

111TH CONGRESS
1ST SESSION

H. R. 1179

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 25, 2009

Mr. SMITH of New Jersey (for himself, Mr. WOLF, Mr. STUPAK, and Mr. HOLDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To provide for the expansion of Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

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 “Lyme and Tick-Borne
5 Diseases Prevention, Education, and Research Act of
6 2009”.

1 **SEC. 2. FINDINGS.**

2 The Congress makes the following findings:

3 (1) Lyme disease is a common but frequently
4 misunderstood illness that, if not caught early and
5 treated properly, can cause serious health problems.

6 (2) Lyme disease is caused by the bacterium
7 *Borrelia burgdorferi*, which belongs to the class of
8 spirochetes, and is transmitted to humans by the
9 bite of infected black-legged ticks. Early signs of in-
10 fection may include a rash and flu-like symptoms
11 such as fever, muscle aches, headaches, and fatigue.

12 (3) Although Lyme disease can be treated with
13 antibiotics if caught early, the disease often goes un-
14 detected because it mimics other illnesses or may be
15 misdiagnosed.

16 (4) If an individual with Lyme disease does not
17 receive treatment, such individual can develop severe
18 heart, neurological, eye, and joint problems.

19 (5) Although Lyme disease accounts for 90 per-
20 cent of all vector-borne infections in the United
21 States, the ticks that spread Lyme disease also
22 spread other diseases, such as anaplasmosis,
23 babesiosis, and tularemia, and carry *Bartonella* and
24 other strains of *Borrelia*. Other tick species, such as
25 the aggressive lone star, spread ehrlichiosis, Rocky
26 Mountain spotted fever, and southern tick-associated

1 rash illness (STARI). Multiple diseases in 1 patient
2 make diagnosis and treatment more difficult.

3 (6) The Centers for Disease Control and Pre-
4 vention reported 27,444 new cases of Lyme disease
5 in 2007, a 38 percent increase nationally from 2006.
6 Studies indicate that the actual number of tick-
7 borne disease cases is approximately 10 times the
8 amount reported.

9 (7) According to the Centers for Disease Con-
10 trol and Prevention, from 1992 to 2006, the inci-
11 dence of Lyme disease was highest among children
12 aged 5 to 14 years of age.

13 (8) Persistence of symptomatology in many pa-
14 tients without reliable testing makes treatment of
15 patients more difficult.

16 **SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVI-**
17 **SORY COMMITTEE.**

18 (a) ESTABLISHMENT.—Not later than 180 days after
19 the date of the enactment of this Act, the Secretary of
20 Health and Human Services (referred to in this Act as
21 the “Secretary”) shall establish within the Office of the
22 Secretary an advisory committee to be known as the Tick-
23 Borne Diseases Advisory Committee (referred to in this
24 section as the “Committee”).

1 (b) DUTIES.—The Committee shall advise the Sec-
2 retary and the Assistant Secretary for Health regarding
3 the manner in which such officials can—

4 (1) ensure interagency coordination and com-
5 munication and minimize overlap regarding efforts
6 to address tick-borne diseases;

7 (2) identify opportunities to coordinate efforts
8 with other Federal agencies and private organiza-
9 tions addressing such diseases;

10 (3) ensure interagency coordination and com-
11 munication with constituency groups;

12 (4) ensure that a broad spectrum of scientific
13 viewpoints is represented in public health policy deci-
14 sions and that information disseminated to the pub-
15 lic and physicians is balanced; and

16 (5) advise relevant Federal agencies on prior-
17 ities related to the Lyme and tick-borne diseases.

18 (c) MEMBERSHIP.—

19 (1) APPOINTED MEMBERS.—

20 (A) IN GENERAL.—The Secretary shall ap-
21 point the voting members of the Committee
22 from among individuals who are not officers or
23 employees of the Federal Government.

24 (B) GROUPS.—The voting members of the
25 Committee shall include the following:

1 (i) At least 4 members from the sci-
2 entific community representing the broad
3 spectrum of viewpoints held within the sci-
4 entific community related to Lyme and
5 other tick-borne diseases.

6 (ii) At least 2 representatives of tick-
7 borne disease voluntary organizations.

8 (iii) At least 2 health care providers,
9 including at least 1 full-time practicing
10 physician, with relevant experience pro-
11 viding care for individuals with a broad
12 range of acute and chronic tick-borne dis-
13 eases.

14 (iv) At least 2 patient representatives
15 who are individuals who have been diag-
16 nosed with a tick-borne disease or who
17 have had an immediate family member di-
18 agnosed with such a disease.

19 (v) At least 2 representatives of State
20 and local health departments and national
21 organizations that represent State and
22 local health professionals.

