

The President's Emergency Plan for AIDS Relief (PEPFAR), U.S. Global HIV/AIDS, Tuberculosis, and Malaria Programs: A Description of Permanent and Expiring Authorities

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Summary

Fighting HIV/AIDS, tuberculosis (TB), and malaria globally is a priority for Congress. The 108th and 110th Congresses enacted two pieces of legislation that have shaped U.S. responses to these diseases: P.L. 108-25, the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Leadership Act), and P.L. 110-293, the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Lantos-Hyde Act). The Leadership Act authorized \$15 billion to be spent from FY2004 through FY2008 on fighting HIV/AIDS, TB, and malaria. The Lantos-Hyde Act amended the Leadership Act to authorize \$48 billion for fighting the three diseases from FY2009 through FY2013.

The Leadership Act (and the legislation that it amends) is the primary vehicle through which U.S. global assistance for fighting these diseases is authorized. The Lantos-Hyde Act mostly amends the Leadership Act, though it amends some other acts, such as the Foreign Assistance Act of 1961, and includes some stand-alone authorities. The Leadership Act and the Lantos-Hyde Act (primarily through amendments to the Leadership Act) created frameworks for how the funds should be spent, established program goals and targets, and established coordinating offices for managing government-wide responses.

The Leadership Act required the President to establish the Coordinator of the United States Government Activities to Combat HIV/AIDS Globally (known as the Global AIDS Coordinator) at the Department of State. Congress appropriates the bulk of global HIV/AIDS funds to the Office of the Global AIDS Coordinator, which leads the President's Emergency Plan for AIDS Relief (PEPFAR). The Global AIDS Coordinator distributes the majority of these funds to U.S. federal agencies and departments and multilateral groups like the Global Fund to Fight AIDS, Tuberculosis and Malaria. The Lantos-Hyde Act amended the Leadership Act to establish the Coordinator of the United States Government Activities to Combat Malaria Globally (known as the Malaria Coordinator) at the U.S. Agency for International Development (USAID) to oversee implementation of related efforts by USAID and the Centers for Disease Control and Prevention.

Some authorities within these Acts are enduring, such as those that created the Global AIDS and Malaria Coordinator positions (Leadership Act, as amended) and permitted U.S. participation in advance market commitments for vaccine development (Lantos-Hyde Act). Other authorities, however, are set to expire, such as language authorizing funding for global HIV/AIDS, TB, and malaria programs.

This report explains which authorities within the Leadership and Lantos-Hyde Acts are set to expire and which are permanent. **Table A-1** in the **Appendix A** offers a side-by-side comparison of the Leadership Act in its original form and the Lantos-Hyde Act, which amends the Leadership Act and other legislation. A third column explains which sections are set to expire and summarizes language in S. 1545 and H.R. 3177 that amend the Leadership Act, as amended. The Leadership Act, as amended and Lantos-Hyde Act include comprehensive reporting requirements. **Table A-2** in the **Appendix A** lists the reporting requirements and describes the extent to which the Administration has complied with the requirements.

Rather than revisit some of the contentious issues that dominated debate when crafting the Lantos-Hyde Act, House and Senate Members introduced legislation (H.R. 3177 and S. 1545) that is narrowly aimed at key priorities: enhancing oversight of U.S. global HIV/AIDS, TB, and

malaria programs; authorizing appropriations for the Global Fund through FY2018; and allocating a portion of HIV/AIDS funds for orphans and vulnerable children (OVC) and for HIV/AIDS treatment and care. **Table B-1** in **Appendix B** summarizes key amendments in the bills, entitled the PEPFAR Stewardship and Oversight Act.

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Background

In January 2003, President Bush announced the President's Emergency Plan for AIDS Relief (PEPFAR), a government-wide initiative to combat global HIV/AIDS. PEPFAR supports a wide range of HIV/AIDS prevention, treatment, and care activities and is the largest commitment by any nation to combat a single disease. Later that year, Congress enacted the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (Leadership Act), P.L. 108-25, which authorized \$15 billion to be spent from FY2004 to FY2008 on bilateral and multilateral HIV/AIDS, tuberculosis (TB), and malaria programs. The Act included language that instructed how the funds should be spent, listed several goals and targets, and required the President to establish the Coordinator of the United States Government Activities to Combat HIV/AIDS Globally (known as the Global AIDS Coordinator) at the Department of State. The Office of the Global AIDS Coordinator (OGAC) distributes the majority of the funds it receives from Congress for global HIV/AIDS programs to U.S. federal agencies and departments and multilateral groups like the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

In 2008, Congress enacted the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (Lantos-Hyde Act), P.L. 110-293, which amended the Leadership Act to authorize the appropriation of \$48 billion for global HIV/AIDS, TB, and malaria efforts from FY2009 to FY2013. Key amendments in the Act established the Coordinator of the United States Government Activities to Combat Malaria Globally (known as the Malaria Coordinator) at the U.S. Agency for International Development (USAID). The Malaria Coordinator oversees implementation of related efforts by USAID and the Centers for Disease Control and Prevention (CDC) and is advised by an Interagency Advisory Group that includes representatives from USAID, Department of Health and Human Services (HHS), Department of State (State), Department of Defense (DOD), the National Security Council (NSC), and the Office of Management and Budget (OMB).

Certain provisions within the Leadership Act, as amended, and the Lantos-Hyde Act are set to expire at the end of FY2013. The 113th Congress is considering whether to reauthorize these authorities. On September 24 and 25, 2013, respectively, companion bills were introduced in the Senate and House (S. 1545 and H.R. 3177) entitled the PEPFAR Stewardship and Oversight Act. The bills extend authorities related to key priority areas: authorizing appropriations for the Global Fund, expanding reporting requirements, and allocating a portion of global HIV/AIDS funds for orphans and vulnerable children (OVC) and for HIV/AIDS treatment and care.

Table A-1 in **Appendix A** offers a side-by-side comparison of the Leadership Act in its original form and the Lantos-Hyde Act, which amends the Leadership Act and other legislation. A third column explains which sections are set to expire and summarizes language in S. 1545 and H.R. 3177 that amend the Leadership Act, as amended. The Leadership Act, as amended, Lantos-Hyde Act, and legislation that these Acts amend include language to facilitate oversight of U.S. global HIV/AIDS, TB, and malaria programs, as well as to ensure key congressional priorities are met. The related reporting requirements are listed in **Table A-2** of **Appendix A**. This report explains briefly which authorities in these two Acts are set to expire and which are permanent.

Congressional Issues

Congressional interest in combating HIV/AIDS, TB, and malaria has been unwavering. The Leadership and Lantos-Hyde Acts are important tools Congress has used to influence the design of projects aimed at fighting the three diseases and to oversee their implementation. The 108th and 110th Congresses were able to overcome ideological and political differences to enact the Leadership and Lantos-Hyde Acts. It does not appear some of the contentious issues that dominated debate when crafting the Leadership and Lantos-Hyde Acts (such as family planning) will be revisited at this time. S. 1545, the PEPFAR Stewardship and Oversight Act and its House companion (H.R. 3177) do not offer a comprehensive extension of the Leadership Act, as amended. Instead, it focuses on key priorities related to strengthening oversight, extending funding authorities for the Global Fund, orphans and vulnerable children, and HIV/AIDS treatments and care programs. A summary of the authorities that S. 1545 and H.R. 3177 seek to amend are listed in **Table B-1** of **Appendix B**.

Key authorities that are set to expire revolve around four themes:

- establishing performance targets;
- evaluating and overseeing program implementation;
- advancing research on curative and preventive tools; and
- directing how funds are to be utilized.

There are far more permanent authorities than expiring ones. Enduring legislation authorized:

- the establishment of HIV/AIDS and malaria coordinators;
- regular reporting on program evaluation and implementation;
- research for the identification and development of improved tools;
- mechanisms for advancing country ownership and cost sharing;
- the integration of nutritional support into HIV/AIDS programs;
- exemption from certain HIV/AIDS prevention activities due to moral objections (known as the conscience clause); and
- HIV-positive individuals to enter the United States.

Public statements by the Obama Administration and several Members of Congress suggest that support for maintaining global HIV/AIDS, TB, and malaria programs remains strong in both branches. Prospects remain high that the Administration will continue to request that Congress maintain funding levels for these programs in the coming years and Congress may comply, whether or not Congress enacts another five-year authorization for the diseases.² The following

¹ For more information on congressional debates surrounding the Lantos-Hyde Act, see archived CRS Report RL34569, *PEPFAR Reauthorization: Key Policy Debates and Changes to U.S. International HIV/AIDS, Tuberculosis, and Malaria Programs and Funding.* For more on global family planning debates, see CRS Report RL33250, *International Family Planning Programs: Issues for Congress.*

² Budgetary requests for global HIV/AIDS, TB, and malaria programs have remained mostly level throughout the Obama Administration. Key documents by the Obama Administration, such as *PEPFAR Blueprint: Creating an AIDS*-(continued...)

sections describe which authorities in the Leadership Act, as amended, and the Lantos-Hyde Act are set to expire and which are enduring.

Expiring Authorities

Some of the provisions in the Leadership and Lantos-Hyde Acts that shape U.S. global HIV/AIDS, TB, and malaria programs are set to expire at the end of FY2013. These primarily entail the establishment of performance targets and interagency strategies for addressing the three diseases. Other expiring authorities enhance congressional oversight capacity, promote research, and direct how funds are to be spent. The discussion below summarizes authorizing language in the Leadership and Lantos-Hyde Acts that includes a precise end date. The subsections are discussed sequentially.

