin America, and other countries and regions confronting HIV/AIDS epidemics in a coordinated global strategy to help address generalized and concentrated epidemics through HIV/AIDS prevention, treatment, care, monitoring and evaluation, and related activities.

(3) PRIORITIES.—The United States Government's response to the global HIV/AIDS pandemic and the Government's efforts to help countries assume leadership of sustainable campaigns to combat their local epidemics should place high priority on—

(A) the prevention of the transmission of HIV; and

(B) moving toward universal access to HIV/AIDS prevention counseling and services.

(c) AUTHORIZATION.—

(1) IN GENERAL.—Consistent with section 104(c), the President is authorized to furnish assistance, on such terms and conditions as the President may determine, for HIV/AIDS, including to prevent, treat, and monitor HIV/AIDS, and carry out related activities, in countries in sub-Saharan Africa, the Caribbean, [and other countries and areas.] *Central Asia, Eastern Europe, Latin America, and other countries and areas, particularly with respect to refugee populations or those in postconflict settings in such countries and areas with significant or increasing HIV incidence rates.*

(2) ROLE OF NGOS.—It is the sense of Congress that the President should provide an appropriate level of assistance under paragraph (1) through nongovernmental organizations (including faith-based and community-based organizations) in countries in sub-Saharan Africa, the Caribbean, [and other countries and areas affected by the HIV/AIDS pandemic] *Central Asia, Eastern Europe, Latin America, and other countries and areas affected by the HIV/AIDS pandemic, particularly with respect to refugee populations or those in post-conflict settings in such countries and areas with significant or increasing HIV incidence rates.*

(3) COORDINATION OF ASSISTANCE EFFORTS.—The President shall coordinate the provision of assistance under paragraph (1) with the provision of related assistance by the Joint United Nations Programme on HIV/AIDS (UNAIDS), the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), the United Nations Development Programme (UNDP), the Global Fund to Fight AIDS, Tuberculosis and Malaria and other appropriate international organizations (such as the International Bank for Reconstruction and Development), relevant regional multilateral development institutions, national, state, and local governments of [foreign countries]

partner countries, other international actors, appropriate governmental and nongovernmental organizations, and relevant executive branch agencies *within the framework of the principles of the Three Ones*.

(d) ACTIVITIES SUPPORTED.—Assistance provided under subsection (c) shall, to the maximum extent practicable, be used to carry out the following activities:

(1) PREVENTION.—Prevention of HIV/AIDS through activities including—

(A) programs and efforts that are designed or intended to impart knowledge with the exclusive purpose of helping individuals avoid behaviors that place them at risk of HIV infection, including integration of such programs into health programs and the inclusion in counseling programs of information on methods of avoiding infection of HIV, including delaying sexual debut, abstinence, fidelity and monogamy, reduction of casual sexual partnering *and multiple concurrent sexual partnering*, reducing sexual violence and coercion, including child marriage, widow inheritance, and polygamy, and where appropriate, use of **[**condoms**]** *male and female condoms*;

(B) assistance to establish and implement culturally appropriate HIV/AIDS education and prevention **[**programs that**]** *programs that are designed with local input and* focus on helping individuals avoid infection of HIV/AIDS, implemented through nongovernmental organizations, including faith-based and community-based organizations, particularly **[**those organizations**]** *those locally based organizations* that utilize both professionals and volunteers with appropriate skills, experience, and community presence;

(C) assistance for the purpose of encouraging men to be responsible in their sexual behavior, child rearing, and to respect women;

(D) assistance for the purpose of providing voluntary testing and counseling (including the incorporation of confidentiality protections with respect to such testing and counseling) *and promoting the use of provider-initiated or "opt-out" voluntary testing in accordance with World Health Organization guidelines*;

(E) assistance for the purpose of preventing mother-to-child transmission of the HIV infection, including medications to prevent such transmission and access to infant formula and other alternatives for infant feeding;

(F) assistance to—

(i) achieve the goal of reaching 80 percent of pregnant women for prevention and treatment of mother-to-child transmission of HIV in countries in which the United States is implementing HIV/AIDS programs by 2013; and

(ii) promote infant feeding options and treatment protocols that meet the most recent criteria established by the World Health Organization;

(G) medical male circumcision programs as part of national strategies to combat the transmission of HIV/AIDS;

[(F)] *(H)* assistance to ensure a safe blood supply and sterile medical equipment;

[(G)] *(I)* assistance to help avoid substance abuse and intravenous drug use that can lead to HIV infection; [and]

[(I)] *(J)* assistance for the purpose of increasing women's access to employment opportunities, income, productive resources, and microfinance programs, where appropriate[.], *including education and services demonstrated to be effective in reducing the transmission of HIV infection without increasing illicit drug use; and*

(K) assistance for counseling, testing, treatment, care, and support programs, including—

(i) counseling and other services for the prevention of reinfection of individuals with HIV/AIDS;

(ii) counseling to prevent sexual transmission of HIV, including—

(I) life skills development for practicing abstinence and faithfulness;

(II) reducing the number of sexual partners;

(III) delaying sexual debut; and

(IV) ensuring correct and consistent use of condoms;

(iii) assistance to engage underlying vulnerabilities to HIV/AIDS, especially those of women and girls, through structural prevention programs;

(iv) assistance for appropriate HIV/AIDS education programs and training targeted to prevent the transmission of HIV among men who have sex with men;

(v) assistance to provide male and female condoms;

(vi) diagnosis and treatment of other sexually transmitted infections;

(vii) strategies to address the stigma and discrimination that impede HIV/AIDS prevention efforts; and

(viii) assistance to facilitate widespread access to microbicides for HIV prevention, if safe and effective products become available, including financial and technical support for culturally appropriate introductory programs, procurement, distribution, logistics management, program delivery, acceptability studies, provider training, demand generation, and postintroduction monitoring.

