

113TH CONGRESS
1ST SESSION

H. R. 1515

To amend the Foreign Assistance Act of 1961 to codify the cooperative agreement, known as the Health Technologies program, under which the United States Agency for International Development supports the development of technologies for global health, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 11, 2013

Mr. SIRES (for himself and Mr. DIAZ-BALART) introduced the following bill;
which was referred to the Committee on Foreign Affairs

A BILL

To amend the Foreign Assistance Act of 1961 to codify the cooperative agreement, known as the Health Technologies program, under which the United States Agency for International Development supports the development of technologies for global health, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “21st Century Global
5 Health Technology Act”.

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Research and development is a critical com-
2 ponent of United States leadership in global health.
3 Research and innovation can help to break the cycle
4 of aid dependency by providing sustainable solutions
5 to long-term problems. Research and development
6 for global health is crucial for meeting new and
7 emerging challenges, creating efficiencies, strength-
8 ening health systems, shifting tasks and strength-
9 ening workforces, and increasing access to health
10 services for the most vulnerable. Research suggests
11 that advances in health and medical technologies
12 have been the major drivers behind massive improve-
13 ments in health worldwide over the past century, re-
14 sulting in an average increase in life expectancies of
15 21 years in low- and middle-income countries be-
16 tween 1960 and 2002. Additionally, new health tech-
17 nologies have a high return on investment. For ex-
18 ample, it is estimated that a new meningitis A vac-
19 cine developed in collaboration with the United
20 States Agency for International Development
21 (USAID), the Centers for Disease Control and Pre-
22 vention (CDC), the National Institutes of Health
23 (NIH), and the Food and Drug Administration
24 (FDA), will save \$570,000,000 over the next decade
25 in costs that would otherwise be incurred for emer-

1 agency vaccination campaigns, freeing much needed
2 resources for use elsewhere in overstretched health
3 systems.

4 (2) Five Federal agencies—NIH, USAID, the
5 Department of Defense, CDC, and FDA—provide
6 significant contributions each year to global health
7 research and development. The United States Gov-
8 ernment is supporting the development of 200—55
9 percent—of the 365 products in the global pipeline
10 of products for neglected and poverty-related dis-
11 eases.

12 (3) This commitment from the United States
13 Government and its Federal agencies has led to a re-
14 markable increase in global health products. Forty-
15 five new health tools were registered between 2000
16 and 2010, and the United States Government was
17 involved in 24, or 53 percent, of these new global
18 health products in the last decade including 6 drugs
19 for malaria, 2 vaccines for pneumonia, 6 diagnostics
20 for tuberculosis, and 2 drugs for leishmaniasis.

21 (4) United States investments have enabled tre-
22 mendous progress in the introduction of new tech-
23 nologies for global health; however, gaps exist in
24 bringing certain technologies through the develop-
25 ment process and rapidly scaling them up in the

1 field. Better coordination is needed between Federal
2 agencies to align research strategies, identify and
3 address gaps in product development activity and
4 move products efficiently along the research-to-intro-
5 duction continuum.

6 (5) Infectious diseases disproportionately im-
7 pact populations in low-income nations across Latin
8 America, sub-Saharan Africa, and Asia. However,
9 even in the United States, poor and vulnerable com-
10 munities are at much greater risk for contracting
11 diseases usually considered to be diseases of the de-
12 veloping world. For example, cases of Chagas dis-
13 ease, which is found throughout Latin America, and
14 dengue fever, endemic to Mexico and Central Amer-
15 ica, have been detected in southern States along the
16 United States border with Mexico, in communities
17 where poverty rates are high.

18 (6) In collaboration with the World Health Or-
19 ganization (WHO) and its member states, the
20 United States is a leading participant in discussions
21 to improve coordination and financing of global
22 health research and development. This process will
23 establish mechanisms to map research needs, iden-
24 tify resource gaps, and set priorities to ensure that

1 the most crucial global health products are developed
2 and delivered for maximum global health impact.

3 (7) Because of its presence in the field, USAID
4 is uniquely placed to assess local health conditions,
5 then partner with public and private stakeholders to
6 ensure the development and timely introduction and
7 scale-up of tools that are culturally acceptable, ad-
8 dress serious and all-too-common health problems,
9 and contribute to the strengthening of health sys-
10 tems. In a recent report to Congress, USAID calls
11 health research “integral” to its “ability to achieve
12 its health and development objectives worldwide”
13 and states that innovation through research allows
14 the agency “to develop and introduce affordable
15 health products and practices and contribute to poli-
16 cies appropriate for addressing health-related con-
17 cerns in the developing world”. The elevation of the
18 Office of Science and Technology would assist
19 USAID in achieving its global health and develop-
20 ment goals. In 2011, USAID outlined a 5-year
21 health research strategy: “Report to Congress:
22 Health-Related Research and Development Activities
23 at USAID (HRRD), May 2011”, with a timeline
24 through 2010. This strategy is an important source
25 of information on USAID’s programs for global

1 health product development and is an effective tool
2 for measuring expected results from 2011 through
3 2015. The strategy does not articulate USAID's in-
4 vestments and programming for research and devel-
5 opment in several critical areas such as—

6 (A) new tools to diagnose, prevent and
7 treat neglected tropical diseases;

8 (B) biomedical products, technologies and
9 devices for conditions and diseases impacting
10 maternal health, newborns, and children, in-
11 cluding research for vaccines for the leading
12 causes of death in children; and

13 (C) new tuberculosis vaccines.