Performance Targets/Strategy

Throughout the Leadership and Lantos-Hyde Acts, Congress included language that shaped the scope and breadth of PEPFAR. Section 101 of the Leadership Act, for example, required the President to develop a five-year strategy for combatting HIV/AIDS worldwide from FY2004 through FY2008. The section also set several program targets for HIV/AIDS programs. Section 101 of the Lantos-Hyde Act amended the Leadership Act to require the President to develop another five year strategy for FY2009 through FY2013. The law mandates that the strategy describe how the Administration would reach new targets by the end of FY2013. These are:

- prevent 12 million new HIV infections;
- care for 12 million people affected by HIV/AIDS, including 5 million orphans;
- treat at least 2 million more people;
- ensure at least 80% of target populations have access to counseling, testing, and treatment; and
- train at least 140,000 health care professionals and paraprofessionals.

Congress also used the Leadership and Lantos-Hyde Acts to set targets for combatting TB worldwide. Section 302 of the Leadership Act amended section 104B of the Foreign Assistance Act of 1961 (FAA) to authorize U.S. participation in several multilateral anti-TB efforts and specified treatment targets. Section 302 of the Lantos-Hyde Act amended section 104B(b) of the FAA to direct the President to establish a five-year strategy for expanding and improving U.S. TB programs and achieving the following targets by 2013:

- treat 4.5 million new sputum smear TB patients under Directly Observed Treatment, Short Course (DOTS) programs; and
- diagnose and treat 90,000 new multiple drug resistant TB (MDR-TB) cases.

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Free Generation, indicate an enduring commitment to expanding access to HIV/AIDS tools worldwide.

^{(...}continued)

There is growing discussion about the utility of setting treatment and other numeric targets. On the one hand, such targets can be effective tools in demonstrating congressional intent and motivating an expansive and swift response. On the other hand, it could be argued that other indicators, such as changes in disease prevalence or survival rates, are better measures of program effectiveness. It can be difficult, however, to link these broader outcomes to particular project activities

Efforts to attribute results to a particular activity have become complicated by the growing cadre of actors who often collaborate to address these diseases. The Global Fund and the United States, for example, frequently provide various elements of support to the same population. For instance, grantees of the Global Fund may purchase treatments for any of the three diseases but use U.S.-funded supply chain networks to distribute the medication.

PEPFAR has undergone tremendous expansion and transformation since its early years. Some question whether numerical targets are the appropriate measure of its impact at this current stage. During the first phase of PEPFAR, the United States and other stakeholders rushed to expand access to treatment and care for people affected by HIV/AIDS in low-resource countries. Numerical targets helped to leverage support for addressing HIV/AIDS both within the United States and in the global arena. As the program progressed, it became increasingly evident that the poor state of health systems in recipient countries encumbered efforts to rapidly implement treatment and care programs. Health system strengthening has become an increasingly important part of PEPFAR and has become a critical strategy for advancing country ownership. Some groups are calling for more qualitative studies that measure impact (declines in transmission rates, for example) rather than a count of beneficiaries.

Section 204 of the Leadership Act as amended made the strengthening of health policies and health systems a policy of the United States. The section requires the Global AIDS Coordinator, in collaboration with USAID, to develop and implement a plan to combat HIV/AIDS by strengthening health policies and health systems of partner countries. The section also authorizes the Secretary of the Treasury to provide assistance for the improvement of public finance management systems in recipient countries. The section authorizes such sums as necessary to carry out these activities for each of FY2009 through FY2013. It remains to be seen whether the Administration will continue to aim for achieving ambitious prevention, care, and treatment goals without congressional directives. The strategy for strengthening health systems and health policy worldwide, however, will likely remain a priority, evidenced in part by the creation of the Office of Health Systems at USAID in 2012.³

Evaluation and Oversight

The \$15 billion authorization included in the Leadership Act for global HIV/AIDS, TB, and malaria programs was the largest authorization for global health programs until that date. Congress included language in the Act to require the President to submit several reports detailing how the funds were spent. Congress amended these reporting requirements through the Lantos-Hyde Act and added some additional ones. A number of the reporting requirements were for a

³ For background discussion on the creation of the office, see http://blog.usaid.gov/2012/09/a-kid-in-a-candy-store-building-the-foundations-for-sustainable-healthcare/.

specific period of time, while others were included in permanent statute. This section summarizes the reporting requirements that were set for a particular time period.

Section 101 of the Leadership Act required the President to submit a report to Congress no later than 270 days after enactment of the Act that described the five-year global AIDS strategy and required the Institute of Medicine (IOM) to assess U.S. global HIV/AIDS, TB, and malaria programs. The Lantos-Hyde Act amended section 101 of the Leadership Act to require the President to develop another five-year global AIDS strategy plan and authorize IOM to conduct another evaluation study of U.S. efforts to combat the three diseases. The amended section includes additional oversight and evaluation requirements. These are:

- an authorization of such sums as necessary for the Comptroller General to develop and submit a report evaluating PEPFAR;
- a requirement for OGAC to submit a best practices report; and
- an authorization of up to \$15 million for the Inspectors General of USAID, the
 Department of State and Broadcasting Board of Governors, and Department of
 Health and Human Services (HHS) to jointly develop five coordinated annual
 plans for oversight activity through FY2013.

The IOM and Obama Administration have largely adhered to these reporting requirements (see **Table A-2**). It is unclear, however, whether parties will continue to submit such reports without a congressional mandate. Language in the PEPFAR Stewardship and Oversight Acts extended and expanded reporting requirements. The bills focus on extending authorities for:

- the State Department, USAID, and HHS Inspectors General to develop annual, joint oversight/audit plans through FY2018;
- the President to submit annual reports through FY2019 that detail per-patient costs for PEPFAR-supported treatment and care programs, including a comparative study of per-patient costs by the Global Fund and recipient countries; and
- the President to submit comprehensive annual reports on PEPFAR implementation. The language in the PEPFAR Stewardship and Oversight Acts expand the reporting requirements.

Funding/Spending Requirements

Discussions about the Leadership and Lantos-Hyde Acts have tended to centralize on funding levels. The Leadership Act authorized \$15 billion for the U.S. fight against HIV/AIDS, TB, and malaria from FY2004 through FY2008; and the Lantos-Hyde Act amended the Leadership Act to authorize \$48 billion from FY2009 through FY2013 for the acceleration of U.S. efforts to combat the three diseases. Several sections in the Lantos-Hyde Act amended the FAA and Leadership Act to specify how much of the funds were to be spent on each disease. These sections are listed below.

 Section 302 of the FAA, as amended, authorizes the United States to make contributions to the Aeras Global TB Vaccine Foundation and GAVI Fund from FY2009 through FY2013.

- Section 202 202(d) of the Leadership Act, as amended, authorizes \$2 billion for the Global Fund in FY2009 and such sums as necessary through FY2013.
- Section 302(b) of the Leadership Act, as amended, authorizes \$4 billion for global TB efforts from FY2009 through FY2013.
- Section 104C(b) of the FAA, as amended, authorizes \$5 billion for global malaria efforts from FY2009 through FY2013.
- Section 401(a) of the Leadership Act, as amended, authorizes \$48 billion from FY2009 through FY2013 to carry out the Leadership Act and the amendments made by the Act.

The Lantos-Hyde Act also amended the Leadership Act to apportion the funds among certain activities or to limit how the funds could be used. These sections of the Leadership Act, as amended are listed below.

- Section 202(d) permits the Secretary of State to withhold portions of U.S. contributions for various purposes, including amounts that would have been provided to a country that "has repeatedly provided support for acts of international terrorism"
- Section 403 requires 10% of funds appropriated under the Act to be expended for children affected by or vulnerable to HIV/AIDS from FY2009 through FY2013.
- Section 403 requires more than half of funds appropriated for each of FY2009 through FY2013 to be expended for:
 - HIV/AIDS treatments:
 - clinical monitoring of HIV-positive people in need of treatment;
 - care for associated opportunistic infections;
 - nutrition and food support for people living with HIV/AIDS; and
 - other essential HIV/AIDS-related medical care.

Irrespective of decisions to reauthorize expiring legislation for HIV/AIDS, TB, and malaria programs, the global efforts can continue to be funded through annual appropriations. The PEPFAR Stewardship and Oversight Acts do not authorize funding levels for any program, though they do authorize continued support for the Global Fund and maintain funding allocations for orphans and vulnerable children, as well as HIV/AIDS treatment and care efforts. Through FY2018, the bills:

- maintain provisions limiting U.S. Global Fund contributions to 33% of contributions from all sources and continue withholding requirements related to Global Fund reforms and state sponsors of terrorism;
- require that at least 10% of all U.S.HIV/AIDS spending is allocated to orphans and vulnerable children; and
- require that at least 50% of all HIV/AIDS spending is allocated to care and treatment programs.