(2) TREATMENT.—The treatment and care of individuals with HIV/AIDS, including—

(A) assistance to establish and implement programs to strengthen and broaden indigenous healthcare delivery systems and the capacity of such systems to deliver HIV/AIDS pharmaceuticals and otherwise provide for the treatment of individuals with HIV/AIDS, including clinical training for indigenous organizations and healthcare providers;

(B) assistance to strengthen and expand hospice and palliative care programs to assist patients debilitated by HIV/

AIDS, their families, and the primary caregivers of such patients, including programs that utilize faith-based and community-based organizations; [and]

(C) assistance for the purpose of the care and treatment of individuals with HIV/AIDS through the provision of pharmaceuticals, including antiretrovirals and other pharmaceuticals and therapies for the treatment of opportunistic infections, *pain management,* nutritional support, and other treatment modalities[.]*;*

(D) as part of care and treatment of HIV/AIDS, assistance (including prophylaxis and treatment) for common HIV/AIDS-related opportunistic infections for free or at a rate at which it is easily affordable to the individuals and populations being served; and

(E) as part of care and treatment of HIV/AIDS, assistance or referral to available and adequately resourced service providers for nutritional support, including counseling and where necessary the provision of commodities, for persons meeting malnourishment criteria and their families;

(3) PREVENTATIVE INTERVENTION EDUCATION AND TECHNOLOGIES.—(A) With particular emphasis on specific populations that represent a particularly high risk of contracting or spreading HIV/AIDS, including those exploited through the sex trade, victims of rape and sexual assault, individuals already infected with HIV/AIDS, and in cases of occupational exposure of healthcare workers, assistance with efforts to reduce the risk of HIV/AIDS infection including post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(B) Bulk purchases of available test kits, condoms, and, when proven effective, microbicides that are intended to reduce the risk of HIV/AIDS transmission and for appropriate program support for the introduction and distribution of these commodities, as well as education and training on the use of the technologies.

(4) MONITORING.—The monitoring of programs, projects, and activities carried out pursuant to paragraphs (1) through (3), including—

(A) monitoring to ensure that adequate controls are established and implemented to provide HIV/AIDS pharmaceuticals and other appropriate medicines to poor individuals with HIV/AIDS;

(B) appropriate evaluation and surveillance activities;

(C) monitoring to ensure that appropriate measures are being taken to maintain the sustainability of HIV/AIDS pharmaceuticals (especially antiretrovirals) and ensure that drug resistance is not compromising the benefits of such pharmaceuticals; [and]

(D) monitoring to ensure appropriate law enforcement officials are working to ensure that HIV/AIDS pharmaceuticals are not diminished through illegal counterfeiting or black market sales of such pharmaceuticals[.]*;*

(E) carrying out and expanding program monitoring, impact evaluation research and analysis, and operations research and disseminating data and findings through mechanisms to be developed by the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, in coordination with the Director of the Centers for Disease Control, in order to—

(i) improve accountability, increase transparency, and ensure the delivery of evidence-based services through the collection, evaluation, and analysis of data regarding gender-responsive interventions, disaggregated by age and sex;

(ii) identify and replicate effective models; and

(iii) develop gender indicators to measure outcomes and the impacts of interventions; and

(F) establishing appropriate systems to—

(i) gather epidemiological and social science data on HIV; and

(ii) evaluate the effectiveness of prevention efforts among men who have sex with men, with due consideration to stigma and risks associated with disclosure.

(5) PHARMACEUTICALS.—

(A) PROCUREMENT.—The procurement of HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines, including medicines to treat opportunistic infections.

(B) MECHANISMS FOR QUALITY CONTROL AND SUSTAINABLE SUPPLY.—Mechanisms to ensure that such HIV/AIDS pharmaceuticals, antiretroviral therapies, and other appropriate medicines are quality-controlled and sustainably supplied.

(C) MECHANISM TO ENSURE COST-EFFECTIVE DRUG PURCHASING.—Subject to subparagraph (B), mechanisms to ensure that safe and effective pharmaceuticals, including antiretrovirals and medicines to treat opportunistic infections, are purchased at the lowest possible price at which such pharmaceuticals may be obtained in sufficient quantity on the world market.

[(C)**]** *(D)* DISTRIBUTION.—The distribution of such HIV/AIDS pharmaceuticals, antiviral therapies, and other appropriate medicines (including medicines to treat opportunistic infections) to qualified national, regional, or local organizations for the treatment of individuals with HIV/AIDS in accordance with appropriate HIV/AIDS testing and monitoring requirements and treatment protocols and for the prevention of mother-to-child transmission of the HIV infection.

