

113TH CONGRESS
2^D SESSION

H. R. 4847

To facilitate effective research on and treatment of neglected tropical diseases through coordinated domestic and international efforts.

IN THE HOUSE OF REPRESENTATIVES

JUNE 11, 2014

Mr. SMITH of New Jersey (for himself, Mr. MEEKS, Mr. SALMON, and Mr. JOHNSON of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Foreign Affairs and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To facilitate effective research on and treatment of neglected tropical diseases through coordinated domestic and international efforts.

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 “End Neglected Trop-
5 ical Diseases Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

Sec. 1. Short title.

- Sec. 2. Table of contents.
- Sec. 3. Statement of policy.
- Sec. 4. Findings.
- Sec. 5. Definition.
- Sec. 6. Rule of construction.

TITLE I—FOREIGN AFFAIRS

- Sec. 101. Expansion of USAID NTDs Program.
- Sec. 102. Actions by Department of State.
- Sec. 103. Multilateral development and health institutions.

TITLE II—DEPARTMENT OF HEALTH AND HUMAN SERVICES

- Sec. 201. Promoting efforts through interagency working groups and international forums.
- Sec. 202. Report on neglected tropical diseases in the United States.
- Sec. 203. Centers of excellence.
- Sec. 204. Panel on worm infection solutions.

1 **SEC. 3. STATEMENT OF POLICY.**

2 It is the policy of the United States to support a
3 broad range of implementation and research and develop-
4 ment activities that work toward the achievement of cost-
5 effective and sustainable treatment, control and, where
6 possible, elimination of neglected tropical diseases for the
7 economic and social well-being for all people.

8 **SEC. 4. FINDINGS.**

9 Congress finds the following:

10 (1) The World Health Organization (WHO) has
11 identified 17 neglected tropical diseases (NTDs).
12 Approximately two billion people—almost one-third
13 of the world’s population—are at risk of contracting
14 an NTD, and more than 1.4 billion people are cur-
15 rently afflicted with one or more NTDs.

16 (2) In 2013, WHO adopted a comprehensive
17 resolution on NTDs recognizing that increased na-

1 tional and international investments in prevention
2 and control of neglected tropical diseases have suc-
3 ceeded in improving health and social well-being in
4 many countries.

5 (3) NTDs have an enormous impact in terms of
6 disease burden and quality of life. NTDs cause the
7 loss of up to 534,000 lives and 57 million disability-
8 adjusted life years each year. NTDs surpass both
9 malaria and tuberculosis in causing greater loss of
10 life-years to disability and premature death. Many
11 NTDs cause disfigurement and disability, leading to
12 stigma, social discrimination, and societal
13 marginalization.

14 (4) NTDs create an economic burden of billions
15 of dollars through the loss of productivity and high
16 costs of health care required for treatment. People
17 afflicted by NTDs are less productive than their
18 healthy counterparts. NTDs jeopardize the ability of
19 people to attend work and school, or to produce at
20 full capacity. For example, controlling one NTD,
21 hookworm, in children can result in a 43-percent in-
22 crease in future wage earnings.

23 (5) The social, economic, and health burden of
24 NTDs falls primarily on low- and middle-income
25 countries, where access to safe water, sanitation,

1 and health care is limited. At least 100 countries
2 face two endemic NTD burdens, and 30 countries
3 carry six or more endemic NTDs.

4 (6) NTDs are not confined to the developing
5 world, however. Several NTD outbreaks have been
6 reported in the United States and other developed
7 countries, especially among the poor. In the United
8 States, NTDs disproportionately affect people living
9 in poverty, and especially minorities, including up to
10 2.8 million African-Americans with toxocariasis and
11 300,000 or more people, mostly Hispanic-Americans,
12 with Chagas disease.

13 (7) Many NTDs can be controlled, prevented,
14 and even eliminated using low-cost, effective, and
15 feasible solutions. Understanding the economic bur-
16 den of NTDs on productivity and health care costs
17 can help to assure governments and donors that the
18 resources directed toward NTDs represent a good
19 investment.

20 (8) Research and development efforts are imme-
21 diately needed for all NTDs, especially those for
22 which limited or no treatment currently exists.

