

H.R. 5501
***THE TOM LANTOS AND HENRY J. HYDE UNITED STATES LEADERSHIP AGAINST
HIV/AIDS, TUBERCULOSIS, AND MALARIA REAUTHORIZATION ACT AS PASSED BY
THE SENATE, JULY 16, 2008***
SECTION BY SECTION

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 and malaria around the world and the impact of U.S. assistance in combating these diseases since the 2003 Leadership Act was passed. 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 in the coming years.

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 requires a new five-year coordinated strategy to combat HIV/AIDS, tuberculosis, and malaria as part of the overall United States health and development agenda; calls for increased resources for bilateral and multilateral efforts to combat these diseases; seeks to intensify prevention, treatment, and care efforts and 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.

TITLE I--POLICY PLANNING AND COORDINATION

Sec. 101. Development of a comprehensive, five-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 five-year plan to combat HIV/AIDS globally and requiring a subsequent report to Congress.

The section 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 five years to prevent 12 million new HIV infections, to support care for 12 million adults and children infected with or affected by HIV/AIDS (including 5 million orphans and other children), and to support treatment for persons with HIV/AIDS through bilateral efforts as well as through multilateral programs. The treatment target itself will rise above 2 million persons as resources and cost efficiencies allow, as established in Sec. 403 of the reauthorization act.

The section establishes targets to promote universal access (defined as 80 percent) to prevention of mother to child transmission services, 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, this section requires a timetable for achieving treatment targets. It instructs the President to strengthen health capacity 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.

The section calls for a plan for regional priorities for resource distribution and a framework for potential new compacts or framework agreements. It underscores the importance of addressing the needs and vulnerabilities of women and girls to HIV/AIDS. Finally, it calls for a long-range estimate of projected resource needs and progress toward sustainability and greater country ownership of their HIV/AIDS programs.

In terms of oversight and evaluation, this section instructs the Global AIDS Coordinator to commission a study by the Institute of Medicine (with prior design and budget established in consultation with the Coordinator) to assess progress and outcomes of United States global HIV/AIDS programs. It 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 of the three largest agencies carrying out this program (State Department, United States Agency for International Development (USAID) and the Department of Health and Human Services (HHS)) and authorizes up to \$15 million to support financial audits 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 USAID and HHS.

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 of 1961 (22 USC 2222) 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 research and development of a tuberculosis vaccine.

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 that Act and expresses the Sense of Congress regarding transparency, accountability, and coordination. This section also includes a Sense of the Senate that the Global Fund should not support activities involving the “Affordable Medicines Facility-Malaria” initiative pending compelling evidence of their effectiveness. Subsection (b) establishes a policy that the Global AIDS Coordinator shall, in conjunction with the Global Fund, work to prevent the imposition of duties, tariffs and taxes on goods and services provided by the Global Fund. Subsection (c) increases the annual authorization for the U.S. contribution to the Global Fund from \$1 billion to up to \$2 billion for fiscal year 2009, and such sums as necessary for fiscal years 2010-2013. Additionally a Presidential waiver is included to allow the Global Fund to work in Southern Sudan without incurring a deduction in the U.S. contribution.

This section 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 unless the Secretary of State certifies achievement of these benchmarks. This Section also requires the Coordinator to report on a publically available website a summary of the Global Fund Board decisions, as well as the votes and positions of the United States government on Board matters.

Sec. 203. Microbicide Research and Development

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 non-vaccine prevention methods that can be controlled by women.

Subsection (b) requires the Director of the National Institutes of Health (NIH) Office of AIDS Research to expedite the implementation of the Federal strategic plans required by Section 403(a) of the Public Health Service Act (42 USC 283 (a)(5)) regarding the conduct and support of research on, and development of, a microbicide to prevent the transmission of HIV. The Director shall review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness. In implementing, reviewing and prioritizing elements of the plan, the Director shall consult as appropriate with representatives of other Federal agencies, the research community and health advocates.

