

113TH CONGRESS  
2D SESSION

# S. 2407

To amend the Foreign Assistance Act of 1961 by authorizing the United States Agency for International Development to continue supporting the development of technologies for global health under the Health Technologies Program, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MAY 22, 2014

Mrs. MURRAY introduced the following bill; which was read twice and referred to the Committee on Foreign Relations

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# A BILL

To amend the Foreign Assistance Act of 1961 by authorizing the United States Agency for International Development to continue supporting the development of technologies for global health under the Health Technologies Program, 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                             (2) Research and innovation can help to break  
4                             the cycle of aid dependency by providing sustainable  
5                             solutions to long-term problems.

6                             (3) Research and development for global health  
7                             is crucial for meeting new and emerging challenges,  
8                             creating efficiencies, strengthening health systems,  
9                             shifting tasks, strengthening workforces, and in-  
10                             creasing access to health services for the most vul-  
11                             nerable people.

12                             (4) Advances in health and medical technologies  
13                             have been the major drivers behind massive improve-  
14                             ments in health worldwide during the past century,  
15                             resulting in an average increase in life expectancy of  
16                             21 years in low- and middle-income countries be-  
17                             tween 1960 and 2002.

18                             (5) New health technologies have a high return  
19                             on investment. For example, a new meningitis A  
20                             vaccine developed in collaboration with the United  
21                             States Agency for International Development (re-  
22                             ferred to in this section as “USAID”), the Centers  
23                             for Disease Control and Prevention, the National In-  
24                             stitutes of Health, and the Food and Drug Adminis-  
25                             tration, will save an estimated \$570,000,000 in costs

1       that would otherwise be incurred for emergency vac-  
2       cination campaigns during the next decade, freeing  
3       much needed resources for use elsewhere in over-  
4       stretched health systems.

5                 (6) USAID, the Centers for Disease Control  
6       and Prevention, the National Institutes of Health,  
7       the Food and Drug Administration, and the Depart-  
8       ment of Defense provide significant contributions  
9       each year to global health research and development.  
10      The United States Government is supporting the de-  
11      velopment of 200 of the 365 products in the global  
12      pipeline of products for neglected and poverty-re-  
13      lated diseases.

14                 (7) This commitment from the United States  
15      Government has led to a remarkable increase in  
16      global health products. Forty-five new health tools  
17      were registered between 2000 and 2010, and the  
18      United States Government was involved in 24 of  
19      these new global health products in the last decade,  
20      including—

- 21                         (A) 6 drugs for malaria;  
22                         (B) 2 vaccines for pneumonia;  
23                         (C) 6 diagnostics for tuberculosis; and  
24                         (D) 2 drugs for leishmaniasis.

1                             (8) Although investments from the United  
2                             States Government have enabled tremendous  
3                             progress in the introduction of new technologies for  
4                             global health, gaps still exist in bringing certain  
5                             technologies through the development process and  
6                             rapidly scaling them up in the field.

7                             (9) Better coordination is needed between Fed-  
8                             eral agencies—

- 9                                 (A) to align research strategies;
- 10                                (B) to identify and address gaps in prod-  
11                                uct development activity; and
- 12                                (C) to move products efficiently along the  
13                               research-to-introduction continuum.

14                             (10) Infectious diseases disproportionately im-  
15                             pact populations in low-income nations across Latin  
16                             America, sub-Saharan Africa, and Asia. Poor and  
17                             vulnerable communities in the United States are also  
18                             at risk for contracting diseases usually considered to  
19                             be diseases of the developing world. For example,  
20                             cases of Chagas disease, which is found throughout  
21                             Latin America, and dengue fever, endemic to Mexico  
22                             and Central America, have been detected in commu-  
23                             nities with high poverty rates in States along the  
24                             United States border with Mexico.

1                         (11) In collaboration with the World Health Or-  
2 ganization and its member states, the United States  
3 is a leading participant in discussions to improve co-  
4 ordination and financing of global health research  
5 and development. This process will establish mecha-  
6 nisms to map research needs, identify resource gaps,  
7 and set priorities to ensure that the most crucial  
8 global health products are developed and delivered  
9 for maximum global health impact.