23 (9) Critical to developing robust NTD control
24 strategies are epidemiological data that identify at-
25 risk populations, ensure appropriate treatment fre-

1 quency, and inform decisions about when treatment
2 can be reduced or stopped.

3 (10) Of the 14 most common NTDs, roughly
4 80 percent of infections are caused by soil-trans-
5 mitted helminths (STH) and schistosomiasis. STH
6 are a group of three parasitic worms (roundworms,
7 whipworms, and hookworms) that afflict more than
8 one billion people worldwide, including 600 million
9 school-age children, of whom more than 300 million
10 suffer from severe morbidity. Schistosomiasis is an-
11 other helminth infection affecting at least 200 mil-
12 lion people in developing countries, but some esti-
13 mates indicate that the true number of people af-
14 fected may be double or even triple that number.

15 (11) The main health problems caused by STH
16 are related to their negative effect on childhood nu-
17 tritional status, which can cause stunting and wast-
18 ing. For example, STH infection may lead to ane-
19 mia, malabsorption of nutrients, loss of appetite,
20 nausea, abdominal pain, diarrhea, and reduced food
21 intake. When such health problems are experienced
22 in early childhood, a peak growth and development
23 period, the mental and physical damage—and loss of
24 future productivity and wage-earning potential—will
25 likely be irreversible. Schistosomiasis causes end-

1 organ damage to the urinary tract, female genital
2 tract, liver and intestines. It also results in chronic
3 health conditions in children.

4 (12) STH and schistosomiasis are also particu-
5 larly detrimental to the health of women of repro-
6 ductive age and pregnant women. Their underlying
7 poor iron status makes these women most suscep-
8 tible to developing anemia. Iron deficiency anemia
9 resulting from hookworm infection during pregnancy
10 has been linked to poor pregnancy outcomes such as
11 prematurity, low birth weight, and impaired lacta-
12 tion. Female genital schistosomiasis may be one of
13 the most common gynecologic conditions in Africa
14 leading to genital pain, itching, and bleeding and
15 markedly increased susceptibility to HIV/AIDS.

16 (13) Fortunately, there is a simple, cost-effec-
17 tive solution to STH and schistosomiasis infections:
18 single-dose deworming pills that can be safely ad-
19 ministered once or twice annually to those at risk.
20 Pharmaceutical companies have committed to donate
21 the drugs needed to treat all at-risk, school-age chil-
22 dren in developing countries. Regular administration
23 of deworming pills reduces morbidity associated with
24 STH and schistosomiasis infections by reducing
25 prevalence and transmission rates.

1 (14) The benefits of deworming are immediate
2 and enduring. A rigorous randomized controlled trial
3 has shown school-based deworming treatment to re-
4 duce school absenteeism by 25 percent. School-based
5 deworming also benefits young siblings and other
6 children who live nearby but are too young to be
7 treated, leading to large cognitive improvements
8 equivalent to half a year of schooling.

9 **SEC. 5. DEFINITION.**

10 In this Act, the term “neglected tropical diseases” or
11 “NTDs”—

12 (1) means infections caused by pathogens, in-
13 cluding viruses, bacteria, protozoa, and helminths
14 that disproportionately impact individuals living in
15 extreme poverty, especially in developing countries;
16 and

17 (2) includes—

18 (A) Buruli ulcer (*Mycobacterium Ulcerans*
19 infection);

20 (B) Chagas disease;

21 (C) dengue or severe dengue fever;

22 (D) dracunculiasis (Guinea worm disease);

23 (E) echinococcosis;

24 (F) foodborne trematodiasis;

- 1 (G) human African trypanosomiasis (sleep-
2 ing sickness);
3 (H) leishmaniasis;
4 (I) leprosy;
5 (J) lymphatic filariasis (elephantiasis);
6 (K) onchocerciasis (river blindness);
7 (L) rabies;
8 (M) schistosomiasis;
9 (N) soil-transmitted helminthiases (STH)
10 (round worm, whip worm, and hook worm);
11 (O) taeniasis/cysticercosis;
12 (P) trachoma; and
13 (Q) yaws (endemic treponematoses).