14 (8) Congress notes the interrelated initiatives
15 that USAID has taken to advance science, tech-
16 nology, and innovation for development, including
17 the Grand Development Challenges, the Innovation
18 Fund, Higher Education Science Network, the De-
19 velopment Lab, and the Innovation Fellowship.

20 (9) Research and development at USAID—

21 (A) facilitates public-private collaboration
22 in the development of global health tech-
23 nologies;

24 (B) leverages public and private sector
25 support for early stage research and develop-

1 ment of health technologies to encourage pri-
2 vate sector investment in late-stage technology
3 development and product introduction in devel-
4 oping countries;

5 (C) benefits the United States economy by
6 investing in the growing United States global
7 health technology sector, which—

8 (i) provides skilled jobs for American
9 workers for example, 64 cents of every
10 United States dollar invested in global
11 health research benefits United States-
12 based researchers;

13 (ii) creates opportunities for United
14 States businesses in the development and
15 production of new technologies; and

16 (iii) enhances United States competi-
17 tiveness in the increasingly technological
18 and knowledge-based global economy; and

19 (D) enhances United States national secu-
20 rity by—

21 (i) reducing the risk of pandemic dis-
22 ease; and

23 (ii) contributing to economic develop-
24 ment and stability in developing countries.

1 (10) Investments by the United States in af-
2 fordable, appropriate health technologies, such as
3 medical devices for maternal, newborn, and child
4 care; new vaccines; new vaccine technologies and de-
5 livery tools; safe injection devices; diagnostic tests
6 for infectious diseases; new tools for water, sanita-
7 tion, and nutrition; multipurpose prevention tech-
8 nologies; information systems and mobile health and
9 information systems; and innovative disease preven-
10 tion strategies—

11 (A) reduce the risk of disease transmission;

12 (B) accelerate access to life-saving global
13 health interventions for the world’s poor;

14 (C) reduce the burden on local health sys-
15 tems; and

16 (D) have been found by the United States
17 Government and WHO to result in significant
18 cost savings for development assistance funds.

19 (11) Where markets fail, public-private partner-
20 ships are an effective way to develop, introduce and
21 scale up new health technologies. Product develop-
22 ment partnerships (PDPs) are one model of public
23 private partnership that is successfully accelerating
24 research to benefit the developing world. PDPs are
25 non-profit, nongovernmental entities that work to

1 accelerate the development of new tools to fight dis-
2 eases in resource-poor settings. Typically, PDPs
3 manage resources and partnerships from across pub-
4 lic, private, and philanthropic sectors to drive the
5 development of a full pipeline of potential new prod-
6 ucts that could save and improve lives in the devel-
7 oping world. USAID has played a significant role in
8 advancing the PDP model through its financial sup-
9 port. Over the past decade, the achievements of
10 PDPs have become increasingly successful at ad-
11 vancing new products through the development pipe-
12 line towards registration, product introduction, and
13 use.

14 (12) USAID supports research and introduction
15 activities along a research-to-use continuum includ-
16 ing—

17 (A) evidence reviews and health assess-
18 ments in developing countries; and

19 (B) the development, testing, adaptation,
20 and introduction of appropriate products and
21 interventions within the context of strength-
22 ening health systems.

23 (13) A Center for Accelerating Innovation and
24 Impact has been established at USAID to address
25 technical, supply and policy barriers in the develop-

1 ment, introduction and scale-up of new products and
2 technologies for global health. For diseases and con-
3 ditions where market forces have proven insufficient
4 to generate and rapidly deliver new technologies, the
5 Center promotes and reinforces solutions to over-
6 come obstacles such as regulatory inefficiencies in
7 developing countries, limited user demand, gaps in
8 market data and supply chain hurdles. The Center
9 also catalyzes partnerships with the public and pri-
10 vate sectors to develop and rapidly deploy new prod-
11 ucts.

12 (14) Through a cooperative agreement, known
13 as the Health Technologies program, USAID sup-
14 ports the development of technologies that—

15 (A) maximize the limited resources avail-
16 able for global health; and

17 (B) ensure that products and medicines
18 developed for use in low-resource settings reach
19 the people that need such products and medi-
20 cines.