Subsection(c) requires the Director of the National Institute of Allergy and Infectious Diseases, consistent with the peer-review process of NIH, to carry out research on, and development of, safe and effective methods for use by women to prevent the transmission of HIV, which may include microbicides.

Subsection (d) strongly encourages the Director of the Centers for Disease Control and Prevention (CDC) to fully implement the Centers' microbicide agenda to support research and development of microbicides to prevent the transmission of HIV.

Subsection (e) authorizes the Administrator of the USAID, in coordination with the Global AIDS Coordinator, to facilitate availability and accessibility of microbicides, provided that such pharmaceuticals are approved, tentatively approved, or otherwise authorized for use by the Food and Drug Administration (FDA) or another stringent regulatory agency or quality assurance mechanism acceptable to the Secretary of HHS. This subsection also authorizes, of the amounts authorized by section 401 of the 2003 Leadership Act, 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 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

This section amends the Public Health Service Act (42 USC 242l) by providing additional authorities for the Secretary of Health and Human Services to facilitate CDC's international activities as part of PEPFAR.

Sec. 206 Facilitating Vaccine Development

Subsection (a) of this section authorizes the Administrator of USAID, utilizing public-private partnerships and in coordination with other international development agencies, to gather and analyze data and review protocols that could lead to the development of vaccines for HIV/AIDS, tuberculosis and malaria. Subsection (b) calls for a report on the status of the United States' participation in programs for the advanced market commitments for the development of such vaccines.

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 FY2009-2013 to assist countries in:

- Preventing 12 million new HIV infections;
- Supporting treatment of people with HIV/AIDS through bilateral and multilateral efforts above an initial target of 2 million persons as established under Sec. 403;
- Supporting care for 12 million people infected with or affected by HIV/AIDS (including 5 million orphans and vulnerable children);
- Providing 80 percent access (the level often defined as universal access) to counseling and services for prevention of mother to child transmission;
- Providing care and treatment services to children with HIV/AIDS in proportion to their percentage within the population of persons who are infected; and
- Training 140,000 new healthcare paraprofessionals and professionals, with an emphasis on doctors and nurses where needed.

This section underscores 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. This section provides for a more integrated 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.

This section emphasizes 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, lists required elements of such compacts, and defines the parameters under which direct services and technical assistance compacts may be negotiated. It also requires congressional and public notification regarding compacts.

Section 301 addresses cost-effective drug purchasing by authorizing assistance for mechanisms to ensure that safe and effective pharmaceuticals, including antiretroviral medications (ARVS) and medicines to treat opportunistic infections, are purchased at the lowest possible price at which they may be obtained on the world market, provided that they are approved, tentatively approved, or otherwise authorized for use by the FDA, a stringent regulatory agency acceptable to the Secretary of HHS, or a quality assurance mechanism acceptable to the Secretary of HHS.

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

Subsection (h) states that an organization, including a faith based organization, that is otherwise eligible for funding for HIV/AIDS prevention, treatment, or care programs shall not be required to endorse or utilize multisectoral or comprehensive approaches, or participate in or make referrals to programs or activities to which it has a moral or religious objection. It further states that organizations shall not be discriminated against in the issuance of grants, contracts, or cooperative agreements for such decisions.

Sec. 302. Assistance to combat tuberculosis

Subsections (a) and (b) make amendments to section 104B of the Foreign Assistance Act of 1961 (22 USC 215b-3(b)) 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. This section supports achievement of the goals established in the Global Plan to Stop TB. It also includes 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. Reporting requirements for TB activities are substantially increased and targets are defined. Subsection (c) provides an authorization to provide 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 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 (22 USC 2151-4(b)) 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 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.

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. This section also delineates further responsibilities of the Coordinator.

Sec. 305. Amendment to the Immigration and Nationality Act

Section 305 amends Section 212(a)(1)(A) of the Immigration and Nationality Act (INA) by striking the statutory ban on persons with HIV entering the country. This provision was enacted into law in 1993. This provision does not affect the regulatory power under the INA for the Secretary to bar admission of individuals who have a “communicable disease of public health significance.” Nor does it affect the current regulation, pursuant to the INA, that includes HIV as one such disease. Potential costs, estimated by CBO at \$83 million in direct spending over the next 10 years, are offset by increased visa fees under Sec. 501.)