National Institutes of Health/Research

Until a cure or vaccine is identified, people will continue to die from HIV/AIDS if left untreated. Section 203 of the Lantos-Hyde Act amended subpart 1 of part D of title XXII of the Public Health Service Act to require the Director of the National Institutes of Health (NIH) Office of AIDS Research to develop a federal strategic plan for researching and developing tools to cure or prevent HIV/AIDS. The Public Health Service Act, as amended, also authorizes such sums as may be necessary from FY2009 through FY2013 for the Director of CDC to support research and development of microbicides for HIV prevention and for USAID to facilitate availability and accessibility of microbicides, provided they are authorized for use by the U.S. Food and Drug Administration (FDA) or some other quality assurance mechanism acceptable to the Secretary of HHS. Section 206 of the Lantos-Hyde Act requires the Secretary of the Treasury to negotiate the terms of U.S. participation in advanced market commitments for vaccine development and to submit a report to the appropriate congressional committees on the status of the negotiations no later than one year after the date of the enactment of the Lantos-Hyde Act.

Research and development can be an expensive endeavor. The quest to find improved tools for diagnosing, preventing, treating, and curing HIV/AIDS, TB, and malaria is still subsidized primarily by donor governments and philanthropic organizations. One study found, for example, that roughly 80% of all funding for TB research in 2010 was supported by public or philanthropic funding. Although language stipulating support for research and development, as described above, is set to expire, other language in other parts of the Leadership and Lantos-Hyde Acts that encourage research and development are enduring (for the permanent authorities, see "National Institutes of Health (NIH)/Research" in the "Permanent Authorities" section below). The PEPFAR Stewardship and Oversight Acts do not include language extending support for research and development efforts.

Permanent Authorities

Congress has played a key role not only in ensuring that global HIV/AIDS, TB, and malaria programs are adequately funded, but also in shaping how the programs are to be implemented. The section below highlights the sections in these Acts that are enduring.

Program Coordination

Section 102 of the Lantos-Hyde Act amended section 1(f)(2) of the State Department Basic Authorities Act of 1956 to establish an interagency working group on HIV/AIDS headed by OGAC and comprised of representatives from USAID and HHS to coordinate overall U.S. global HIV/AIDS policy and programs, among other things.

⁴ David Walwyn, "Determining Quantitative Targets for Public Funding of Tuberculosis Research and Development," *Health Research Policy and Systems*, vol. 11, no. 10 (2013).

Reporting/Best Practices

In an effort to oversee PEPFAR implementation and assess its impact, several sections in the Leadership Act, as amended, direct several groups to evaluate the initiative. These sections are listed below. (A complete list of reporting requirements and the status of compliance is outlined in **Table A-2**).

- Section 101 requires OGAC to publish annually 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.
- Section 101 requires OGAC to publish annually a report on per-patient HIV/AIDS treatment costs.
- Section 403 requires the President to submit annual reports on the U.S. global HIV sexual transmission prevention strategy.

National Institutes of Health (NIH)/Research

The Lantos-Hyde Act (primarily through amendments to permanent statutes) includes authorities that expanded U.S. engagement in research and development for the identification of improved tools for controlling and curing the three diseases. The relevant sections are summarized below.

- Subpart 1 of part D of title XXII of the Public Health Service Act, as amended, requires NIH to carry out research on identifying safe and effective methods of preventing HIV transmission, including microbicides, among women.
- Section 307 of the Public Health Service Act, as amended, authorizes HHS to
 enter into cooperative agreements with other countries for the advancement of
 biomedical research, health care technology, health services research, and
 statistical analysis, and permitted HHS to provide financial assistance for the
 construction of facilities in foreign countries as part of related research efforts.
- Section 206 of the Lantos-Hyde Act requires USAID to coordinate with other development agencies to collect evidence for informed decision-making and introduction of new vaccines, including potential HIV/AIDS, TB, and malaria vaccines; and to review protocols for clinical trials. The section also requires the United States to participate in negotiations for advance market commitments for the development of future vaccines, including potential vaccines for HIV/AIDS, TB, and malaria. Language in the section requires the President to produce a comprehensive report that sets forth a coordinated strategy to accelerate development of vaccines for infectious diseases.

Country Ownership/Cost Sharing

As discussed earlier, the sustainability of PEPFAR programs and country ownership of related activities became an increasingly important part of debates about PEPFAR implementation. Section 301(c)(6) of the Lantos-Hyde Act amended section 104A(d) of the FAA to require the development of compacts or framework agreements at the country level that promote host government commitment; contribute to deeper integration of HIV/AID services into health

systems; strengthen health systems; and enhance sustainability. Among other things, the country compacts outline the role of the United States and recipient countries in achieving national HIV/AIDS plans and specify cost sharing over a five-year period.⁵

Nutrition

During the first phase of PEPFAR, a large body of research demonstrated how insufficient nutritional intake reduced the efficacy of HIV/AIDS treatment. Support for including nutritional support in PEPFAR programs grew and Congress amended section 301(c) of the FAA to require OGAC and USAID to adhere to World Health Organization (WHO) standards for HIV/AIDS food and nutrition services, integrate nutrition programs with HIV/AIDS activities, and provide food and nutritional support as a component of HIV/AIDS care and treatment programs.

Conscience Clause/ HIV Prevention

Debate about appropriate methods of preventing sexual transmission of HIV/AIDS has been intense, particularly in the early years of PEPFAR. Congress amended section 301(c) of the FAA and added language, known as the "conscience clause," to exempt faith-based groups and other organizations from engaging in activities that they deem morally objectionable. Specifically the FAA, as amended, specifies that organizations, including faith-based organization (FBOs), shall not be required to

- endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS;
- endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and
- shall not be discriminated against in the solicitation or issuance of such grants.

Meanwhile, Congress amended section 403(a) of the Leadership Act to ensure that the promotion of abstinence and monogamy would remain a central focus in any U.S. HIV/AIDS sexual prevention strategy. Specifically, the Leadership Act, as amended requires OGAC to establish an HIV sexual transmission prevention strategy governing the expenditure of funds. If any country does not allocate at least 50% of sexual transmission prevention funds to activities promoting abstinence, delay of sexual debut, monogamy, fidelity, and partner reduction, the Act directs OGAC to submit a report to Congress no later than 30 days after issuance of the strategy justifying the decision. Programs and activities that implement or purchase new prevention technologies or modalities, such as medical male circumcision and microbicides, are not to be included in determining compliance.

⁵ For more information on partnership frameworks, see the PEPFAR webpage http://www.pepfar.gov/countries/frameworks/index.htm. For a discussion on debates of the frameworks, see CRS Report R43115, *U.S. Global Health Assistance: Background and Issues for the 113th Congress*, by (name redacted).

⁶ For more on these debates, see archived CRS Report RL34569, *PEPFAR Reauthorization: Key Policy Debates and Changes to U.S. International HIV/AIDS, Tuberculosis, and Malaria Programs and Funding.*

Tuberculosis and Malaria

Although discussions about reauthorizing the Lantos-Hyde Act and Leadership Act, as amended, tend to focus on global HIV/AIDS programs, the Acts also featured language that authorizes support for global TB and malaria programs. In addition to expiring authorities cited above, language in the Leadership Act, as amended and Lantos-Hyde Act (and the legislation that they amended) set program targets for TB programs, prioritized U.S. efforts to fight TB and malaria worldwide, and established a coordinator of all U.S. global malaria programs. Specific language included:

- Section 104B(b) of the FAA, as amended, makes TB a major objective of U.S. foreign assistance, supports the objectives of the multilateral Global Plan to Stop TB⁷, and establishes related goals for U.S. programs, which are to:
 - halve the TB death and disease burden from 1990 levels and
 - sustain or exceed the detection of at least 70% sputum smear-positive cases of TB and successfully treating at least 85% of the cases detected in countries with USAID programs.
- Section 302(d) of the Lantos-Hyde Act requires the President to submit an annual report to Congress that describes the impact of U.S. foreign assistance on efforts to control TB.
- Section 303 of the Leadership Act, as amended, makes the prevention, control, treatment, and ultimate eradication of malaria a major U.S. objective.
- Section 304 of the Leadership Act, as amended, establishes a Malaria Coordinator at USAID to oversee and coordinate all U.S. resources for combating malaria worldwide.
- Section 304 of the Leadership Act, as amended required the President to submit an annual report to Congress on U.S. assistance for preventing, treating, controlling, and eliminating malaria.

Immigration

HIV/AIDS advocates have long fought U.S. laws prohibiting HIV-positive people without special waivers from entering the United States. Section 305 of the Lantos-Hyde Act ended this practice by amending section 212(a)(1)(A)(i) of the Immigration and National Act. The amendment removed HIV/AIDS as a health-related ground for making an individual ineligible to receive a visa or be admitted into the United States. Due to the amendment, the United States was able to host the International AIDS Conference for the first time in July 2012. People living with HIV/AIDS are critical participants in the biannual conference.

⁷ For more information on the Global Plan to Stop TB, see http://www.stoptb.org/global/plan/.

Appendix A. Legislative Tables

Table A-I. The Leadership, Lantos-Hyde, and PEPFAR Stewardship and Oversight Acts: A Side-By-Side Summary

Leadership Act

Lantos-Hyde Act

PEPFAR Stewardship and Oversight Act

Section 101: Strategy and Program Evaluation.

Directs the President to develop a five year strategy to combat global HIV/AIDS and to submit the strategy to Congress no later than 270 days after enactment. The act directs the Institute of Medicine (IOM) to publish a report evaluating the various components of U.S. global HIV/AIDS program no later than three years after enactment.

Section 101: Strategy and Program Evaluation.