(6) **[**RELATED ACTIVITIES.—**]** *RELATED AND COORDINATED ACTIVITIES.*—The conduct of related activities, including—

(A) the care and support of children who are orphaned by the HIV/AIDS pandemic, including services designed to care for orphaned children in a family environment which rely on extended family members;

(B) improved infrastructure and institutional capacity to develop and manage education, prevention, and treatment programs, including training and the resources to collect and maintain accurate HIV surveillance data to target programs and measure the effectiveness of interventions; [and]

(C) vaccine research and development partnership programs with specific plans of action to develop a safe, effective, accessible, preventive HIV vaccine for use throughout the world[.]*;*

(D) coordinated or referred activities to—

(i) enhance the clinical impact of HIV/AIDS care and treatment; and

(ii) ameliorate the adverse social and economic costs often affecting AIDS-impacted families and communities through the direct provision, as necessary, or through the referral, if possible, of support services, including—

(I) nutritional and food support;

(II) nutritional counseling;

(III) income-generating activities and livelihood initiatives;

(IV) maternal and child healthcare;

(V) primary healthcare;

(VI) the diagnosis and treatment of other infectious or sexually transmitted diseases;

(VII) substance abuse and treatment services; and

(VIII) legal services;

(E) coordinated or referred activities to link programs addressing HIV/AIDS with programs addressing gender-based violence in areas of significant HIV prevalence to assist countries in the development and enforcement of women's health, children's health, and HIV/AIDS laws and policies that—

(i) prevent and respond to violence against women and girls;

(ii) promote the integration of screening and assessment for gender-based violence into HIV/AIDS programming;

(iii) promote appropriate HIV/AIDS counseling, testing, and treatment into gender-based violence programs; and

(iv) assist governments to develop partnerships with civil society organizations to create networks for psychosocial, legal, economic, or other support services;

(F) coordinated or referred activities to—

(i) address the frequent coinfection of HIV and tuberculosis, in accordance with World Health Organization guidelines;

(ii) promote provider-initiated or "opt-out" HIV/AIDS counseling and testing and appropriate referral for treatment and care to individuals with tuberculosis

or its symptoms, particularly in areas with significant HIV prevalence; and

(iii) strengthen programs to ensure that individuals testing positive for HIV receive tuberculosis screening and appropriate screening and to improve laboratory capacities, infection control, and adherence; and

(G) activities to—

(i) improve the effectiveness of national responses to HIV/AIDS; and

(ii) strengthen overall health systems in high-prevalence countries, including support for workforce training, retention, and effective deployment, capacity building, laboratory development, equipment maintenance and repair, and public health and related public financial management systems and operations.

(7) COMPREHENSIVE HIV/AIDS PUBLIC-PRIVATE PARTNERSHIPS.—The establishment and operation of public-private partnership entities within countries in sub-Saharan Africa, the Caribbean, and other countries affected by the HIV/AIDS pandemic that are dedicated to supporting the national strategy of such countries regarding the prevention, treatment, and monitoring of HIV/AIDS. Each such public-private partnership should)

(A) support the development, implementation, and management of comprehensive HIV/AIDS plans in support of the national HIV/AIDS strategy;

(B) operate at all times in a manner that emphasizes efficiency, accountability, and results-driven programs;

(C) engage both local and foreign development partners and donors, including businesses, government agencies, academic institutions, nongovernmental organizations, foundations, multilateral development agencies, and faith-based organizations, to assist the country in coordinating and implementing HIV/AIDS prevention, treatment, and monitoring programs in accordance with its national HIV/AIDS strategy;

(D) provide technical assistance, consultant services, financial planning, monitoring and evaluation, and research in support of the national HIV/AIDS strategy; and

(E) establish local human resource capacities for the national HIV/AIDS strategy through the transfer of medical, managerial, leadership, and technical skills.

(8) COMPACTS AND FRAMEWORK AGREEMENTS.—The development of compacts or framework agreements, tailored to local circumstances, with national governments or regional partnerships in countries with significant HIV/AIDS burdens to promote host government commitment to deeper integration of HIV/AIDS services into health systems, contribute to health systems overall, and enhance sustainability.

(e) COMPACTS AND FRAMEWORK AGREEMENTS.—

(1) FINDINGS.—Congress makes the following findings:

(A) The congressionally mandated Institute of Medicine report entitled "PEPFAR Implementation: Progress and Promise' states: "The next strategy [of the U.S. Global AIDS

Initiative] should squarely address the needs and challenges involved in supporting sustainable country HIV/AIDS programs, thereby transitioning from a focus on emergency relief."

(B) One mechanism to promote the transition from an emergency to a public health and development approach to HIV/AIDS is through compacts or framework agreements between the United States Government and each participating nation.

(C) Key components of a transition toward a more sustainable approach toward fighting HIV/AIDS, tuberculosis, and malaria and thus priorities for such compacts include—

(i) building capacity to expand the size of the trained healthcare workforce in partner countries and improve its retention, safety, deployment, and utilization of skills and to improve public health infrastructure and systems;

(ii) partner governments increasing their national investments in health and education systems, as called for in the Abuja Declaration;

(iii) increasing the focus of United States government efforts to address the factors that put women and girls at greater risk of HIV/AIDS and to strengthen the legal, economic, educational, and social status of women, girls, orphans, and vulnerable children and encouraging partner governments to do the same;

(iv) building on the New Partners Initiative and other efforts currently underway to strengthen the capacities of community- and faith-based organizations and civil society in partner countries to contribute to country efforts to prevent or manage the effects of HIV/AIDS, tuberculosis, and malaria epidemics and to improve healthcare delivery;

(v) improving the coordination of efforts to combat HIV/AIDS, tuberculosis, and malaria with broader national health and development strategies;

(vi) promoting HIV/AIDS-related laws, regulations, and policies that support voluntary diagnostic counseling and rapid testing, pediatric diagnosis, rapid, tariff-free regulatory procedures for drugs and commodities, and full inclusion of people living with HIV/AIDS in a multisectoral national response.

(vii) sharing and implementing findings based on program evaluations and operations research; and

(viii) reducing the disease burden of HIV/AIDS, tuberculosis, and malaria through improved prevention efforts.