10                        (12) Because of its presence in the field,  
11 USAID is uniquely placed—

12                        (A) to assess local health conditions;  
13                        (B) to partner with public and private  
14 stakeholders to ensure the development and  
15 timely introduction and scale-up of tools that  
16 are culturally acceptable;  
17                        (C) to address serious and all-too-common  
18 health problems; and  
19                        (D) to contribute to the strengthening of  
20 health systems.

21                        (13) In a recent report to Congress, USAID as-  
22 serts that—

23                        (A) health research is “integral” to its  
24 “ability to achieve its health and development  
25 objectives worldwide”; and

1                                 (B) innovation through research allows the  
2                                 agency “to develop and introduce affordable  
3                                 health products and practices and contribute to  
4                                 policies appropriate for addressing health-re-  
5                                 lated concerns in the developing world”.

6                                 (14)(A) In “Report to Congress: Health-Re-  
7                                 lated Research and Development Activities at  
8                                 USAID (HRRD), May 2011”, USAID analyzed its  
9                                 activities from 2006 through 2010 and set forth a  
10                                 5-year health research strategy for the next 5 years.

11                                 (B) The new strategy is—

12                                 (i) an important source of information on  
13                                 USAID’s programs for global health product  
14                                 development; and

15                                 (ii) an effective tool for measuring ex-  
16                                 pected results from 2011 through 2015.

17                                 (C) The strategy does not articulate USAID’s  
18                                 investments and programming for research and de-  
19                                 velopment in several critical areas, including—

20                                 (i) new tools to diagnose, prevent, and  
21                                 treat neglected tropical diseases;

22                                 (ii) research addressing the leading causes  
23                                 of death and illness of women, newborns, and  
24                                 children; and

25                                 (iii) new tuberculosis vaccines.

1                         (15) USAID has established a variety of instruments to promote innovation and global health, such  
2                         as—  
3

- 4                             (A) Grand Challenges for Development;  
5                             (B) the Innovation Fund for the Americas;  
6                             (C) Higher Education Solutions Network  
7                             (HESN);  
8                             (D) university Development Labs; and  
9                             (E) Research and Innovation Fellowships.

10                         (16) Research and development at USAID—

11                             (A) facilitates public-private collaboration  
12                             in the development of global health technologies;

13                             (B) leverages public and private sector support for early stage research and development of health technologies to encourage private sector investment in late-stage technology development and product introduction in developing countries;

14                             (C) benefits the United States economy by investing in the growing United States global  
15                             health technology sector, which—

16                                 (i) provides skilled jobs for American  
17                             workers (64 cents of every United States

1                   dollar invested in global health research  
2                   benefits United States-based researchers);

3                   (ii) creates opportunities for United  
4                   States businesses in the development and  
5                   production of new technologies; and

6                   (iii) enhances United States competi-  
7                   tiveness in the increasingly technological  
8                   and knowledge-based global economy; and

9                   (D) enhances United States national secu-  
10                  rity by—

11                  (i) reducing the risk of pandemic dis-  
12                  ease; and

13                  (ii) contributing to economic develop-  
14                  ment and stability in developing countries.

15                  (17) The United States should invest in afford-  
16                  able, appropriate health technologies, including—

17                  (A) medical devices for maternal, newborn,  
18                  and child care;

19                  (B) new vaccines;

20                  (C) new vaccine technologies and delivery  
21                  tools;

22                  (D) safe injection devices;

23                  (E) diagnostic tests for infectious diseases;

24                  (F) new tools for water, sanitation, and  
25                  nutrition;

- 1                             (G) multipurpose prevention technologies;
- 2                             (H) information systems and mobile health
- 3                             and information systems; and
- 4                             (I) innovative disease prevention strategies.
- 5                         (18) United States investments in the health
- 6                             technologies set forth in paragraph (17) would—
- 7                             (A) reduce the risk of disease transmission;
- 8                             (B) accelerate access to life-saving global
- 9                             health interventions for the world’s poor;
- 10                          (C) reduce the burden on local health sys-
- 11                          tems; and
- 12                          (D) result in significant cost savings for
- 13                          development assistance funds.
- 14                         (19) In circumstances where markets fail, pub-
- 15                          lic-private partnerships are an effective way to de-
- 16                          velop, introduce and scale up new health tech-
- 17                          nologies.
- 18                         (20)(A) Product development partnerships (re-
- 19                          ferred to in this paragraph as “PDPs”) are a model
- 20                          of public-private partnership that is successfully ac-
- 21                          celerating research to benefit the developing world.
- 22                         (B) PDPs are non-profit, nongovernmental en-
- 23                          tities that work to accelerate the development of new
- 24                          tools to fight diseases in resource-poor settings.