Amends section 101(a) of the Leadership Act by requiring the President to develop an updated, comprehensive five year global strategy to combat global HIV/ADS by October I, 2009. The strategy was to outline how the United States would reach key targets (see "Performance Targets/Strategy"), among other things. The section requires the Global AIDS Coordinator (GAC) to submit an annual report from September 30, 2009 through September 30, 2013 that includes information on HIV/AIDS treatment costs. The section also authorizes the Secretary of State to contract the IOM to evaluate U.S. global HIV/AIDS programs. The budget for the assessment was to be submitted no later than 18 months after enactment and the evaluation no later than four years after enactment. The act authorizes such sums as necessary to conduct the study. Additional reporting requirements in this section are outlined in Table A-2.

Amends Section 101 to extend annual reporting requirements for the GAC and for the Inspectors General of the U.S. Agency for International Development (USAID), Department of Health and Human Services (HHS), and State through FY2018. The amended section also extends reporting requirements for the GAC on treatment costs through FY2019. The amended section also requires annual reports by the GAC to detail spending by the Global Fund and national partners.

Section 102: Global AIDS Coordinator. Amends section I of the State Department Basic Authorities Act of 1956 (State Department Act) by establishing the position of the GAC within the Department of State who is responsible for oversight and coordination of all U.S. global HIV/AIDS resources. The section also establishes a separate account, known as the "Activities to Combat HIV/AIDS Globally Fund," to be administered by the GAC. The act directs all of the authorized funds (\$15 billion) to be deposited into the account, except the amount appropriated for the Global Fund.

Section 102: Global AIDS Coordinator. Amends section 1(f)(2) of the State Department Act by establishing an interagency working group on HIV/AIDS headed by the GAC, in conjunction with the Department of Health and Human Services (HHS) and USAID, to review progress in partnering countries and share in the coordination and execution of participating country programs. The section also makes Vietnam a focus country of PEPFAR.

Permanent authority. Did not amend.

Section 103: Country Level Coordination. Amends section 102 of the Leadership Act by calling for country level coordinators to head country specific HIV/AIDS programs for the United States mission in an effort to maintain oversight and implementation.

Permanent authority. Did not amend.

Section 201: Public-Private Partnerships.Promotes the sustainment and advancement of public-private partnership as a priority element of the five-yea

private partnership as a priority element of the five-year HIV/AIDS strategy and calls for a systematic tracking of these partnerships.

Section 202: Global Fund. Authorizes U.S. participation in the Global Fund and includes several reporting requirements (see **Table A-2**). Up to \$1 billion is authorized in support of the Fund for FY2004

Section 201: International Vaccine Funds. Amends section 302 of the Foreign Assistance Act of 1961 (FAA) by authorizing appropriations for tuberculosis vaccine development programs, including Aeras Global TB Vaccine Foundation, from FY2009 through FY2013.

Section 202: Global Fund. Amends section 202(a) of the Leadership Act by identifying the Global Fund as the international AIDS trust fund, as specified in the Global AIDS and Tuberculosis Relief Act of 2000.^a The section

Expires at the end of FY2013. Did not amend.

Extends funding authority through FY2018, including withholding

Leadership Act

Lantos-Hyde Act

PEPFAR Stewardship and Oversight Act

and such sums as necessary through FY2008. The section limits U.S. contributions to the Fund from exceeding 33% of all contributions and describes several withholding requirements, including those under circumstances of:

- supporting terrorism;
- excessive overhead expenditures; and
- exorbitant salaries.

The section requires the GAC to establish an interagency technical review panel to review Global Fund grant proposals.

Section 203: International Vaccine Funds. Amends section 302 of the FAA by authorizing such sums as necessary from FY2004 through FY2008 for several vaccine initiatives, including the Vaccine Fund, the International AIDS Vaccine Initiative, and the Malaria Vaccine Initiative.

also calls on the Global Fund to establish and maintain a system to strengthen oversight capacity, including tracking sub-recipient spending, among other things. Section 202 encourages national authorities to exempt products financed by Global Fund grants from duties and taxes; and discourages the Global Fund from supporting the Affordable Medicines Facility-Malaria pending evaluation. The section amends section 202(d)(1)(A) of the Leadership Act to authorize up to \$2 billion for the Fund in FY2009, and such sums as necessary through FY2013. The section permits U.S. contributions, which may have been previously withheld to be spent in Sudan and Southern Sudan, pending a waiver from the President.

Section 203: Microbicides and AIDS Prevention Research. Amends subpart I of part D of title XXIII of the Public Health Service Act by authorizing such sums as necessary from FY2009 through FY2013 in support of advancing research on microbicides and directs several agencies to expedite related research efforts.

Section 204: Health Policies and Health Systems. Amends Title II of the Leadership Act by authorizing such sums as necessary from FY2009 through FY2013 to support activities that strengthen health systems, as well as HIV/AIDS, TB, and malaria policies of partner countries.

Section 205: Research. Amends section 307 of the Public Health Service Act by permitting the Secretary of HHS to engage in biomedical research and other endeavors to strengthen research capacity in other countries.

Section 206: Vaccine Development. Authorizes the USAID Administrator to provide technical assistance for developing countries to produce vaccines and requires the United States to participate in negotiations for advance market commitments for the development of future vaccines. The section includes reporting requirements on these activities (see **Table A-2**).

Section 301: HIV/AIDS Assistance. Amends section 104A of the FAA by authorizing the appropriation of funds to be used from FY2009 through FY2013 for HIV/AIDS prevention, treatment, and related activities worldwide. The section also establishes a set of program targets for U.S.-supported HIV/AIDS programs (see "Performance Targets/Strategy"); prioritizes country ownership through the development of compacts and framework agreements,b among other things; and expands U.S. global HIV/AIDS program objectives. Among program objectives is a requirement that the GAC and USAID provide food and nutritional support as a component of HIV/AIDS care; and to adhere to the World Health Organization's (WHO) guidelines for HIV/AIDS food and nutrition services. The act includes several reporting requirements, including those related to partnership frameworks and gender-based programs (see Table A-2).

requirements. The bills also include some language that expands withholding requirements.

Expires at the end of FY2013. Did not amend.

Expires at the end of FY2013. Did not amend.

Permanent authority. Did not amend.

Technical assistance directives are permanent; reporting requirements have expired.

Authorization for financial support expires at the end of FY2013. Some reporting requirements expire after a specific time period, others are permanent. Replaces reporting requirements with more expansive reporting requirements.

Section 301: HIV/AIDS Assistance. Amends section 104 of the FAA (becomes section 104A of the FAA) by authorizing appropriations from FY2004 through FY2008 for HIV/AIDS prevention, treatment, and related activities worldwide; and directs the integration of nutritional support within those efforts. No later than January 31 of each year, the President shall submit a report to Congress on program implementation (see Table A-2). Includes several withholding requirements, including:

- no more than 7% of associated funds may be used for administrative functions at USAID;
- no funds may be used to promote or advocate the legalization or practice of prostitution or sex trafficking;
- no funds may be used to support any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking (known

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as "the prostitution pledge").

Section 302: TB Assistance. Amends section 104A of the FAA (becomes section 104B of the FAA) by authorizing such sums as necessary from FY2004 through FY2008 for TB prevention, treatment, control and elimination. The section also includes directives on policy, coordination, and program targets.

Section 303: Malaria Assistance. Amends section 104B of the FAA (becomes section 104C of the FAA) by authorizing appropriations from FY2004 through FY2008 for the prevention, treatment, control and elimination of malaria, including support for the Medicines for Malaria Venture.

Section 304: U.S. Medical Professional Pilot Program. Authorizes such sums as necessary through FY2008 for the establishment of a pilot program to send U.S. health care professionals to sub-Saharan Africa and other parts of the world severely affected by HIV/AIDS, tuberculosis and malaria. Not later than 18 months after enactment of this act, the President is directed to submit a report on progress towards implementing the pilot project.

Section 305: Report on HIV/AIDS Treatment. Not later than 15 months after enactment of this act, the President shall submit a report to Congress on HIV/AIDS treatment activities of U.S. implementing agencies.

Section 306: Injection Safety. Amends section 307 of the Public Health Service Act by requiring the Director of the Centers for Disease Control and Prevention (CDC), in coordination with other U.S. Agencies and organizations, to develop and implement strategies to improve injection safety.

Section 307: Report on Misuse of Donated Prescription Drugs. Requires the Secretary of HHS to submit a report to Congress no later than 180 days after enactment of this act that includes an accounting of illegal diversion of prescription drugs donated or sold for humanitarian efforts and recommendations for improving enforcement mechanisms that curb such practices.

Section 302: TB Assistance. Amends section 104B of the FAA by authorizing \$4 billion from FY2009 through FY2013 for TB prevention, treatment, control and elimination. In addition to requirements associated with enhancing TB policy and improving coordination of U.S. and global resources, the section directs the President to establish a five-year strategy to combat TB and achieve program targets, see "Performance Targets/Strategy." The section also includes reporting requirements (see Table A-2).

Section 303: Malaria Assistance. Amends section 104C of the FAA by authorizing \$5 billion from FY2009 through FY2013 for the prevention, control, and elimination of malaria; and directs the President to develop a five-year strategy for combating malaria globally.

Section 304: Global Malaria Coordinator. Amends the Section 304 of the Leadership Act by establishing the Global Malaria Coordinator at USAID to oversee and coordinate all U.S. global malaria resources. The section also includes reporting requirements (see **Table A-2**).