(D) Such compacts should also take into account the overall national health and development and national HIV/AIDS and public health strategies of each country and should contain provisions including—

(i) the specific objectives that the country and the United States expect to achieve during the term of a compact;

(ii) the respective responsibilities of the country and the United States in the achievement of such objectives;

(iii) regular benchmarks to measure, where appropriate, progress toward achieving such objectives;

(iv) an identification of the intended beneficiaries, disaggregated by gender and age, and including information on orphans and vulnerable children, to the maximum extent practicable;

(v) the methods by which the compact is intended to address the factors that put women and girls at greater risk of HIV/AIDS and to strengthen the legal, economic, educational, and social status of women, girls, orphans, and vulnerable children;

(vi) the methods by which the compact will strengthen the healthcare capacity, including the training, retention, deployment, and utilization of healthcare workers, improve supply chain management, and improve the health systems and infrastructure of the partner country, including the ability of compact participants to maintain and operate equipment transferred or purchased as part of the compact;

(vii) proposed mechanisms to provide oversight;

(viii) the role of civil society in the development of a compact and the achievement of its objectives;

(ix) a description of the current and potential participation of other donors in the achievement of such objectives, as appropriate; and

(x) a plan to ensure appropriate fiscal accountability for the use of assistance.

(2) LOCAL INPUT.—In entering into a compact authorized under subsection (d)(8), the Coordinator of United States Government Activities to Combat HIV/AIDS Globally shall seek to ensure that the government of a country—

(A) takes into account the local perspectives of the rural and urban poor, including women, in each country; and

(B) consults with private and voluntary organizations, including faith-based organizations, the business community, and other donors in the country.

(3) CONGRESSIONAL AND PUBLIC NOTIFICATION AFTER ENTERING INTO A COMPACT.—Not later than 10 days after entering into a compact authorized under subsection (d)(8), the Global AIDS Coordinator shall—

(A) submit a report containing a detailed summary of the compact and a copy of the text of the compact to—

(i) the Committee on Foreign Relations of the Senate;

(ii) the Committee on Appropriations of the Senate;

(iii) the Committee on Foreign Affairs of the House of Representatives; and

(iv) the Committee on Appropriations of the House of Representatives; and

(B) publish such information in the Federal Register and on the Internet website of the Office of the Global AIDS Coordinator.

[(e)] *(f)* ANNUAL REPORT.—

(1) IN GENERAL.—Not later than January 31 of each year, the President shall submit to the Committee on Foreign Relations of the Senate and the [Committee on International Relations] *Committee on Foreign Affairs* of the House of Representatives a report on the implementation of this section for the prior fiscal year.

(2) REPORT ELEMENTS.—Each report shall include—

(A) a description of efforts made by each relevant executive branch agency to implement the policies set forth in this section, section 104B, and section 104C;

(B) a description of the programs established pursuant to such sections; [and]

[(C) a detailed assessment of the impact of programs established pursuant to such sections, including

[(i)(I) the effectiveness of such programs in reducing the spread of the HIV infection, particularly in women and girls, in reducing mother-to-child transmission of the HIV infection, and in reducing mortality rates from HIV/AIDS; and

[(II) the number of patients currently receiving treatment for AIDS in each country that receives assistance under this Act.

[(ii) the progress made toward improving healthcare delivery systems (including the training of adequate numbers of staff) and infrastructure to ensure increased access to care and treatment;

[(iii) with respect to tuberculosis, the increase in the number of people treated and the increase in number of tuberculosis patients cured through each program, project, or activity receiving United States foreign assistance for tuberculosis control purposes; and

[(iv) with respect to malaria, the increase in the number of people treated and the increase in number of malaria patients cured through each program, project, or activity receiving United States foreign assistance for malaria control purposes.]

(C) a detailed breakdown of funding allocations, by program and by country, for prevention activities; and

(D) a detailed assessment of the impact of programs established pursuant to such sections, including—

(i)(I) the effectiveness of such programs in reducing—

(aa) the transmission of HIV, particularly in women and girls;

(bb) mother-to-child transmission of HIV, including through drug treatment and therapies, either directly or by referral; and

(cc) mortality rates from HIV/AIDS;

(II) the number of patients receiving treatment for AIDS in each country that receives assistance under this Act;

(III) an assessment of progress towards the achievement of annual goals set forth in the timetable required under the 5-year strategy established under section 101 of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 and, if annual goals are not being met, the reasons for such failure; and

(IV) retention and attrition data for programs receiving United States assistance, including mortality and loss to follow-up rates, organized overall and by country;

(ii) the progress made toward—

(I) improving healthcare delivery systems (including the training of healthcare workers, including doctors, nurses, midwives, pharmacists, laboratory technicians, and compensated community health workers);

(II) advancing safe working conditions for healthcare workers; and

(III) improving infrastructure to promote progress toward universal access to HIV/AIDS prevention, treatment, and care by 2013;

(iii) with respect to tuberculosis—

(I) the increase in the number of people treated and the number of tuberculosis patients cured through each program, project, or activity receiving United States foreign assistance for tuberculosis control purposes through, or in coordination with, HIV/AIDS programs;

(II) a description of drug resistance rates among persons treated;

(III) the percentage of such United States foreign assistance provided for diagnosis and treatment of individuals with tuberculosis in countries with the highest burden of tuberculosis, as determined by the World Health Organization; and

(IV) a detailed description of efforts to integrate HIV/AIDS and tuberculosis prevention, treatment, and care programs; and