14 **SEC. 6. RULE OF CONSTRUCTION.**

15 Nothing in this Act shall be construed to increase au-
16 thorizations of appropriations for the United States Agen-
17 cy for International Development or authorizations of ap-
18 propriations for the Department of Health and Human
19 Services.

20 **TITLE I—FOREIGN AFFAIRS**

21 **SEC. 101. EXPANSION OF USAID NTDS PROGRAM.**

22 (a) FINDINGS.—Congress finds the following:

- 23 (1) Since fiscal year 2006, the United States
24 Government has been an essential leading partner in
25 advancing control and elimination efforts for seven

1 targeted neglected tropical diseases: lymphatic fila-
2 riasis (elephantiasis), onchocerciasis (river blind-
3 ness), schistosomiasis, soil-transmitted helminthiases
4 (STH) (round worm, whip worm, and hook worm),
5 and trachoma. Additional information suggests that
6 such efforts could also produce collateral benefits for
7 at least three other NTDs: foodborne trematodiasis,
8 rabies, and yaws (endemic treponematoses).

9 (2) The United States Agency for International
10 Development (USAID) Neglected Tropical Diseases
11 Program has made important and substantial con-
12 tributions to the global fight to control and eliminate
13 the seven most common NTDs. Leveraging more
14 than \$6.7 billion in donated medicines, USAID has
15 supported the distribution of more than one billion
16 treatments in 25 countries across Africa, Asia, and
17 Latin America and the Caribbean.

18 (3) United States Government leadership has
19 been instrumental in maintaining the global fight
20 against NTDs and is a partner in the 2012 London
21 Declaration on NTDs, which represents a new, co-
22 ordinated push to accelerate progress toward elimi-
23 nating or controlling 10 neglected tropical diseases
24 by 2020.

1 (4) The USAID NTDs Program is a clear ex-
2 ample of a successful public-private partnership be-
3 tween the Government and the private sector and
4 should be judiciously expanded.

5 (b) SENSE OF CONGRESS.—It is the sense of Con-
6 gress that the USAID NTDs Program (as in effect on
7 the date of the enactment of this Act) should be modified
8 as follows:

9 (1) Provide rapid impact package treatments to
10 as many individuals suffering from NTDs or at risk
11 of acquiring NTDs as logistically feasible.

12 (2) Better integrate rapid impact package
13 treatments with programs to control and eliminate
14 HIV/AIDS and malaria, including—

15 (A) by coordinating HIV/AIDS programs
16 with the control of female genital schistosomiasis,
17 now revealed as one of Africa’s most im-
18 portant co-factors in its AIDS epidemic; and

19 (B) by coordinating malaria programs with
20 programs to control schistosomiasis and hook
21 worm—together these diseases produce pro-
22 found and severe anemia.

23 (3) Establish school-based NTD programs to
24 provide an opportunity to reach large numbers of
25 school-age children who require treatments for

1 NTDs, including rapid impact package treatments
2 as feasible and at very low cost.

3 (4) For other NTDs, such as human African
4 trypanosomiasis (sleeping sickness), chagas disease,
5 leishmaniasis, and dengue fever, develop new ap-
6 proaches to reach the goals relating to the elimi-
7 nation of NTDs as set forth in the World Health
8 Organization (WHO) NTD Roadmap.

9 (c) EXPANSION OF PROGRAM.—The Administrator of
10 USAID shall expand the USAID NTDs Program (as in
11 effect on the date of the enactment of this Act) as follows:

12 (1) Carry out monitoring and evaluation to pro-
13 vide accurate measurements to inform future NTD
14 control and elimination strategies.

15 (2) Coordinate with USAID development sec-
16 tors, such as sectors relating to water and sanita-
17 tion, hygiene, food security and nutrition, and edu-
18 cation (both primary and preprimary), to establish
19 programs that address NTDs and advance the goals
20 of the 2012 London Declaration on NTDs.

21 (3) Include morbidity management in treatment
22 plans for high-burden NTDs, such as lymphatic fila-
23 riasis (elephantiasis).

24 (4) Include NTDs that are recognized as high-
25 burden diseases in the Global Burden of Disease

1 Study 2010, including foodborne trematodiasis,
2 human African trypanosomiasis (sleeping sickness),
3 chagas disease, leishmaniasis, and dengue fever and
4 related arbovirus infections.