Section 305: Amendment to Immigration and Nationality Act. Amends section 212(a)(1)(A)(i) of the Immigration and Nationality Act by striking HIV/AIDS as a health-related ground for making an individual ineligible to receive a visa or be admitted into the United States.

Section 306: Clerical Amendment. Clerical amendment to rename Title III of the Leadership Act.

Section 307: Prevention of Mother to Child Transmission (PMTCT) of HIV and Vulnerable Children. Amends section 312(b) of the Leadership Act by establishing targets for the treatment and prevention of HIV from mother to child (PMTCT) within the five-year HIV/AIDS strategy. Other elements to be included in the strategy include:

- targets for making care and treatment of children affected by HIV/AIDS proportionate to their population size;
- a timeline for expanding access to PMTCT; and
- plans for expanding programs aimed at caring for children orphaned or made vulnerable by HIV/AIDS.

Section 308: PMTCT Annual Report. Amends section 313(a) of the Leadership Act by requiring an annual report

Authorization for financial support expires at the end of FY2013. Some reporting requirements expire after a specific time period, others are permanent. Did not amend.

Expires at the end of FY2013. Did not amend.

The Malaria Coordinator position is permanent. Some reporting requirements expire after a specific time period, others are permanent. Did not amend.

Permanent authority. Did not amend.

Permanent authority. Did not amend.

Expires at the end of FY2013. Did not amend.

Expires at the end of FY2013. Did not amend.

Leadership Act	Lantos-Hyde Act	PEPFAR Stewardship and Oversight Act
	on U.S. global PMTCT activities through FY2013.	
	Section 309: PMTCT Expert Panel. Amends section 312 of the Leadership Act by establishing a panel to assess U.S. global PMTCT efforts and recommend strategies for improvement to the GAC.	Expired at the end of FY2011. Did not amend.
Section 311: Findings. Findings of Congress regarding the impact of global HIV/AIDS.		
Section 312: PMTCT and Vulnerable Children. Establishes PMTCT targets to be included in the five-year strategy, as well as programs to expand access to care for children orphaned by AIDS.		Expires at the end of FY2013, as amended by the Lantos-Hyde Act. Did not amend.
Section 313: PMTCT Annual Report. Not later than one year after enactment of this act, and annually thereafter, the President is required to report to Congress on progress towards reaching PMTCT goals.		Expires at the end of FY2013, as amended by the Lantos-Hyde Act. Did not amend.
Section 314: Pilot Program for Children and Families Affected by HIV/AIDS. Authorizes such sums as necessary from FY2004 through FY2008 for the establishment of a program to provide for the care and treatment of orphans and other young people affected by HIV/AIDS in foreign countries. Not later than 18 months after enactment of this act, the President is to submit a report to Congress on program implementation.		Expired at the end of FY2008. Did not amend.
Section 315: Pilot Program on Family Survival Partnerships. Authorizes such sums as necessary from FY2004 through FY2008 for the establishment of a public-private partnership program for the provision of medical care and support services to HIV positive parents and their children through existing PMTCT programs. Each grantee shall report an annual report on program implementation. Not more than 7% of the grant amount can be used for administrative expenses.		Expired at the end of FY2008. Did not amend.
Section 401: Authorization of Appropriations. Authorizes \$3 billion per fiscal year from FY2004 through FY2008 for implementation of this Act.	Section 401: Authorization of Appropriations. Amends section 401(a) of the Leadership Act by authorizing \$48 billion for implementation of this act from FY2008 through FY2013.	Expires at the end of FY2013. Did not amend.
Section 402: HIV/AIDS Treatment. Sense of Congress establishing treatment targets and outlining allocation of funds among HIV/AIDS programs aimed at care, treatment, and prevention, as well as supporting orphans and vulnerable children.	Section 402: Clerical Amendment. Amends section 402(b) of the Leadership Act to make a clerical amendment regarding the spending target for orphans and vulnerable children.	Permanent authority. Did not amend.
Section 403: Allocation of Funds. Directs how funds for HIV/AIDS treatment are to be allocated and directs that at least 10% of funds appropriated from FY2006 through FY2008 are spent on care for children orphaned or made vulnerable by HIV/AIDS.	Section 403: Allocation of Funds. Amends section 403 of the Leadership Acct by directing the GAC to establish an HIV sexual transmission prevention strategy. The section also requires the GAC to submit a report annually from FY2010 through FY2013 on implementation of the prevention strategy, including an explanation of any deviation from prevention funding targets (see Table A-2). The section directs how HIV/AIDS funds are to be apportioned and establishes HIV/AIDS treatment, prevention, and care goals.	Extends authorities through FY2018 that require not less than 10% of U.S. global HIV/AIDS assistance funds be expended for OVC and more than half of all bilateral HIV/AIDS funds be expended for care and treatment.

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Section 404: Private Sector HIV/AIDS Support.

Sense of Congress that encourages U.S. businesses to assist sub-Saharan African countries to prevent and reduce HIV/AIDS infections.

Source: Created by CRS from the Leadership and Lantos-Hyde Acts.

Notes: This table does not describe language in the acts that is unrelated to global HIV/AIDS, TB, and malaria programs. These include sections 501 through 503 of the Leadership Act and sections 501 and 601 of the Lantos-Hyde Act.

- a. P.L. 106-264, the Global AIDS and Tuberculosis Relief Act of 2000 (Global AIDS Act) authorized the establishment of a "World Bank AIDS Trust Fund." The act also authorized \$150 million to be appropriated to the trust fund in each of FY2001 and FY2002. Section 202(a) of the Leadership Act, as amended, recognizes the Global Fund to Fight AIDS, Tuberculosis, and Malaria (established in January 2002) as the trust fund referred to in the Global AIDS Act.
- b. For more information on partnership frameworks, see CRS Report R42776, The President's Emergency Plan for AIDS Relief (PEPFAR): Funding Issues After a Decade of Implementation, FY2004-FY2013, by (name redacted).

The Leadership Act, as amended, Lantos-Hyde Act, and Foreign Assistance Act as amended, include several reporting requirements. The tables below list each requirement by section. The status column provides an interpretation of the extent to which the requirements have been addressed in formal reporting documents. "/" means some elements of the reporting requirement were included in the report, but not all. "\(\mathbb{T}\)" means all elements of the reporting requirement were included in the report. "x" means no elements of the reporting requirement were included in the report. The Administration may have submitted reports to Congress that adhered to reporting requirements but not made them publically available. "?" indicates that the report was not available on an executive agency website, but may have been made available elsewhere. This review of compliance is described chronologically and is limited to the reports indicated within the table notes.

Table A-2. Compliance with Reporting Requirements: Leadership Act, as Amended

Leadership Act, as Amended	Status of Compliance
Section 101 requires the Global AIDS Coordinator (GAC) to publish annual studies that estimates the per-patient cost of antiretroviral HIV/AIDS treatment (ART) across categories of service providers.	1
Section 101(b) requires the President to submit a report no later than October 1, 2009, which includes: ^a	
Purpose, scope, methodology and objectives of the strategy.	1
Problems, risks and threats to the successful pursuit of the strategy.	V
Desired goals, objectives, activities and outcome-related performance measures of the strategy.	Ī
Description of future costs and resources needed to carry out the strategy.	х
Delineation of U.S. government roles, responsibility and coordination mechanisms of the strategy.	X
Description of the strategy.	✓
Description of how the strategy will seek to achieve program targets.	\square
Description of, and rationale for annual global treatment targets.	x
Description of how operations research is addressed and how it can be integrated into care, treatment and prevention activities.	✓
Analysis of U.Sassisted strategies to prevent the transmission of HIV/AIDS.	✓
Description of efforts to assist partner countries and communities in identifying social, economic and cultural factors we contribute to the transmission of HIV.	rhich X
Description of specific targets, goals and strategies developed to address the needs and vulnerabilities of women and gire HIV/AIDS.	rls to X
Description of strategies to address male norms which contribute to the transmission of HIV.	x
Description of strategies to address the needs of orphans and vulnerable children.	x
Description of the strategy to strengthen health capacity in the public sector and help countries to develop and implem national health workforce strategies.	ent /
Description of criteria for selection, objectives, methodology and structure of compacts.	X
Strategy to better coordinate HIV/AIDS assistance with nutrition and food assistance programs.	x
Description of transnational or regional initiatives to combat regionalized epidemics in highly affected areas.	x
Description of planned resource distribution and global investment by region.	x
Description of coordination efforts to better implement the Stop TB strategy.	x
Description of coordination efforts to address malaria and comorbidity with malaria and HIV/AIDS.	X
Section 101(c) requires the GAC to enter into contract with IOM no later than 18 months after enactment of the Lantos- the GAC with a design plan and budget for the evaluation and collection of baseline and subsequent data to assess the global HIV/AIDS programs. Not later than four years after enactment of the Lantos-Hyde Act, the IOM is to publish a	performance of U.S.
Assessment of the performance of U.Sassisted global HIV/AIDS programs.	✓
 Evaluation of the impact on health of prevention, treatment, and care efforts that are supported by U.S. funding, including multilateral and bilateral programs involving joint operations.^c 	х
Assessment of progress toward prevention, treatment, and care targets.	✓