(iv) a description of coordination efforts with relevant executive branch agencies to link HIV/AIDS clinical and social services with non-HIV/AIDS services as part of the United States health and development agenda;

(v) a detailed description of integrated HIV/AIDS and food and nutrition programs and services, including—

(I) the amount spent on food and nutrition support;

(II) the types of activities supported; and

(III) an assessment of the effectiveness of interventions carried out to improve the health status of persons with HIV/AIDS receiving food or nutritional support;

(vi) a description of efforts to improve harmonization, in terms of relevant executive branch agencies, coordination with other public and private entities, and coordination with partner countries' national strategic plans as called for in the "Three Ones";

(vii) a description of—

(I) the efforts of partner countries that were signatories to the Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases to adhere to the goals of such Declaration in terms of investments in public health, including HIV/AIDS; and

(II) a description of the HIV/AIDS investments of partner countries that were not signatories to such Declaration;

(viii) a detailed description of any compacts or framework agreements reached or negotiated between the United States and any partner countries, including a description of the elements of compacts described in subsection (e);

(ix) a description of programs serving women and girls, including—

(I) HIV/AIDS prevention programs that address the vulnerabilities of girls and women to HIV/AIDS;

(II) information on the number of individuals served by programs aimed at reducing the vulnerabilities of women and girls to HIV/AIDS and data on the types, objectives, and duration of programs to address these issues;

(III) information on programs to address the particular needs of adolescent girls and young women; and

(IV) programs to prevent gender-based violence or to assist victims of gender based violence as part, of or in coordination with, HIV/AIDS programs;

(x) a description of strategies, goals, programs, and interventions to—

(I) address the needs and vulnerabilities of youth populations;

(II) expand access among young men and women to evidence-based HIV/AIDS healthcare services and HIV prevention programs, including abstinence education programs; and

(III) expand community-based services to meet the needs of orphans and of children and adolescents affected by or vulnerable to HIV/AIDS without increasing stigmatization;

(xi) a description of—

(I) the specific strategies funded to ensure the reduction of HIV infection among injection drug users;

(II) the number of injection drug users, by country, reached by such strategies;

(III) medication-assisted drug treatment for individuals with HIV or at risk of HIV; and

(IV) HIV prevention programs demonstrated to be effective in reducing HIV transmission without increasing drug use;

(xii) a detailed description of program monitoring, operations research, and impact evaluation research, including—

(I) the amount of funding provided for each research type;

(II) an analysis of cost-effectiveness models; and

(III) conclusions regarding the efficiency, effectiveness, and quality of services as derived from previous or ongoing research and monitoring efforts; and

(xiii) a description of staffing levels of United States government HIV/AIDS teams in countries with significant HIV/AIDS programs, including whether or not a full-time coordinator was on staff for the year.

[(f)] *(g)* FUNDING LIMITATION.—Of the funds made available to carry out this section in any fiscal year, not more than 7 percent may be used for the administrative expenses of the United States Agency for International Development in support of activities described in section 104(c), this section, section 104B, and section 104C. Such amount shall be in addition to other amounts otherwise available for such purposes.

[(g)] *(h)* DEFINITIONS.—In this section:

(1) AIDS.—The term "AIDS" means acquired immune deficiency syndrome.

(2) HIV.—The term "HIV" means the human immunodeficiency virus, the pathogen that causes AIDS.

(3) HIV/AIDS.—The term "HIV/AIDS" means, with respect to an individual, an individual who is infected with HIV or living with AIDS.

(4) RELEVANT EXECUTIVE BRANCH AGENCIES.—The term "relevant executive branch agencies" means the Department of State, the United States Agency for International Development, the Department of Health and Human Services (including its agencies and offices), and any other department or agency of the United States that participates in international HIV/AIDS activities pursuant to the authorities of such department or agency or this Act.

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SEC. 104B. ASSISTANCE TO COMBAT TUBERCULOSIS.

(a) FINDINGS.—Congress makes the following findings:

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[(b) POLICY.—It is a major objective of the foreign assistance program of the United States to control tuberculosis, including the detection of at least 70 percent of the cases of infectious tuberculosis, and the cure of at least 85 percent of the cases detected, not later than December 31, 2005, in those countries classified by the World

Health Organization as among the highest tuberculosis burden, and not later than December 31, 2010, in all countries in which the United States Agency for International Development has established development programs.]

(b) POLICY.—It is a major objective of the foreign assistance program of the United States to control tuberculosis. In all countries in which the Government of the United States has established development programs, particularly in countries with the highest burden of tuberculosis and other countries with high rates of tuberculosis, the United States Government should prioritize the achievement of the following goals by not later than December 31, 2015:

(1) Reduce by half the tuberculosis death and disease burden from the 1990 baseline.

(2) Sustain or exceed the detection of at least 70 percent of sputum smear-positive cases of tuberculosis and the cure of at least 85 percent of those cases detected.

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[(e) PRIORITY TO DOTS COVERAGE.—In furnishing assistance under subsection (c), the President shall give priority to activities that increase Directly Observed Treatment Short-course (DOTS) coverage and treatment of multi-drug resistant tuberculosis where needed using DOTS-Plus, including funding for the Global Tuberculosis Drug Facility, the Stop Tuberculosis Partnership, and the Global Alliance for TB Drug Development. In order to meet the requirement of the preceding sentence, the President should ensure that not less than 75 percent of the amount made available to carry out this section for a fiscal year should be expended for antituberculosis drugs, supplies, direct patient services, and training in diagnosis and treatment for Directly Observed Treatment Short-course (DOTS) coverage and treatment of multi-drug resistant tuberculosis using DOTS-Plus, including substantially increased funding for the Global Tuberculosis Drug Facility.]