5 (5) Include research and development, con-
6 sistent with other USAID disease prevention pro-
7 grams, to ensure the tools required for elimination
8 of these diseases are available, such as drugs,
9 diagnostics, vaccines.

10 (d) RESEARCH AND DEVELOPMENT.—

11 (1) ESTABLISHMENT.—The Administrator of
12 USAID shall establish a research and development
13 program within the USAID NTDs Program (as in
14 effect on the date of the enactment of this Act).

15 (2) PRIORITY.—The research and development
16 program shall focus on the prevention and control of
17 those diseases with the highest need for new treat-
18 ments, diagnostics, and vaccines, including soil-
19 transmitted helminthiasis (STH) (round worm, whip
20 worm, and hook worm), schistosomiasis, chagas dis-
21 ease, human African trypanosomiasis (sleeping sick-
22 ness), leishmaniasis, and dengue fever and other
23 arbovirus infections.

1 **SEC. 102. ACTIONS BY DEPARTMENT OF STATE.**

2 (a) OFFICE OF THE GLOBAL AIDS COORDINATOR.—

3 Section 1(f)(2)(B)(ii) of the State Department Basic Au-
4 thorities Act of 1956 (22 U.S.C. 2651a(f)(2)(B)(ii)) is
5 amended by adding at the end the following:

6 “(XIV) NEGLECTED TROPICAL
7 DISEASES.—

8 “(aa) IN GENERAL.—Ensuring
9 coordination of activities of
10 the United States (including
11 funding) relating to combatting
12 HIV/AIDS with activities of the
13 United States (including funding)
14 relating to combatting neglected
15 tropical diseases to include the
16 control and elimination of ne-
17 glected tropical diseases, particu-
18 larly in countries and regions
19 that are highly endemic for fe-
20 male genital schistosomiasis.

21 “(bb) DEFINITION.—In this
22 subclause, the term ‘neglected
23 tropical diseases’ has the mean-
24 ing given the term in section 5 of
25 the End Neglected Tropical Dis-
26 eases Act.”.

1 (b) GLOBAL FUND.—

2 (1) IN GENERAL.—The Secretary of State
3 should seek to engage the Global Fund in discus-
4 sions on whether to expand the authority of the
5 Global Fund for the control and elimination of ne-
6 glected tropical diseases.

7 (2) GLOBAL FUND.—In this subsection, the
8 term “Global Fund” means the public-private part-
9 nership known as the Global Fund to Fight AIDS,
10 Tuberculosis and Malaria established pursuant to
11 Article 80 of the Swiss Civil Code.

12 (c) G–20 COUNTRIES.—The Secretary of State, act-
13 ing through the Office of Global Health Diplomacy, should
14 engage G–20 countries to significantly increase their role
15 in the control and elimination of neglected tropical dis-
16 eases, particularly Argentina, Brazil, China, India, Indo-
17 nesia, Mexico, the Republic of Korea, Saudi Arabia, and
18 South Africa.

19 **SEC. 103. MULTILATERAL DEVELOPMENT AND HEALTH IN-**
20 **STITUTIONS.**

21 (a) CONGRESSIONAL FINDING.—Congress finds that
22 the treatment of high burden neglected tropical diseases,
23 including school-based deworming programs, has proven
24 to be a highly cost-effective education intervention and
25 schools can serve as the best delivery mechanism for

1 reaching large numbers of children with safe treatment for
2 soil-transmitted helminthiases (STH) (round worm, whip
3 worm, and hook worm) in particular.

4 (b) UNITED NATIONS.—The President shall direct
5 the United States permanent representative to the United
6 Nations to use the voice, vote, and influence of the United
7 States to urge the World Health Organization, the United
8 Nations Educational, Scientific and Cultural Organiza-
9 tion, and the United Nations Development Programme to
10 take the actions described in subsection (d).

11 (c) WORLD BANK INSTITUTE.—The President shall
12 direct the United States Executive Director at the Inter-
13 national Bank for Reconstruction and Development to use
14 the voice, vote, and influence of the United States to urge
15 the World Bank Institute to take the actions described
16 in subsection (d).