Leadership Act, as Amended	Status of Compliance
 Assessment of the effects on health systems, including on the financing and management of health systems and the quality of service delivery and staffing. 	✓
 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. 	✓
 Evaluation of the impact of treatment and care programs on five-year survival rates, drug adherence, and the emergence of drug resistance.^d 	x
Evaluation of the impact of prevention programs on HIV incidence in relevant population groups. ^e	Х
Evaluation of the impact on child health and welfare of interventions for orphans and vulnerable children (OVC).f	1
Evaluation of the impact of programs and activities on child mortality. ^g	1
Recommendations for improving U.S. global HIV/AIDS programs.	✓
Section 101(d) requires the Comptroller General to publish a report no later than three years after the enactment of the Lantos includes:	-Hyde Act that
 Description and assessment of the monitoring and evaluation practices and policies in place for U.S. global HIV/AIDS programs.^h 	✓
Assessment of coordination within federal agencies involved in implementation.	✓
Assessment of procurement policies and practices.	1
 Assessment of harmonization with national government HIV/AIDS and public health strategies as well as other global efforts.^k 	V
Assessment of the impact of global HIV/AIDS funding and programs on other U.S. global health programs.	Х
Recommendation for improving U.S. global HIV/AIDS programs.	1
Section 101(e) requires the GAC to publish a best practices report, no later than one year after the date of enactment and annually thereafter, that highlights the programs receiving financial assistance from the United States that have potential for replication or adaptation, particularly at a low cost, across the global AIDS programs, including those that focus on both generalized and localized epidemics.	x
Section 101(f) requires the Inspectors General of the Department of State and Broadcasting Board of Governors, the Department of Health and Human Services (HHS), and the U.S. Agency for International Development (USAID) to jointly develop five coordinated annual plans for oversight activity in each of FY2009 through FY2013 that include a schedule for financial audits, inspections, and performance reviews. ^m	Ø
 Section 101(g)(1) requires the GAC to complete a study of treatment providers no later than September 30, 2009, and annually thereafter that: represents a range of countries and service environments; estimates the per-patient cost of antiretroviral HIV/AIDS treatment and the care of people with HIV/AIDS not receiving antiretroviral treatment, including a comparison of the costs for equivalent services provided by programs not receiving assistance under this Act; estimates per-patient costs across the program and in specific categories of service providers, including urban and rural providers, country-specific providers and other subcategories, as appropriate.ⁿ 	1
Section 101(g)(2) requires the GAC to make the results of such study available on a publicly accessible website no later than 90 days after the completion of each study.	V
Section 202(c) requires the President to submit to Congress not later than one year after enactment of the Leadership Act and annually thereafter a report on the Global Fund that includes contributions pledged to the Global Fund, contributions (including donations from the private sector) received by, and projects funded by the Global Fund, and the mechanisms established for transparency and accountability in the grant making process.º	Ø
Section 202(c)(6) requires the GAC to publish a report on the OGAC website following each meeting of the Global Fund Board, a summary of Board decisions and how the U.S. government voted and its positions on such decisions.	✓

Leadership Act, as Amended	Status of Compliance
Section 202(f)(2) requires the Comptroller General to prepare and submit to the appropriate congressional committees a report biennially that contains the results of the monitoring and evaluation of Global Fund projects.	\checkmark
Section 206(a)(4)(A) requires the Secretary of the Treasury to submit a report to Congress no later than one year enactment of the Lantos-Hyde Act on the status of U.S. negotiations to participate in advanced market commitments for vaccines.	?
Section 206(a)(4)(B) requires the President to produce a comprehensive report, written by a study group of qualified professionals from relevant federal agencies and initiatives, NGOs, and industry representatives, that sets forth a coordinated strategy to accelerate development of vaccines for infectious diseases, such as HIV/AIDS, malaria, and TB, which includes:	
 initiatives to create economic incentives for the research, development, and manufacturing of vaccines for HIV/AIDS, TB, malaria, and other infectious diseases; 	✓
• an expansion of public-private partnerships and leveraging of resources from other countries and the private sector; and	
 efforts to maximize U.S. capabilities to support clinical trials of vaccines in developing countries and to address the challenges of delivering vaccines in developing countries to minimize delays in access once vaccines are available. 	
Section 304(h) requires the President to submit, no later than one year after the enactment of this Act and annually thereafter, describing U.S. assistance for prevention, treatment, control and elimination of malaria, which:	a report
Details the countries and activities to which malaria resources have been allocated.	✓
Describes the number of people reached through malaria assistance programs.	>
Details research efforts to develop new tools to combat malaria.	✓
Highlights collaboration and coordination of U.S. antimalarial efforts with the WHO, the Global Fund, the World Bank, and other donor government and private efforts.	✓
Outlines coordination of U.S. antimalarial efforts with the national malarial strategies or other donor or partner government and major private initiatives.	✓
Provides estimated impact of U.S. assistance on childhood mortality and morbidity from malaria.	V
Outlines coordination of antimalarial efforts with broader health and development programs.	✓
Describes constraints on implementation of programs posed by health workforce shortages or capacities. ^t	1
Provides number of personnel trained as health workers and the training levels achieved.	✓
Section 305 requires the President to submit a report to Congress not later than 15 months after enactment of the Leadership A programs and activities of implementing executive agencies that are directed to treat individuals in foreign countries infected living with AIDS. The report is to include:	
A description of the activities of relevant executive branch agencies with respect to:	?
the treatment of opportunistic infections	?
the use of antiretrovirals;	?
the status of research into successful treatment protocols for individuals in the developing world;	?
 technical assistance and training of local health care workers (in countries affected by the pandemic) to administer antiretrovirials, manage side effects, and monitor patients' viral loads and immune status; 	?
 the status of strategies to promote sustainability of HIV/AIDS pharmaceuticals (including antiretrovirals) and the effects of drug resistance on HIV/AIDS patients; and 	?
 the status of appropriate law enforcement officials working to ensure that HIV/AIDS pharmaceutical treatment is not diminished through illegal counterfeiting and black market sales of such pharmaceuticals. 	?
Information on existing pilot projects, including a discussion of why a given population was selected, the number of	?

Leadership Act, as Amended	Status of Compliance
people treated, the cost of treatment, the mechanisms established to ensure that treatment is being administered effectively and safely, and plans for scaling up pilot projects (including projected timelines and required resources).	
An explanation of how those activities relate to efforts to prevent the transmission of HIV infection.	?
Section 307 requires the Secretary of Health and Human Services to submit a report to Congress not later than 180 days after e Leadership Act that includes:	nactment of the
• A thorough accounting of evidence indicating illegal diversion into the United States of prescription drugs donated or sold for humanitarian efforts, and an estimate of the extent of such diversion.	?
 Recommendations to increase the administrative and enforcement powers of the United States to identify, monitor, and prevent the illegal diversion into the United States of prescription drugs donated or sold for humanitarian efforts. 	?
 Recommendations and guidelines to advise and provide technical assistance to developing countries on how to implement a program that minimizes diversion into the United States of prescription drugs donated or sold for humanitarian efforts. 	?
Section 312(c)(4) requires the GAC to establish a panel to review PMTCT activities, recommend strategies for expanding the program, and submit a report detailing its findings to Congress.	Ø
Section 313(a) requires an annual report on U.S. PMTCT programs through FY2013.The report is to include:w	1
a statement of whether all implementing agencies have met PMTCT goals.	х
a description of efforts to expand PMTCT activities, particularly:	
information on the number of sites supporting PMTCT activities;	X
the specific activities supported;	Х
the number of women tested and counseled; and	✓
the number of women receiving preventative drug therapies.	✓
Section 314 requires the President to submit a report to Congress not later than 18 months after enactment of the Leadership Act on the implementation of a pilot program of assistance that would demonstrate the feasibility of providing care and treatment to orphans and other children and young people affected by HIV/AIDS in foreign countries. The report is to include a description of activities undertaken to ensure the importance to inheritance rights of women.	?
Section 403 requires the President to submit a report no later than one year after enactment of this act, and annually thereafter, implementation of the U.S. prevention strategy.*	on the
 Outlines various spending requirements, including providing balanced funding for prevention activities for sexual transmission of HIV/AIDS, and promoting abstinence, delayed sexual debut, monogamy, fidelity and partner reduction. 	1
 Requires notification to Congress from host countries if the prevention strategies established provide less than 50 percent of allocated funds for previously outlined prevention activities. 	?
Specifies that more than half of funds appropriated during each of fiscal years 2009-2013 be expended for: antiretroviral treatment, clinical monitoring of HIV-seropositive people not needing antiretroviral treatment, care for opportunistic infections, nutrition and food support for people living with HIV/AIDS, and other essential HIV/AIDS related medical care.	?

Source: Created by CRS from several sources, as listed in the table notes below.

Notes: This review of compliance is limited to the reports indicated within the table notes. The Administration may have published additional information addressing aspects of the reporting requirements in other sources, such as press releases, public statements, and other mechanisms; or it may have sent supporting documentation directly to Congress. The Administration may also have released information responding to reporting requirements after the deadline for compliance passed. In the case of the five-year strategy, for example, the Administration released several documents following the publication of the five-year strategy that responded to some of the reporting requirements. A gender strategy, for instance, was released in March 2013, entitled *PEPFAR: Addressing Gender and HIV/AIDS*. Since the gender strategy was not included in the five-year strategy report, as mandated by the Lantos-Hyde Act, this review indicates that the Administration is not fully in compliance with gender-related reporting requirements. If a deadline was not specified in the Lantos-

Hyde Act, the date of submission was not considered a factor in determining compliance. This review includes, the OGAC document entitled, *PEPFAR Blueprint: Creating an AIDS-Free Generation*, which was published in November 2012 and offers many of the details lacking in the 2009 five-year strategy report, including a strategy for reaching vulnerable groups such as orphans, women, and children.