1                   (C) PDPs typically manage resources and part-  
2         nerships from across public, private, and philan-  
3         thropic sectors to drive the development of a full  
4         pipeline of potential new products that could save  
5         and improve lives in the developing world.

6                   (D) USAID has played a significant role in ad-  
7         vancing the PDP model through its financial sup-  
8         port.

9                   (E) Between 2004 and 2013, the achievements  
10        of 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                  (21) 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                  (22)(A) A Center for Accelerating Innovation  
24        and Impact (referred to in this paragraph as the  
25        “Center”) has been established at USAID to ad-

1       dress technical, supply, and policy barriers in the de-  
2       velopment, introduction, and scale-up of new prod-  
3       ucts and technologies for global health.

4                 (B) For diseases and conditions in which mar-  
5       ket forces have proven insufficient to generate and  
6       rapidly deliver new technologies, the Center pro-  
7       motes and reinforces solutions to overcome obstacles  
8       such as regulatory inefficiencies in developing coun-  
9       tries, limited user demand, gaps in market data and  
10      supply chain hurdles.

11                 (C) The Center also catalyzes partnerships with  
12      the public and private sectors to develop and rapidly  
13      deploy new products.

14                 (23) Since 1982, USAID has carried out a pro-  
15      gram to support the development of health tech-  
16      nologies through which USAID—

17                         (A) has maximized the limited resources  
18      available for global health;

19                         (B) has ensured that products and medi-  
20      cines developed for use in low-resource settings  
21      have reached the people that need such prod-  
22      ucts and medicines;

23                         (C) has invented, designed, developed, or  
24      co-developed 85 health technologies; and

1                   (D) has collaborated with more than 100  
2                   private-sector organizations, which have  
3                   matched the funds received from USAID by a  
4                   2:1 ratio.

5                   (24) The research and development activities of  
6                   USAID are complementary to the work of other  
7                   Federal agencies.

8 **SEC. 3. PURPOSES.**

9                   The purposes of this Act are—

10                  (1) to acknowledge the role of the United  
11                  States Agency for International Development (re-  
12                  ferred to in this section as “USAID”) in product de-  
13                  velopment, introduction, and scale-up of new global  
14                  health tools; and

15                  (2) to establish the Technologies for Health  
16                  Program within USAID to support the development  
17                  of technologies for global health that will—

18                   (A) improve global health;

19                   (B) reduce maternal, newborn, and child  
20                  mortality rates;

21                   (C) improve health and nutrition;

22                   (D) reverse the incidence of HIV/AIDS,  
23                  malaria, tuberculosis, and other infectious dis-  
24                  eases;

25                   (E) reduce the burden of chronic diseases;

1                             (F) overcome technical, supply, and policy  
2                             hurdles to product introduction and scale-up;  
3                             and

4                             (G) support research and development that  
5                             is consistent with a global development strategy  
6                             and other related strategies developed by  
7                             USAID.

8                             **SEC. 4. ESTABLISHMENT OF HEALTH TECHNOLOGIES PRO-**  
9                             **GRAM.**

10                         (a) IN GENERAL.—Section 107 of the Foreign Assist-  
11                         ance Act of 1961 (22 U.S.C. 2151e) is amended by adding  
12                         at the end the following:

13                         “(c) TECHNOLOGIES FOR HEALTH.—

14                         “(1) ESTABLISHMENT.—There is established,  
15                         within the Health and Infectious Diseases and Nu-  
16                         trition Section of the Global Health Bureau of the  
17                         United States Agency for International Development  
18                         (referred to in this subsection as ‘USAID’), the  
19                         Technologies for Health Program (referred to in this  
20                         subsection as the ‘Program’).