17 (d) ACTIONS DESCRIBED.—The actions described in
18 this subsection are the following:

19 (1) Ensure the dissemination of best practices
20 and programming on NTDs to governments and
21 make data accessible to practitioners in an open and
22 timely fashion.

23 (2) Highlight impacts of school-based
24 deworming programs on children's health and edu-

1 cation, emphasizing the cost-effectiveness of such
2 programs.

3 (3) Encourage governments to implement
4 deworming campaigns at the national level.

5 (4) Designate a portion of grant funds of the
6 institutions to deworming initiatives and cross-sec-
7 toral collaboration with water and sanitation and hy-
8 giene efforts and nutrition or education program-
9 ming.

10 (5) Encourage accurate monitoring and evalua-
11 tion of NTD programs, including deworming pro-
12 grams.

13 (6) Engage governments in cross-border initia-
14 tives for the treatment, control, prevention, and
15 elimination of NTDs, and assist in developing
16 transnational agreements, when necessary.

17 **TITLE II—DEPARTMENT OF**
18 **HEALTH AND HUMAN SERVICES**

19 **SEC. 201. PROMOTING EFFORTS THROUGH INTERAGENCY**
20 **WORKING GROUPS AND INTERNATIONAL FO-**
21 **RUMS.**

22 The Secretary of Health and Human Services shall
23 continue to promote the need for robust programs and ac-
24 tivities to diagnose, prevent, control, and treat neglected
25 tropical diseases—

1 (1) through interagency working groups on
2 health; and

3 (2) through relevant international forums on
4 behalf of the United States, including the post-2015
5 United Nations development agenda.

6 **SEC. 202. REPORT ON NEGLECTED TROPICAL DISEASES IN**
7 **THE UNITED STATES.**

8 (a) IN GENERAL.—Not later than 12 months after
9 the date of enactment of this Act, the Secretary of Health
10 and Human Services, acting through the Director of the
11 Centers for Disease Control and Prevention, shall submit
12 to the Congress a report on neglected tropical diseases in
13 the United States.

14 (b) CONTENTS.—The report required by this section
15 shall—

16 (1) assess the epidemiology of, impact of, and
17 appropriate funding required to address neglected
18 tropical diseases in the United States; and

19 (2) include the information necessary—

20 (A) to guide future health policy with re-
21 spect to such diseases;

22 (B) to accurately evaluate the current
23 state of knowledge concerning such diseases;

24 and

25 (C) to define gaps in such knowledge.

1 **SEC. 203. CENTERS OF EXCELLENCE.**

2 Part P of title III of the Public Health Service Act
3 is amended by inserting after section 399V-5 of such Act
4 (42 U.S.C. 280g-16) the following:

5 **“SEC. 399V-6. NEGLECTED TROPICAL DISEASE CENTERS OF**
6 **EXCELLENCE.**

7 “(a) COOPERATIVE AGREEMENTS AND GRANTS.—

8 “(1) IN GENERAL.—The Secretary, acting
9 through the Director of the National Institute of Al-
10 lergy and Infectious Diseases or the Administrator
11 of the Health Resources and Services Administra-
12 tion, as appropriate, may enter into cooperative
13 agreements with, and make grants to, public or pri-
14 vate nonprofit entities to pay all or part of the cost
15 of planning, establishing, or strengthening, and pro-
16 viding basic operating support for, one or more cen-
17 ters of excellence for research into, training in, and
18 development of diagnosis, prevention, control, and
19 treatment methods for neglected tropical diseases.

20 “(2) ELIGIBILITY.—To be eligible for a cooper-
21 ative agreement or grant under this section, an enti-
22 ty must—

23 “(A) have demonstrated expertise in re-
24 search on, and the epidemiology and surveil-
25 lance of, the major neglected tropical diseases
26 that are endemic to the United States, such as

1 Chagas disease, dengue, leishmaniasis, and
2 West Nile virus infection, and helminth infec-
3 tions; and

4 “(B) participate in one or more not-for-
5 profit product development partnerships.