(e) PRIORITY TO STOP TB STRATEGY.—In furnishing assistance under subsection (c), the President shall give priority to—

(1) activities described in the Stop TB Strategy, including expansion and enhancement of Directly Observed Treatment Short-course (DOTS) coverage, rapid testing, treatment for individuals infected with both tuberculosis and HIV, and treatment for individuals with multi-drug resistant tuberculosis (MDR-TB), strengthening of health systems, use of the International Standards for Tuberculosis Care by all providers, empowering individuals with tuberculosis, and enabling and promoting research to develop new diagnostics, drugs, and vaccines, and program-based operational research relating to tuberculosis; and

(2) funding for the Global Tuberculosis Drug Facility, the Stop Tuberculosis Partnership, and the Global Alliance for TB Drug Development.

(f) ASSISTANCE FOR THE WORLD HEALTH ORGANIZATION AND THE STOP TUBERCULOSIS PARTNERSHIP.—In carrying out this section, the President, acting through the Administrator of the United States Agency for International Development, is authorized to provide increased resources to the World Health Organization and the Stop Tuberculosis Partnership to improve the capacity of countries with

high rates of tuberculosis and other affected countries to implement the Stop TB Strategy and specific strategies related to addressing multiple drug resistant tuberculosis (MDR-TB) and extensively drug resistant tuberculosis (XDR-TB).

[(f)] *(g)* DEFINITIONS.—In this section:

(1) DOTS.—The term "DOTS" or "Directly Observed Treatment Short-course" means the World Health Organization-recommended strategy for treating tuberculosis[.] *including*

(A) low–cost and effective diagnosis, treatment, and monitoring of tuberculosis;

(B) a reliable drug supply;

(C) a management strategy for public health systems;

(D) health system strengthening;

(E) promotion of the use of the International Standards for Tuberculosis Care by all care providers;

(F) bacteriology under an external quality assessment framework;

(G) short-course chemotherapy; and

(H) sound reporting and recording systems.

(2) DOTS-PLUS.—The term "DOTS-Plus" means a comprehensive tuberculosis management strategy that is built upon and works as a supplement to the standard DOTS strategy, and which takes into account specific issues (such as use of second line anti-tuberculosis drugs) that need to be addressed in areas where there is high prevalence of multi-drug resistant tuberculosis.

(3) GLOBAL ALLIANCE FOR TUBERCULOSIS DRUG DEVELOPMENT.—The term "Global Alliance for Tuberculosis Drug Development" means the public-private partnership that brings together leaders in health, science, philanthropy, and private industry to devise new approaches to tuberculosis and to ensure that new medications are available and affordable in high tuberculosis burden countries and other affected countries.

(4) GLOBAL TUBERCULOSIS DRUG FACILITY.—The term "Global Tuberculosis Drug Facility (GDF)" means the new initiative of the Stop Tuberculosis Partnership to increase access to high-quality tuberculosis drugs to facilitate DOTS expansion.

(5) STOP TB STRATEGY.—The term "Stop TB Strategy" means the 6-point strategy to reduce tuberculosis developed by the World Health Organization, which is described in the Global Plan to Stop TB 2006–2015: Actions for Life, a comprehensive plan developed by the Stop TB Partnership that sets out the actions necessary to achieve the millennium development goal of cutting tuberculosis deaths and disease burden in half by 2015.

[(5)] *(6)* STOP TUBERCULOSIS PARTNERSHIP.—The term "Stop Tuberculosis Partnership" means the partnership of the World Health Organization, donors including the United States, high tuberculosis burden countries, multilateral agencies, and non-governmental and technical agencies committed to short- and long-term measures required to control and eventually eliminate tuberculosis as a public health problem in the world.

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SEC. 104C. ASSISTANCE TO COMBAT MALARIA.

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(b) POLICY.—It is a major objective of the foreign assistance program of the United States to provide assistance for the prevention, control, *treatment,* and cure of malaria.

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Chapter 3—International Organizations and Programs

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Sec. 302. Authorization.—(a) * * *

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(c) None of the funds available to carry out this chapter shall be contributed to any international organization or to any foreign government or agency thereof to pay the costs of developing or operating any volunteer program of such organization, government, or agency relating to the selection, training, and programing of volunteer manpower.

(d) TUBERCULOSIS VACCINE DEVELOPMENT PROGRAMS.—In addition to amounts otherwise available under this section, there are authorized to be appropriated to the President such sums as may be necessary for each of the fiscal years 2009 through 2013, which shall be used for United States contributions to tuberculosis vaccine development programs, which may include the Aeras Global TB Vaccine Foundation.

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(k) In addition to amounts otherwise available under this section, there is authorized to be appropriated to the President such sums as may be necessary for each of the **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013* to be available only for United States contributions to the Vaccine Fund.

(l) In addition to amounts otherwise available under this section, there is authorized to be appropriated to the President such sums as may be necessary for each of the **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013* to be available only for United States contributions to the International AIDS Vaccine Initiative.

(m) In addition to amounts otherwise available under this section, there are authorized to be appropriated to the President such sums as may be necessary for each of the **[**fiscal years 2004 through 2008**]** *fiscal years 2009 through 2013* to be available for United States contributions to malaria vaccine development programs, including the Malaria Vaccine Initiative of the Program for Appropriate Technologies in Health (PATH).