21                         “(2) FUNCTIONS.—The Program shall develop,  
22                         advance, and introduce affordable, available, and ap-  
23                         propriate and primarily late-stage technologies spe-  
24                         cifically designed—

1               “(A) to improve the health and nutrition of  
2               populations in developing countries;

3               “(B) to reduce maternal, newborn, and  
4               child mortality in such countries; and

5               “(C) to improve the diagnosis, prevention,  
6               and reduction of disease, especially HIV/AIDS,  
7               malaria, tuberculosis, and other infectious dis-  
8               eases, in such countries.

9               “(3) AGREEMENT.—The Program shall be car-  
10          ried out under a cooperative agreement between  
11          USAID and 1 or more institutions with a successful  
12          record of—

13               “(A) advancing the technologies described  
14          in paragraph (2); and

15               “(B) integrating practical field experience  
16          into the research and development process in  
17          order to introduce the most appropriate tech-  
18          nologies.

19               “(d) ACTION PLANS.—The Administrator of USAID  
20          shall—

21               “(1) establish and implement action plans to in-  
22          corporate global health research and product devel-  
23          opment within each of the global health and develop-  
24          ment programs, with support from coordinating  
25          agencies;

1           “(2) establish metrics to measure progress in  
2       implementing the action plans; and

3           “(3) consider all options in implementing the  
4       action plans, including the use of public-private part-  
5       nerships.

6           “(e) PRIORITY GLOBAL HEALTH INTERVENTIONS.—

7       The Center for Accelerating Innovation and Impact of  
8       USAID shall continue its work to speed the development,  
9       introduction, and scale-up of priority global health inter-  
10      ventions.”.

11          (b) SAVINGS PROVISION.—Section 107(c) of the For-  
12      eign Assistance Act of 1961, as added by subsection (a)—

13           (1) authorizes the United States Agency for  
14       International Development (referred to in this sub-  
15       section and section 5 as “USAID”) to continue the  
16       health technologies research and development activi-  
17       ties carried out by USAID before the date of the en-  
18       actment of this Act; and

19           (2) does not establish a new program for such  
20       purposes.

21   **SEC. 5. ANNUAL REPORT ON RESEARCH AND DEVELOP-  
22       MENT ACTIVITIES AT USAID.**

23          (a) IN GENERAL.—Not later than 1 year after the  
24       date of the enactment of this Act, and annually thereafter  
25       for the following 4 years, the Administrator of the United

1 States Agency for International Development, after con-  
2 sultation with the Centers for Disease Control and Preven-  
3 tion, the Department of Defense, the Food and Drug Ad-  
4 ministration, and the National Institutes of Health, shall  
5 submit a separate report to Congress on the research and  
6 development activities carried out by USAID.

7 (b) MATTERS TO BE INCLUDED.—Each report sub-  
8 mitted under subsection (a) shall include—

9 (1) updates on the implementation of USAID's  
10 strategy for using research funds to stimulate the  
11 development and introduction of products in each of  
12 its global health and development programs;

13 (2) a description of USAID's collaborations and  
14 coordination with other Federal departments and  
15 agencies in support of translational and applied  
16 global health research and development;

17 (3) a description of USAID's collaborations and  
18 coordination with partner governments, bilateral and  
19 multilateral donors, and other relevant governmental  
20 entities in support of translational and applied glob-  
21 al health research and development;

22 (4) a description of USAID investments in  
23 science, technology, and innovation;

24 (5) an explanation of how technologies and re-  
25 search products developed by USAID complement

1 work being done by other Federal departments and  
2 agencies; and

3 (6) a list of technologies and research products  
4 that have been introduced into field trials or use.

5 (c) CONSULTATION.—The Administrator of USAID  
6 shall annually consult with the heads of other Federal de-  
7 partments and agencies to improve alignment of USAID's  
8 health-related research strategy with other similar agency  
9 strategies, with the intent of working towards a whole-of-  
10 government strategy for global health research and devel-  
11 opment.