- a. Office of the Global AIDS Coordinator (OGAC), The U.S. President's Emergency Plan for AIDS Relief Five Year Strategy, 2009.
- b. The IOM released the report entitled, *Evaluation of PEPFAR* in 2013. The report followed another IOM report, which was written in adherence to language in the Leadership Act requiring the IOM to assess PEPFAR. The first report, released in 2007, was entitled *PEPFAR Implementation: Progress and Promise*.
- c. Throughout the IOM report, Evaluation of PEPFAR, the authors indicated that incomplete and inconsistent data collection practices inhibited efforts to evaluate the impact of PEPFAR programs on the HIV/AIDS epidemic. For example, on p. 5-16, the authors wrote, "... there is not clarity in the global community on how to routinely track their implementation and effects, especially for structural interventions, behavior change, and combination prevention."
- d. Ibid. The authors noted that limited data inhibited efforts to evaluate the impact of treatment and care programs on drug adherence and drug resistance. On p. 6-48, for example, the researchers indicated, "Although retention of patients in care, as well as patient adherence to anti-retroviral therapy (ART), is considered essential to successful treatment, the centrally reported indicators made available to the committee did not include any data that could serve to assess it over time across PEPFAR country programs." Regarding treatment failure, the authors reported on p. 6-54 that "interviewees expressed concerns about treatment failure that included a need to understand it not only because they were unaware of the proportion of people taking anti-retrovirals (ARVs) who were failing treatment; but also because they were concerned about consequences of interrupted drug treatment regimens that in some countries were due to stock-outs ... and general concerns regarding strategies and a lack of tools to diagnose treatment failure and low treatment failure detection rates for both adults and children." The IOM report also indicated that PEPFAR countries had varying degrees of access to ARV drug resistance testing resources (p. 6-55). Similarly, the IOM committee noted an inability to assess the impact of PEPFAR programs on five-year mortality, although many interviewees indicated that lives were being saved through PEPFAR HIV care and treatment programs. On p. 6-56, the committee reported that "in general for ART programs, data on five-year survival rates is very limited in any setting and for any population, and it is not available across PEPFAR countries and programs."
- e. Ibid. The authors made similar comments regarding particular vulnerable groups. When discussing prevention programs aimed at sex workers, for example, the authors wrote on p. 5-21, "... it is difficult to determine whether their HIV prevention, treatment, and care needs are being adequately covered ..."
- f. Ibid. Although the committee noted on p. 7-11 that "PEPFAR has few centrally reported indicators to reflect the performance of PEPFAR's OVC programs," the section of the report that focused on OVC also included an extensive discussion on the role PEPFAR has played in "elevat[ing] attention to and investments in meeting the needs of OVC (see pp. 7-13 through 7-26).
- g. Ibid. Data limitations inhibited the ability of the committee to conclusively determine the impact of PEPFAR on child mortality, although it noted other longitudinal studies that found downward trends in child mortality rates in countries that had PEPFAR programs (p. 7-25).
- h. Government Accountability Office (GAO), Program Planning and Reporting, July 2011; President's Emergency Plan for AIDS Relief:
 Agencies Can Enhance Evaluation Quality, Planning, and Dissemination, May 2012, GAO, Shift Toward Partner-Country Treatment
 Programs will Require Better Information on Results, April 2013, and GAO, Strategies to Facilitate Agencies' Use of Evaluation in Program
 Management and Policy Making, June 2013.
- i. GAO, Partner Selection and Oversight Follow Accepted Practices but Would Benefit from Enhanced Planning and Accountability, July 2009.
- j. Several GAO reports analyze PEPFAR spending on treatments. While these studies do not evaluate procurement policies overall, they do assess an element of PEFPAR procurement policies and practices. See U.S. AIDS Coordinator Addressing Some Key Challenges to Expanding Treatment but Others Remain, July 2004; A More Country-Based Approach Could Improve Allocation of PEPFAR Funding, April 2008; Per-Patient Costs Have Declined Substantially, but Better Cost Data Would Help Efforts to Expand Treatment, March 2013; and Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks, April 2013;
- k. GAO, Efforts to Align Programs with Partner Countries' HIV/AIDS Strategies and Promote Partner Country Ownership, September 2010.
- I. Nearly all GAO reports include a set of recommendations, though GAO did not release a single report that offered recommendations for improving U.S. global HIV/AIDS programs.
- m. The annual reports can be found on the USAID Office of the Inspector General website at http://oig.usaid.gov/sites/default/files/other-reports/.
- n. The GAC releases reports on HIV/AIDS treatments costs each year, though they do not provide all of the details required by the Leadership Act, as amended. The latest report was released on February 2012.

- o. OGAC maintains a webpage on the Global Fund that makes available reports on a variety of topics, including U.S. participation on the Global Fund Board, Global Fund reforms, and the required annual reports on the Fund. See http://www.pepfar.gov/partnerships/coop/globalfund/reports/index.htm.
- p. OGAC maintains a webpage that documents U.S. participation in Global Fund Board meetings, see http://www.pepfar.gov/partnerships/coop/globalfund/board/index.htm. The latest report was released in June 2013.
- q. See table note h.
- r. See U.S. Government, Report to Congress: Coordinated Strategy to Accelerate Development of Vaccines for Infectious Diseases, October 2009, http://pdf.usaid.gov/pdf_docs/PDACN525.pdf.
- s. The latest interagency annual report on U.S. global malaria programs is entitled, *The President's Malaria Initiative*: Seventh Annual Report to Congress, and was released in April 2013.
- t. The latest annual report on malaria includes discussions about plans to strengthen health worker capacity but does not assess the impact of health worker constraints on program implementation.
- u. CRS did not find a report that fit these criteria on any executive agency website, although OGAC regularly reports on the perpatient cost of HIV/AIDS treatments. See http://www.pepfar.gov/reports/progress/index.htm.
- v. Expert Panel on the Prevention of Mother-To-Child Transmission of HIV, Prevention of Mother-to-Child Transmission of HIV: Expert Panel Report and Recommendations to the U.S. Congress and U.S. Global AIDS Coordinator, January 2010.
- w. OGAC, PEPFAR Annual Report: 9th Annual Report to Congress, 2013.
- x. The 2013 PEPFAR annual report does not provide the prevention details required by the Lantos-Hyde Act. Three other reports released by OGAC describe U.S. global prevention activities and the U.S. sexual transmission prevention strategy. These are: The PEPFAR Blueprint Report to Congress (November 2012), Guidance for the Prevention of Sexually Transmitted HIV Infections (August 2011), and Report to Congress by the U.S. Global AIDS Coordinator on Prevention (June 2010).

Table A-3. Compliance with Reporting Requirements: Lantos-Hyde Act

rusie / t / compilation with reporting requirements = united 1 / ue / tec		
Lantos-Hyde Act	Status of Compliance	
Section 206 requires the Secretary of the Treasury to submit a report, no later than one year after enactment of the Lantos-Hydrostatus of U.S. participation in advanced market commitments programs. Also requires the President to submit a report that s coordinated government strategy for vaccine development. This report shall set forth the following: ^a		
 Initiatives to create economic incentives for the research, development, and manufacturing of vaccines for HIV/AIDS, tuberculosis, malaria and other diseases. 	✓	
Expansion of public-private partnerships and the leveraging of resources from other countries and the private sector.	✓	
• Efforts to maximize United States capabilities to support clinical trials of vaccines in developing countries and to address the challenges of delivering vaccines in developing countries to minimize delays in access once vaccines are available.	✓	

Source: Created by CRS from several sources, as listed in the table notes below.

Notes: This review of compliance is limited to the reports indicated within the table notes. The Administration may have published additional information addressing aspects of the reporting requirements in other sources, such as press releases, public statements, and other mechanisms; or it may have sent supporting documentation directly to Congress. The Administration may also have released information responding to reporting requirements after the deadline for compliance passed. In the case of the five-year strategy, for example, the Administration released several documents following the publication of the five-year strategy that responded to some of the reporting requirements. A gender strategy, for instance, was released in March 2013, entitled *PEPFAR: Addressing Gender and HIV/AIDS*. Since the gender strategy was not included in the five-year strategy report, as mandated by the Lantos-Hyde Act, this review indicates that the Administration is not fully in compliance with gender-related reporting requirements. If a deadline was not specified in the Lantos-Hyde Act, the date of submission was not considered a factor in determining compliance. This review includes, the OGAC document entitled, *PEPFAR Blueprint: Creating an AIDS-Free Generation*, which was published in November 2012 and offers many of the details lacking in the 2009 five-year strategy report, including a strategy for reaching vulnerable groups such as orphans, women, and children.

a. U.S. Interagency Document, Report to Congress: Coordinated Strategy to Accelerate Development of Vaccines for Infectious Diseases, October 2009.

