

## REFERENCES IN TEXT

This chapter, referred to in subsec. (a)(1), was in the original “this Act”, meaning Pub. L. 108-25, May 27, 2003, 117 Stat. 711, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 7601 of this title and Tables.

**§ 7624. Facilitating vaccine development****(a) Technical assistance for developing countries**

The Administrator of the United States Agency for International Development, utilizing public-private partners, as appropriate, and working in coordination with other international development agencies, is authorized to strengthen the capacity of developing countries’ governmental institutions to—

- (1) collect evidence for informed decision-making and introduction of new vaccines, including potential HIV/AIDS, tuberculosis, and malaria vaccines, if such vaccines are determined to be safe and effective;
- (2) review protocols for clinical trials and impact studies and improve the implementation of clinical trials; and
- (3) ensure adequate supply chain and delivery systems.

**(b) Advanced market commitments****(1) Purpose**

The purpose of this subsection is to improve global health by requiring the United States to participate in negotiations for advance market commitments for the development of future vaccines, including potential vaccines for HIV/AIDS, tuberculosis, and malaria.

**(2) Negotiation requirement**

The Secretary of the Treasury shall enter into negotiations with the appropriate officials of the International Bank of Reconstruction and Development (World Bank) and the GAVI Alliance, the member nations of such entities, and other interested parties to establish advanced market commitments to purchase vaccines to combat HIV/AIDS, tuberculosis, malaria, and other related infectious diseases.

**(3) Requirements**

In negotiating the United States participation in programs for advanced market commitments, the Secretary of the Treasury shall take into account whether programs for advance market commitments include—

- (A) legally binding contracts for product purchase that include a fair market price for up to a maximum number of treatments, creating a strong market incentive;
- (B) clearly defined and transparent rules of program participation for qualified developers and suppliers of the product;
- (C) clearly defined requirements for eligible vaccines to ensure that they are safe and effective and can be delivered in developing country contexts;
- (D) dispute settlement mechanisms; and
- (E) sufficient flexibility to enable the contracts to be adjusted in accord with new information related to projected market size and other factors while still maintaining the purchase commitment at a fair price.

**(4) Report**

Not later than 1 year after July 30, 2008—

(A) the Secretary of the Treasury shall submit a report to the appropriate congressional committees on the status of the United States negotiations to participate in programs for the advanced market commitments under this subsection; and

(B) the President shall produce a comprehensive report, written by a study group of qualified professionals from relevant Federal agencies and initiatives, nongovernmental organizations, and industry representatives, that sets forth a coordinated strategy to accelerate development of vaccines for infectious diseases, such as HIV/AIDS, malaria, and tuberculosis, which includes—

- (i) initiatives to create economic incentives for the research, development, and manufacturing of vaccines for HIV/AIDS, tuberculosis, malaria, and other infectious diseases;
- (ii) an expansion of public-private partnerships and the leveraging of resources from other countries and the private sector; and
- (iii) 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.

(Pub. L. 110-293, title II, § 206, July 30, 2008, 122 Stat. 2944.)

## CODIFICATION

Section was enacted as part of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and not as part of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 which comprises this chapter.

## SUBCHAPTER III—BILATERAL EFFORTS

## PART A—GENERAL ASSISTANCE AND PROGRAMS

**§ 7631. Assistance to combat HIV/AIDS****(a) Omitted****(b) Authorization of appropriations****(1) In general**

In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act [22 U.S.C. 2151 et seq.], there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 7671 of this title, such sums as may be necessary for each of the fiscal years 2009 through 2013 to carry out section 104A of the Foreign Assistance Act of 1961, as added by subsection (a) [22 U.S.C. 2151b-2].

**(2) Availability of funds**

Amounts appropriated pursuant to paragraph (1) are authorized to remain available until expended.

**(3) Allocation of funds**

Of the amount authorized to be appropriated by paragraph (1) for the fiscal years 2009

through 2013, such sums as may be necessary are authorized to be appropriated to carry out section 104A(d)(4) of the Foreign Assistance Act of 1961 (as added by subsection (a)) [22 U.S.C. 2151b-2(d)(4)], relating to the procurement and distribution of HIV/AIDS pharmaceuticals.

**(c) Food and nutritional support**

**(1) In general**

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

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

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

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

(i) anthropometric and dietary assessment;

(ii) counseling; and

(iii) therapeutic and supplementary feeding;

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

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

**(2) Authorization of appropriations**

Of the amounts authorized to be appropriated under section 7671 of this title, there are authorized to be appropriated to the President such sums as may be necessary for each of the fiscal years 2009 through 2013 to carry out this subsection.

**(d) Eligibility for assistance**

An organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 [22 U.S.C. 2151b-2], under

this chapter, or under any amendment made by this chapter or by the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, for HIV/AIDS prevention, treatment, or care—

(1) shall not be required, as a condition of receiving such assistance—

(A) to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

(B) to 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

(2) shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements under such provisions of law for refusing to meet any requirement described in paragraph (1).

**(e) Limitation**

No funds made available to carry out this chapter, or any amendment made by this chapter, may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

**(f) Limitation**

No funds made available to carry out this chapter, or any amendment made by this chapter, may be used to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking, except that this subsection shall not apply to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency.

**(g) Sense of Congress relating to food assistance for individuals living with HIV/AIDS**

**(1) Findings**

Congress finds the following:

(A) The United States provides more than 60 percent of all food assistance worldwide.