21 Through the Health Technologies program, 85 tech-
22 nologies have been invented, designed, developed or
23 co-developed and more than 100 private-sector col-
24 laborators have been involved in the Health Tech-
25 nologies program, matching USAID dollars at least

1 two to one. Over its 25-year history, more than 95
2 private-sector collaborators have been involved in the
3 Health Technologies program, matching USAID dol-
4 lars two to one.

5 (15) USAID's research and development is
6 complementary to the work of other agencies.

7 **SEC. 3. PURPOSES.**

8 The purpose of this Act is to acknowledge USAID's
9 role in product development, introduction and scale-up of
10 new global health tools and authorize USAID's Health
11 Technologies program, in effect as of the date of the en-
12 actment of this Act, under which the United States Agen-
13 cy for International Development supports the develop-
14 ment of technologies for global health to—

- 15 (1) improve global health;
- 16 (2) reduce maternal, newborn, and child mor-
17 tality rates;
- 18 (3) reverse the incidence of HIV/AIDS, malaria,
19 tuberculosis, and other infectious diseases;
- 20 (4) reduce the burden of chronic diseases;
- 21 (5) overcome technical, supply and policy hur-
22 dles to product introduction and scale-up; and
- 23 (6) support research and development that is
24 consistent with a global development strategy and
25 other related strategies developed by USAID.

1 **SEC. 4. CODIFICATION OF HEALTH TECHNOLOGIES PRO-**
2 **GRAM.**

3 Section 107 of the Foreign Assistance Act of 1961
4 (22 U.S.C. 2151e) is amended by adding at the end the
5 following:

6 “(c) HEALTH TECHNOLOGIES PROGRAM.—(1) There
7 is established in the United States Agency for Inter-
8 national Development (USAID) a health technologies pro-
9 gram (referred to in this subsection as the ‘program’).

10 “(2) The program shall develop, advance, and intro-
11 duce affordable, available, and appropriate and primarily
12 late-stage technologies specifically designed to—

13 “(A) improve the health and nutrition of popu-
14 lations in developing countries;

15 “(B) reduce maternal, newborn, and child mor-
16 tality in such countries; and

17 “(C) improve the diagnosis, prevention, and re-
18 duction of disease, especially HIV/AIDS, malaria,
19 tuberculosis, and other infectious diseases, in such
20 countries.

21 “(3) The program shall be carried out under a coop-
22 erative agreement between USAID and one or more insti-
23 tutions with a successful record of—

24 “(A) advancing the technologies described in
25 paragraph (2); and

1 “(B) integrating practical field experience into
2 the research and development process in order to in-
3 troduce the most appropriate technologies.

4 “(4) The provisions of this subsection codify the coop-
5 erative agreement, known as the Health Technologies pro-
6 gram, in effect as of the date of the enactment of this
7 subsection, under which USAID supports the development
8 of technologies for global health. The provisions of this
9 subsection do not establish a new cooperative agreement
10 or program for such purposes.

11 “(d) ACTION PLANS.—The Administrator of the
12 United States Agency for International Development
13 (USAID) shall establish and implement action plans to in-
14 corporate global health research and product development
15 within each of the global health and development pro-
16 grams, with support from coordinating agencies, and shall
17 establish metrics to measure progress. In implementing
18 the action plans, the Administrator shall consider all op-
19 tions, including the use of public private partnerships.

20 “(e) PRIORITY GLOBAL HEALTH INTERVENTIONS.—
21 The Center for Accelerating Innovation and Impact of the
22 United States Agency for International Development shall
23 continue its work to speed the development, introduction,
24 and scale-up of priority global health interventions.”.

1 **SEC. 5. REPORT ON RESEARCH AND DEVELOPMENT AC-**
2 **TIVITIES AT USAID.**

3 (a) IN GENERAL.—The Administrator of the United
4 States Agency for International Development (referred to
5 in this section as “USAID”) shall submit to Congress an
6 annual report on research and development activities at
7 USAID.

8 (b) MATTERS TO BE INCLUDED.—The report re-
9 quired by subsection (b) shall describe—

10 (1) updates on the implementation of its strat-
11 egy for using research funds to stimulate the devel-
12 opment and introduction of products in each of its
13 global health and development programs;

14 (2) USAID’s collaborations and coordination
15 with other Federal departments and agencies in sup-
16 port of translational and applied global health re-
17 search and development;

18 (3) its investments for the fiscal year in science,
19 technology, and innovation;

20 (4) how these technologies and research prod-
21 ucts complement the work being done by other Fed-
22 eral departments and agencies, if applicable; and

23 (5) technologies and research products that
24 have been introduced into field trials or use.

25 (c) CONSULTATION.—The Administrator of USAID
26 shall consult on an annual basis with the heads of other

1 Federal departments and agencies to improve alignment
2 of USAID's health-related research strategy with other
3 similar agency strategies, with the intent of working to-
4 wards a whole-of-government strategy for global health re-
5 search and development.