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The Public Health Service Act

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CHAPTER 6A—PUBLIC HEALTH SERVICE

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SUBCHAPTER II.—GENERAL POWERS AND DUTIES

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PART A. RESEARCH AND INVESTIGATIONS

SEC. 307. INTERNATIONAL COOPERATION.

[(a) COOPERATIVE ENDEAVORS; STATEMENT OF PURPOSE.—For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, healthcare technology, and the health services research and statistical activities authorized by section 306 of this title and by subchapter VII of this chapter.]

(a) The Secretary may participate with other countries in cooperative endeavors in—

(1) biomedical research, healthcare technology, and the health services research and statistical analysis authorized under section 306 and title IX; and

(2) biomedical research, healthcare services, healthcare research, or other related activities in furtherance of the activities, objectives or goals authorized under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(b) AUTHORITY OF SECRETARY; BUILDING CONSTRUCTION PROHIBITION.—In connection with the cooperative endeavors authorized by subsection (a) of this section, the Secretary may—

(1) make such use of resources offered by participating foreign countries as he may find necessary and appropriate;

(2) establish and maintain fellowships in the United States and in participating foreign countries;

(3) make grants to public institutions or agencies and to nonprofit private institutions or agencies in the United States and in participating foreign countries for the purpose of establishing and maintaining the fellowships authorized by paragraph (2);

(4) make grants or loans of equipment and materials, for use by public or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;

(5) participate and otherwise cooperate in any international meetings, conferences, or other activities concerned with biomedical research, health services research, health statistics, or healthcare technology;

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or healthcare technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b) of Title 5 for persons in the Government service employed intermittently;

(7) procure, in accordance with section 3109 of Title 5, the temporary or intermittent services of experts or consultants; [and]

(8) enter into contracts with individuals for the provision of services (as defined in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in participating foreign countries, which individuals may not be deemed employees of the United States [for any purpose] *for the purpose of any law administered by the Office of Personnel Management;*

(9) provide such funds by advance or reimbursement to the Secretary of State, as may be necessary, to pay the costs of acquisition, lease, construction, alteration, equipping, furnishing or management of facilities outside of the United States; and

(10) in consultation with the Secretary of State, through grant or cooperative agreement, make funds available to public or nonprofit private institutions or agencies in foreign countries in which the Secretary is participating in activities described under subsection (a) to acquire, lease, construct, alter, or renovate facilities in those countries.

[The Secretary may not, in the exercise of his authority under this section, provide financial assistance for the construction of any facility in any foreign country.]

(c) BENEFITS FOR OVERSEAS ASSIGNEES.—The Secretary may provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of [1990] *1980* (22 U.S.C. 4081 et seq.) *or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083)* . Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of Title 5 to individuals serving in the Foreign Service.

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PART B. FEDERAL-STATE COOPERATION

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SEC. 317S. GENERAL GRANT OF AUTHORITY FOR COOPERATION.

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SEC. 317T. MICROBICIDE RESEARCH.

(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall fully implement the Centers' microbicide agenda to support research and development of microbicides for use in developing countries to prevent the transmission of the human immunodeficiency virus.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out this section.

SUBCHAPTER III—NATIONAL RESEARCH INSTITUTES

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PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SUBPART 6—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SEC. 477. PURPOSE OF INSTITUTE

The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

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SEC. 447C. MICROBICIDE RESEARCH AND DEVELOPMENT.

The Director of the Institute, acting through the head of the Division of AIDS, shall carry out research on, and development of, a microbicide for use in developing countries to prevent the transmission of the human immunodeficiency virus. The Director shall ensure that there are a sufficient number of employees and structure dedicated to carrying out such activities.

SUBCHAPTER XXI—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

PART D—OFFICE OF AIDS RESEARCH

SUBPART I—INTERAGENCY COORDINATION OF ACTIVITIES

SEC. 2351. ESTABLISHMENT OF OFFICE.

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SEC. 2351A. MICROBICIDE RESEARCH.

(a) FEDERAL STRATEGIC PLAN.—

(1) IN GENERAL.—The Director of the Office shall—

(A) expedite the implementation of the Federal strategic plans for the conduct and support of research on, and development of, a microbicide for use in developing countries to prevent the transmission of the human immunodeficiency virus; and

(B) annually review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness.

(2) COORDINATION.—In implementing, reviewing, and prioritizing elements of the plan described in paragraph (1), the Director of the Office shall consult with—

(A) representatives of other Federal agencies involved in microbicide research, including the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the Director of the Centers for Disease Control and Prevention, and the Administrator of the United States Agency for International Development;

(B) the microbicide research and development community; and

(C) health advocates.

(b) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013 to carry out this section.

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The State Department Basic Authorities Act of 1956

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TITLE I—BASIC AUTHORITIES GENERALLY

ORGANIZATION OF THE DEPARTMENT OF STATE

SECTION 1.(a) SECRETARY OF STATE.—* * *

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(f) HIV/AIDS RESPONSE COORDINATOR.—

(1) IN GENERAL.—There shall be established within the Department of State in the immediate office of the Secretary of State a Coordinator of United States Government Activities to Combat HIV/AIDS Globally, who shall be appointed by the President, by and with the advice and consent of the Senate. The Coordinator shall report directly to the Secretary.

(2) AUTHORITIES AND DUTIES; DEFINITIONS.—

(A) AUTHORITIES.—The Coordinator, acting through such nongovernmental organizations (including faith-based and community-based organizations*), partner country finance, health, and other relevant ministries,* and relevant executive branch agencies as may be necessary and appropriate to effect the purposes of this section, is authorized—

(i) to operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities for combatting HIV/AIDS;

(ii) to transfer and allocate funds to relevant executive branch agencies; and

(iii) to provide grants to, and enter into contracts with, nongovernmental organizations (including faith-based and community-based organizations*), partner country finance, health, and other relevant ministries,* to carry out the purposes of section.