(B) According to the United Nations World Food Program and other United Nations agencies, food insecurity of individuals infected or living with HIV/AIDS is a major problem in countries with large populations of such individuals, particularly in African countries.

(C) Although the United States is willing to provide food assistance to these countries in need, a few of the countries object to part or all of the assistance because of fears of benign genetic modifications to the foods.

(D) Healthy and nutritious foods for individuals infected or living with HIV/AIDS are an important complement to HIV/AIDS medicines for such individuals.

(E) Individuals infected with HIV have higher nutritional requirements than indi-

viduals who are not infected with HIV, particularly with respect to the need for protein. Also, there is evidence to suggest that the full benefit of therapy to treat HIV/AIDS may not be achieved in individuals who are malnourished, particularly in pregnant and lactating women.

## (2) Sense of Congress

It is therefore the sense of Congress that United States food assistance should be accepted by countries with large populations of individuals infected or living with HIV/AIDS, particularly African countries, in order to help feed such individuals.

(Pub. L. 108–25, title III, §301, May 27, 2003, 117 Stat. 728; Pub. L. 108–199, div. D, title V, §595(3), Jan. 23, 2004, 118 Stat. 209; Pub. L. 110–293, title III, §301(f)–(h), July 30, 2008, 122 Stat. 2956, 2957.)

### REFERENCES IN TEXT

The Foreign Assistance Act of 1961, referred to in subsec. (b)(1), is Pub. L. 87–195, Sept. 4, 1961, 75 Stat. 424, as amended, which is classified principally to chapter 32 (§2151 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2151 of this title and Tables.

This chapter, referred to in subsecs. (d) to (f), was in the original “this Act”, meaning Pub. L. 108–25, May 27, 2003, 117 Stat. 711, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 7601 of this title and Tables.

The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, referred to in subsec. (d), is Pub. L. 110–293, July 30, 2008, 122 Stat. 2918. For complete classification of this Act to the Code, see Short Title of 2008 Amendment note set out under section 7601 of this title and Tables.

### CODIFICATION

Section is comprised of section 301 of Pub. L. 108–25. Subsec. (a) of section 301 of Pub. L. 108–25 amended section 2151b of this title and enacted section 2151b–2 of this title.

### CONSTITUTIONALITY

For information regarding constitutionality of certain provisions of section 301 of Pub. L. 108–25, see Congressional Research Service, *The Constitution of the United States of America: Analysis and Interpretation*, Appendix I, Acts of Congress Held Unconstitutional in Whole or in Part by the Supreme Court of the United States.

### AMENDMENTS

2008—Subsec. (b)(1), (3). Pub. L. 110–293, §301(f), substituted “fiscal years 2009 through 2013” for “fiscal years 2004 through 2008”.

Subsec. (c). Pub. L. 110–293, §301(g), amended subsec. (c) generally. Prior to amendment, text read as follows: “In recognition of the fact that malnutrition may hasten the progression of HIV to AIDS and may exacerbate the decline among AIDS patients leading to a shorter life span, the Administrator of the United States Agency for International Development shall, as appropriate—

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

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

“(3) provide support for food and nutrition for children affected by HIV/AIDS and to communities and

households caring for children affected by HIV/AIDS.”

Subsec. (d). Pub. L. 110–293, §301(h), amended subsec. (d) generally. Prior to amendment, text read as follows: “An organization that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961 (as added by subsection (a)) or under any other provision of this chapter (or any amendment made by this chapter) to prevent, treat, or monitor HIV/AIDS shall not be required, as a condition of receiving the assistance, to endorse or utilize a multisectoral approach to combatting HIV/AIDS, or to endorse, utilize, or participate in a prevention method or treatment program to which the organization has a religious or moral objection.”

2004—Subsec. (f). Pub. L. 108–199, §595(3), inserted “, except that this subsection shall not apply to the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Health Organization, the International AIDS Vaccine Initiative or to any United Nations agency” after “trafficking”.

## § 7631a. United States Agency for International Development

### (1) In general

The Administrator of the United States Agency for International Development, in coordination with the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, may facilitate availability and accessibility of microbicides, provided that such pharmaceuticals are approved, tentatively approved, or otherwise authorized for use by—

(A) the Food and Drug Administration;

(B) a stringent regulatory agency acceptable to the Secretary of Health and Human Services; or

(C) a quality assurance mechanism acceptable to the Secretary of Health and Human Services.

### (2) Authorization of appropriations

Of the amounts authorized to be appropriated under section 7671 of this title for HIV/AIDS assistance, there are authorized to be appropriated to the President such sums as may be necessary for each of the fiscal years 2009 through 2013 to carry out this section.

(Pub. L. 110–293, title II, §203(e), July 30, 2008, 122 Stat. 2941.)

### CODIFICATION

Section was enacted as part of the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, and not as part of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 which comprises this chapter.

## § 7632. Authorization of appropriations to combat tuberculosis

### (1) In general

In addition to funds available under section 104(c) of the Foreign Assistance Act of 1961 (22 U.S.C. 2151b(c)) for such purpose or under any other provision of that Act [22 U.S.C. 2151 et seq.], there are authorized to be appropriated to the President, from amounts authorized to be appropriated under section 7671 of this title, a total of \$4,000,000,000 for the 5-year period beginning on October 1, 2008.<sup>1</sup> to carry out section

<sup>1</sup> So in original. The period probably should not appear.