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 establishing targets for reaching 80 percent of the target population for prevention of mother-to-child transmission (PMTCT) of HIV and to seek to ensure that the proportion of children receiving care and treatment for HIV/AIDS is proportionate to their numbers within the population of HIV infected persons. 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, for increasing access of women in PMTCT programs to maternal and child health services, and for 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.

Sec. 309 Prevention of Mother-to-Child Transmission Expert Panel

This section establishes such a panel, to be chaired by the Global AIDS Coordinator as a non-voting member, with fifteen other, voting, members serving on the panel. The fifteen shall come from within the U.S. government, health ministries of recipient countries and related PMTCT non-governmental organizations and shall produce a report on findings and recommendations.

TITLE IV—FUNDING ALLOCATIONS

Sec. 401. Authorization of appropriations

This section increases the authorization under section 401(a) of the 2003 Leadership Act to \$48 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.)

This section also authorizes \$2 billion for the establishment of the Emergency Fund for Indian Safety and Health. These funds are to be used for law enforcement, health services and water projects. Law enforcement funds are to be used for the construction, rehabilitation, and replacement of Federal Indian detention facilities; the investigation and prosecution of crimes in Indian country; the Office of Justice Programs for Indian and Alaska Native programs; and cross-deputization or other cooperative agreements between state or local governments and Indian tribes. This section also directs funds to be used for the implementation of water settlement agreements and water infrastructure projects. The Secretary of Health and Human Services is also directed to use funds for the contract health services program at the Indian Health Service; construction, rehabilitation and replacement of health facilities; and domestic and community sanitation facilities.

Sec. 402. Sense of Congress

This section strikes all the directives in this Sense of Congress section of the 2003 Leadership Act except the directive addressing Orphans and Vulnerable Children, which is retained.

Sec. 403. Allocation of funds

This amends section (a) of Sec. 403 of the 2003 Leadership Act to include a requirement that the Coordinator provide balanced funding for prevention activities for sexual transmission of HIV/AIDS and ensure that activities promoting abstinence, delay of 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 amended section 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 with a generalized epidemic, if this strategy provides less than 50 percent of such funds for activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, 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 as well as PMTCT and counseling and testing activities from calculations to determine compliance with the balanced funding reporting requirement.

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.

The section also requires that for each of the fiscal years 2009 through 2013, more than half of the amounts appropriated for bilateral global HIV/AIDS assistance pursuant to section 401 shall be expended for: ARV treatment, clinical monitoring, care for associated opportunistic infections, nutrition and food support, and other essential HIV/AIDS-related medical care for people living with HIV/AIDS.

This section states the treatment goals under Sec. 402(a)(3) shall be increased above 2,000,000 persons by at least the percentage increase in the amount appropriated for the bilateral global HIV/AIDS assistance for such fiscal year compared with fiscal year 2008. Any increase in the aforementioned treatment target above the percentage increase in appropriations (which is the minimum level required under this provision) shall be based on long-term requirements, epidemiological evidence, the share of treatment needs being met by partner governments and other sources of funding, and other appropriate factors. Additionally, this section states that the treatment target shall also be increased above 2 million persons by the same percentage that the average U.S. Government cost per patient of providing treatment in countries receiving bilateral HIV/AIDS assistance has decreased compared with fiscal year 2008. Finally, it states that prevention and care goals shall be increased consistent with epidemiological evidence and available resources.

TITLE V – Miscellaneous

Sec. 501 Machine Readable Visa Fees

Effective, no later than October 1, 2010, this section increases by \$1 the fee charged to cover costs of the Machine Readable Visa fee paid by persons applying for Non-Immigrant Visas to the United States. This fee shall be raised to \$2 no later than October 1, 2013. Under this section, the money would be directed to the Treasury.