(B) DUTIES.—

(i) IN GENERAL.—The Coordinator shall have primary responsibility for the oversight and coordination of all resources and international activities of the United States Government to combat the HIV/AIDS pandemic, including all programs, projects, and activities of the United States Government relating to the HIV/AIDS pandemic under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 or any amendment made by that Act.

(ii) SPECIFIC DUTIES.—The duties of the Coordinator shall specifically include the following:

(I) Ensuring program and policy coordination among the relevant executive branch agencies and nongovernmental organizations, including audit-

ing, monitoring, and evaluation of all such programs.

(II) Ensuring that each relevant executive branch agency undertakes programs primarily in those areas where the agency has the greatest expertise, technical capabilities, and potential for success.

(III) Avoiding duplication of effort.

[(IV) Ensuring coordination of relevant executive branch agency activities in the field.

[(V) Pursuing coordination with other countries and international organizations.]

(IV) Establishing an interagency working group on HIV/AIDS headed by the Global AIDS Coordinator and comprised of representatives from the United States Agency for International Development and the Department of Health and Human Services, for the purposes of coordination of activities relating to HIV/AIDS, including—

(aa) meeting regularly to review progress in partner countries toward HIV/AIDS prevention, treatment, and care objectives;

(bb) participating in the process of identifying countries to consider for increased assistance based on the epidemiology of HIV/AIDS in those countries, including clear evidence of a public health threat, as well as government commitment to address the HIV/AIDS problem, relative need, and coordination and joint planning with other significant actors;

(cc) assisting the Coordinator in the evaluation, execution, and oversight of country operational plans;

(dd) reviewing policies that may be obstacles to reaching targets set forth for HIV/AIDS prevention, treatment, and care; and

(ee) consulting with representatives from additional relevant agencies, including the National Institutes of Health, the Health Resources and Services Administration, the Department of Labor, the Department of Agriculture, the Millennium Challenge Corporation, the Peace Corps, and the Department of Defense.

(V) Coordinating overall United States HIV/AIDS policy and programs, including ensuring the coordination of relevant executive branch agency activities in the field, with efforts led by partner countries, and with the assistance provided by other relevant bilateral and multilateral aid agencies and other donor institutions to promote harmonization with other programs aimed at preventing and treating HIV/AIDS and other health challenges, improving primary health, addressing

food security, promoting education and development, and strengthening healthcare systems.

(VI) Resolving policy, program, and funding disputes among the relevant executive branch agencies.

(VII) Holding annual consultations with nongovernmental organizations in partner countries that provide services to improve health, and advocating on behalf of the individuals with HIV/AIDS and those at particular risk of contracting HIV/AIDS, including organizations with members who are living with HIV/AIDS.

(VIII) Ensuring, through interagency and international coordination, that HIV/AIDS programs of the United States are coordinated with, and complementary to, the delivery of related global health, food security, development, and education.

[(VII)**]** *(IX)* Directly approving all activities of the United States (including funding) relating to combatting HIV/AIDS in each of Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, *Vietnam,* Zambia, and other countries designated by the President, which other designated countries may include those countries in which the United States is implementing HIV/AIDS programs as of the date of the enactment of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 *and other countries in which the United States is implementing HIV/AIDS programs as part of its foreign assistance program. In designating additional countries under this subparagraph, the President shall give priority to those countries in which there is a high prevalence or significantly rising incidence of HIV/AIDS, countries with large populations and inadequate health infrastructure, countries in which a concentrated HIV/AIDS epidemic could become generalized to the entire population of the country, and in countries whose governments demonstrate a commitment to combating HIV/AIDS.*

(X) Working with partner countries in which the HIV/AIDS epidemic is prevalent among injection drug users to establish, as a national priority, national HIV/AIDS prevention programs, including education and services demonstrated to be effective in reducing the transmission of HIV infection among injection drug users without increasing illicit drug use.

(XI) Working with partner countries in which the HIV/AIDS epidemic is prevalent among individuals involved in commercial sex acts to establish, as a national priority, national prevention

programs, including education, voluntary testing, and counseling, and referral systems that link HIV/AIDS programs with programs to eradicate trafficking in persons and support alternatives to prostitution.

[(VIII)] *(XII)* Establishing due diligence criteria for all recipients of [funds section] *funds appropriated for HIV/ AIDS assistance pursuant to the authorization of appropriations under section 401 of the United States Leadership Against HIV/ AIDS, Tuberculosis, and Malaria Act of 2003 (22 U.S.C. 7671)* and all activities subject to the coordination and appropriate monitoring, evaluation, and audits carried out by the Coordinator necessary to assess the measurable outcomes of such activities.

(XIII) Publicizing updated drug pricing data to inform the purchasing decisions of pharmaceutical procurement partners.

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The Immigration and Nationality Act

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The Immigration and Nationality Act, as Amended

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INADMISSIBLE ALIENS

SEC. 212. (a) Except as otherwise provided in this Act, aliens who are inadmissible under the following paragraphs are ineligible to receive visas and ineligible to be admitted to the United States:

(1) HEALTH-RELATED GROUNDS.

(A) IN GENERAL. Any alien—

(i) who is determined (in accordance with regulations prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance, [which shall include infection with the etiologic agent for acquired immune deficiency syndrome,]*;*

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