Table A-4. Compliance with Reporting Requirements: Foreign Assistance Act, as Amended

Foreign Assistance Act, as Amended	Status of Compliance
Section 104A(e)(4) requires the GAC to submit a report to Congress not later than 10 days after entering into a compact with a recipient country that contains a detailed summary of the compact and a copy of the text of the compact.	?
Section 104(A)(f) requires the President to submit annual reports not later than January 31 of each year that include:a	1
A detailed breakdown of funding allocations, by program and by country, for prevention activities.	х
A detailed assessment of the impact of HIV/AIDS programs, particularly on disease transmission, including mother-to-child transmission, and HIV/AIDS mortality rates.	x
The number of patients receiving treatment for AIDS in each country that receives assistance under this Act. ^b	✓
An assessment of progress towards the achievement of annual goals set forth in the timetable required under the five-year strategy including: -retention and attrition data for programs receiving U.S. assistance; -progress made toward improving health care delivery systems; -advancing safe working conditions for health care workers; and -improving infrastructure to promote progress toward universal access to HIV prevention, treatment, and care.	x
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 U.S. health and development agenda.	1
A description of integrated HIV/AIDS and food and nutrition programs and services.d	1
A description of efforts to improve coordination with partner countries' national strategic plans.e	1
A description of efforts of partner countries that were signatories to Abuja Declaration on HIV/AIDS and non-signatory partner countries.	1
Description of any compacts or framework agreements reached between the United States and partner countries.8	1
Description of programs serving women and girls.h	1
Description of strategies, goals, programs and interventions to address the needs of vulnerable populations, expand access to HIV/AIDS health care services and prevention programs, expand a community based services to meet the needs of orphans and children affected by HIV/AIDS.	1
Description of specific strategies funded to ensure the reduction of HIV infection among injection drug users by country.	x
Description of program monitoring, operations research and impact evaluation research.	х
Description of efforts to build host country capacity to identify, investigate and stop transmission of HIV and TB.	✓
Description of staffing levels of U.S. government HIV/AIDS teams in countries with significant HIV/AIDS programs.	1
Section 104B(g) requires the President to submit a report annually that describes the impact of U.S. global TB programs, includi	ng:
The number of TB cases diagnosed and the number of cases cured in countries receiving U.S. foreign assistance.	х
A description of TB activities supported with U.S. resources in each country.k	1
The percentage of assistance provided for direct TB services in each country receiving bilateral U.S. foreign assistance.	х
A description of research efforts and clinical trials to develop new tools to combat TB.	1
The number of persons diagnosed and receiving treatment for multidrug resistant TB in countries receiving U.S. bilateral foreign assistance.	x
A description of the collaborations and coordination of U.S. anti-TB effort with the WHO, the Global Fund and other public and private entities within the Stop TB Strategy. ^m	1

Foreign Assistance Act, as Amended	Status of Compliance
Constraints on the implementation of programs posed by health workforce shortages and capacities.	х
The number of people trained in TB control. ⁿ	1
A breakdown of expenditures for direct patient TB services, drugs, drug management, training in diagnosis and treatment, health systems strengthening, and research.	x

Sources: Created by CRS from several sources, as listed in the table notes below.

Note: This review of compliance is limited to the reports indicated within the table notes. The Administration may have published additional information addressing aspects of the reporting requirements in other sources, such as press releases, public statements, and other mechanisms; or it may have sent supporting documentation directly to Congress. The Administration may also have released information responding to reporting requirements after the deadline for compliance passed. In the case of the five-year strategy, for example, the Administration released several documents following the publication of the five-year strategy that responded to some of the reporting requirements. A gender strategy, for instance, was released in March 2013, entitled *PEPFAR: Addressing Gender and HIV/AIDS*. Since the gender strategy was not included in the five-year strategy report, as mandated by the Lantos-Hyde Act, this review indicates that the Administration is not fully in compliance with gender-related reporting requirements. If a deadline was not specified in the Lantos-Hyde Act, the date of submission was not considered a factor in determining compliance. This review includes, the OGAC document entitled, *PEPFAR Blueprint: Creating an AIDS-Free Generation*, which was published in November 2012 and offers many of the details lacking in the 2009 five-year strategy report, including a strategy for reaching vulnerable groups such as orphans, women, and children.

- a. The 2013 PEPFAR annual report to Congress is seven pages long and does not comply with most of these reporting requirements. OGAC has, however, published several reports that respond to the reporting authorities, though they are not always published annually. Publications that provide information, as required by law, but not included in the 2013 annual report to Congress are listed in the table notes below. A "/" indicates that the information is available, but is not included in the 2013 annual report to Congress.
- b. OGAC, PEPFAR Annual Report: 9th Annual Report to Congress, 2013.
- c. A report published by OGAC in November 2012 entitled, PEPFAR Blueprint: Creating an AIDS-Free Generation, describes efforts to integrate clinical and social services programs.
- d. Three reports published by OGAC describe efforts to integrate nutritional support into HIV/AIDS programs: Report to Congress by the U.S. Global AIDS Coordinator on Food Security (May 2008), Report on Food and Nutrition for People Living with HIVA/IDS (May 2006), and Report on Refugees and Internally Displaced Persons (February 2006).
- e. The 2013 PEPFAR annual report to Congress includes one paragraph on partnership frameworks, which are aimed at promoting country ownership. Several reports on partnership frameworks and operational plans explain U.S. efforts to advance national HIV/AIDS plans. See http://www.pepfar.gov/countries/index.htm.
- f. The webpage on country reports that include the partnership frameworks and operational plans does not make a distinction between countries that have endorsed the Abuja Declaration and those that have not, though information is available on operations within several recipient countries.
- g. Partnership compacts and frameworks are under development. To date, 22 partnership frameworks have been published. See http://www.pepfar.gov/countries/frameworks/index.htm.
- h. One paragraph in the 2013 PEPFAR annual report to Congress discusses the PEPFAR strategy for girls. A longer report, published by OGAC in March 2013 and entitled, PEPFAR: Addressing Gender and HIV/AIDS, describes this matter further.
- i. Several reports published by OGAC discuss efforts to support vulnerable groups, including PEPFAR: Addressing Gender and HIV/AIDS (March 2013), PEPFAR Blueprint: Creating an AIDS-Free Generation (November 2012), Report on Gender-Based Violence and HIV/AIDS (November 2006), and Focusing on Our Future: Prevention, Diagnosis, and Treatment of Pediatric HIV/AIDS (September 2005).
- j. The report, PEPFAR Blueprint: Creating an AIDS-Free Generation describes U.S. efforts to bolster capacity to address HIV-TB comorbidity.
- k. An U.S. interagency report entitled, U.S. Government Report on International Foreign Assistance in TB FY2010: Leading and Leveraging, includes anecdotal data on several countries worldwide.
- I. Ibid.
- m. Coordination efforts are briefly discussed in the U.S. interagency document entitled, Lantos-Hyde United States Government Tuberculosis Strategy.

An U.S. interagency report entitled, U.S. Government Report on International Foreign Assistance in TB FY2010: Leading and Leveraging, includes anecdotal data on the number of people trained in several countries.

Appendix B. Summary of the PEPFAR Stewardship and Oversight Act

The PEPFAR Stewardship and Oversight Act (H.R. 3177 and S. 1545) extend certain funding authorities and strengthen program oversight. The bills do not authorize multi-year funding levels for bilateral HIV/AIDS, tuberculosis (TB), and malaria assistance overall, though they do authorize support for the Global Fund. The table below distinguishes authorities the bills seek to amend from those that are set to expire. Permanent authorities are not detailed here.

Table B-I. Leadership Act Expiring Authorities and PEPFAR Stewardship and Oversight Act Amendments

O versigne Accommends			
Expiring Authorities of the Leadership Act, as Amended	Amended Authorities of the PEPFAR Stewardship and Oversight Act		
Section 201 of the Leadership Act, as amended: International Vaccines Funds for tuberculosis (TB) vaccine development.	Section 101(f)(1) of the Leadership Act, as amended extends annual reporting requirements for a consortium of Inspectors General representing the U.S. Agency for International Development (USAID), State, and Department of Health and Human Services (HHS) through FY2018.		
Section 203 of the Leadership Act, as amended: Funding authority for microbicides research.	Section 101(g) of the Leadership Act, as amended extends annual reporting requirements for the GAC on treatment and care costs in recipient countries and expands the type of information to be provided through FY2019.		
Section 204 of the Leadership Act, as amended: Funding authority for health system strengthening activities.	Section $202(d)(4)$ of the Leadership Act, as amended: extends funding authority for the Global Fund through FY2018, while expanding withholding authorities (Section $202(d)(5)$).		
Section 206 of the Leadership Act, as amended: Reporting requirements on U.S. vaccine development efforts.	Section 104A(f) of the Foreign Assistance Act, as amended: extends annual reporting requirements for the President on U.S. global HIV/AIDS assistance through FY2018.		
Sections 302 and 304 of the Leadership Act, as amended: reporting requirements for U.S. global TB and malaria efforts, respectively.	Section 403(b) of the Leadership Act, as amended: extends requirement that not less than 10% of funds appropriated for global HIV/AIDS assistance be spent on support for orphans and vulnerable children (OVC) and that more than 50% of those funds be spent on care and treatment efforts.		
Sections 302 and 303 of the Leadership Act, as amended: funding authorities for U.S. global TB and malaria programs, respectively.			
Sections 312 and 313 of the Leadership Act, as amended: authorities to establish a panel to advise on strategies for expanding use of tools that prevent mother-to-child HIV transmission (PMTCT), requirements for developing a plan to expand PMTCT efforts, and report on those activities.			
Section 401 of the Leadership Act, as amended: \$48 billion authorization for global HIV/AIDS, TB, and malaria assistance through FY2013.			

Source: Created by CRS from the Leadership Act and PEPFAR Stewardship and Oversight Act.

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