6 “(b) POLICIES.—A cooperative agreement or grant
7 under paragraph (1) shall be entered into or awarded in
8 accordance with policies established by the Director of the
9 National Institutes of Health or the Health Resources and
10 Services Administration, as applicable.

11 “(c) COORDINATION WITH OTHER INSTITUTES.—
12 The Secretary shall coordinate the activities under this
13 section with similar activities conducted by other national
14 research institutes, centers, and agencies of the National
15 Institutes of Health to the extent that such institutes, cen-
16 ters, and agencies have responsibilities that are related to
17 neglected tropical diseases.

18 “(d) USES OF FUNDS.—A cooperative agreement or
19 grant under subsection (a) may be used for—

20 “(1) staffing, administrative, and other basic
21 operating costs, including such patient care costs as
22 are required for research;

23 “(2) clinical training, including training for al-
24 lied health professionals, continuing education for
25 health professionals and allied health professions

1 personnel, and information programs for the public
2 with respect to neglected tropical diseases; and

3 “(3) research and development programs.

4 “(e) PERIOD OF SUPPORT; ADDITIONAL PERIODS.—

5 “(1) IN GENERAL.—Support of a center of ex-
6 cellence under this section may be for a period of
7 not more than 5 years.

8 “(2) EXTENSIONS.—The period specified in
9 paragraph (1) may be extended by the Secretary for
10 additional periods of not more than 5 years if—

11 “(A) the operations of the center of excel-
12 lence involved have been reviewed by an appro-
13 priate technical and scientific peer review
14 group; and

15 “(B) such group has recommended to the
16 Secretary that such period should be extended.

17 “(f) DEFINITIONS.—In this section:

18 “(1) The term ‘neglected tropical disease’ has
19 the meaning given to that term in section 5 of the
20 End Neglected Tropical Diseases Act.

21 “(2) The term ‘product development partner-
22 ship’ means a partnership to bring together public
23 and private sector researchers to develop new, or im-
24 prove on current, global health tools, such as drugs,

1 diagnostics, insecticides, vaccines, and vector man-
2 agement strategies—

3 “(A) that are for neglected tropical dis-
4 eases; and

5 “(B) for which there is generally no profit-
6 able market.

7 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
8 carry out this section, there are authorized to be appro-
9 priated such sums as may be necessary for each of the
10 fiscal years 2015 through 2019.”.

11 **SEC. 204. PANEL ON WORM INFECTION SOLUTIONS.**

12 (a) ESTABLISHMENT.—The Director of the National
13 Institutes of Health, in consultation with the Adminis-
14 trator of the United States Agency for International De-
15 velopment, shall establish a panel to conduct an evaluation
16 of issues relating to worm infections, including potential
17 solutions such as deworming medicines (in this section re-
18 ferred to as the “panel”).

19 (b) STRATEGIES.—The panel shall develop rec-
20 ommendations for strategies for solutions with respect
21 to—

22 (1) repeat infections;

23 (2) vector control;

24 (3) clean water solutions;

1 (4) identifying incentives to encourage basic re-
2 search for less toxic, more effective medicines; and

3 (5) improving the success and cost efficiency of
4 current programs in these areas, based on a thor-
5 ough scan of initiatives already underway in both
6 the public and private sectors.

7 (c) APPOINTMENT OF MEMBERS.—The Director of
8 the National Institutes of Health shall appoint as mem-
9 bers of the panel individuals from the public and private
10 sectors who are knowledgeable about or affected by worm
11 infections, including—

12 (1) at least 2 representatives of nongovern-
13 mental organizations;

14 (2) at least 2 representatives of private industry
15 involved in the development of de-worming medica-
16 tions;

17 (3) at least 2 representatives from academia;
18 and

19 (4) representatives of industries relating to
20 sanitation, clean water, and vector control.

21 (d) REPORT.—Not later than 1 year after the date
22 of the enactment of this Act, the panel shall submit to
23 Congress and the Director of the National Institutes of
24 Health a report on its findings and recommended strate-
25 gies, including recommendations for such administrative

1 action and legislation as the panel determines to be appro-
2 priate.

3 (e) TERMINATION.—The panel shall terminate not
4 later than 6 months after submitting the report required
5 by subsection (d).

○