23 (C) DIVERSITY.—In appointing members
24 under this paragraph, the Secretary shall en-
25 sure that such members, as a group, represent

1 a diversity of scientific perspectives relevant to
2 the duties of the Committee.

3 (2) EX OFFICIO MEMBERS.—The Secretary
4 shall designate, as nonvoting, ex officio members of
5 the Committee, representatives overseeing tick-borne
6 disease activities from each of the following Federal
7 agencies:

8 (A) The Centers for Disease Control and
9 Prevention.

10 (B) The National Institutes of Health.

11 (C) The Agency for Healthcare Research
12 and Quality.

13 (D) The Food and Drug Administration.

14 (E) The Office of the Assistant Secretary
15 for Health.

16 (F) Such additional Federal agencies as
17 the Secretary determines to be appropriate.

18 (3) CO-CHAIRPERSONS.—The Secretary shall
19 designate the Assistant Secretary of Health as the
20 co-chairperson of the Committee. The appointed
21 members of the Committee shall also elect a public
22 co-chairperson. The public co-chairperson shall serve
23 a 2-year term.

1 (4) TERM OF APPOINTMENT.—The term of
2 service for each member of the Committee appointed
3 under paragraph (1) shall be 4 years.

4 (5) VACANCY.—A vacancy in the membership of
5 the Committee shall be filled in the same manner as
6 the original appointment. Any member appointed to
7 fill a vacancy for an unexpired term shall be ap-
8 pointed for the remainder of that term. Members
9 may serve after the expiration of their terms until
10 their successors have taken office.

11 (d) MEETINGS.—The Committee shall hold public
12 meetings, except as otherwise determined by the Sec-
13 retary, after providing notice to the public of such meet-
14 ings, and shall meet at least twice a year with additional
15 meetings subject to the call of the co-chairpersons. Agenda
16 items with respect to such meetings may be added at the
17 request of the members of the Committee, including the
18 co-chairpersons. Meetings shall be conducted, and records
19 of the proceedings shall be maintained, as required by ap-
20 plicable law and by regulations of the Secretary.

21 (e) REPORT.—Not later than 1 year after the date
22 of the enactment of this Act, and annually thereafter, the
23 Committee, through the Director of the Centers for Dis-
24 ease Control and Prevention and the Director of the Na-
25 tional Institutes of Health, shall submit a report to the

1 Secretary. Each such report shall contain, at a min-
2 imum—

3 (1) a description of the Committee's functions;

4 (2) a list of the Committee's members and their
5 affiliations; and

6 (3) a summary of the Committee's activities
7 and recommendations during the previous year, in-
8 cluding any significant issues regarding the func-
9 tioning of the Committee.

10 (f) AUTHORIZATION OF APPROPRIATIONS.—For the
11 purpose of carrying out this section, there is authorized
12 to be appropriated \$250,000 for each of fiscal years 2010
13 through 2014. Amounts appropriated under the preceding
14 sentence shall be used for the expenses and per diem costs
15 incurred by the Committee under this section in accord-
16 ance with the Federal Advisory Committee Act, except
17 that no voting member of the Committee shall be a perma-
18 nent salaried employee.

19 **SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS,**
20 **SURVEILLANCE, PREVENTION, AND RE-**
21 **SEARCH OF LYME AND OTHER TICK-BORNE**
22 **DISEASES.**

23 (a) IN GENERAL.—The Secretary, acting as appro-
24 priate through the Director of the Centers for Disease
25 Control and Prevention, the Director of the National Insti-

1 tutes of Health, the Commissioner of Food and Drugs,
2 and the Director of the Agency for Healthcare Research
3 and Quality, as well as additional Federal agencies as the
4 Secretary determines to be appropriate, and in consulta-
5 tion with the Tick-Borne Diseases Advisory Committee,
6 shall provide for—

7 (1) the conduct or support of activities de-
8 scribed in paragraphs (1) through (4) of subsection
9 (b); and

10 (2) the coordination of all Federal programs
11 and activities related to Lyme disease and other
12 tick-borne diseases.

13 (b) ACTIVITIES.—The activities to be conducted or
14 supported under subsection (a) include the following:

15 (1) DEVELOPMENT OF DIAGNOSTIC TESTS.—

16 (A) The development of sensitive and more
17 accurate diagnostic tools and tests, including a
18 direct detection test for Lyme disease capable
19 of distinguishing active infection from past in-
20 fection.

21 (B) Improving the efficient utilization of
22 diagnostic testing currently available to account
23 for the multiple clinical manifestations of both
24 acute and chronic Lyme disease.

1 (C) Providing for the timely evaluation of
2 promising emerging diagnostic methods.

3 (2) SURVEILLANCE AND REPORTING.—

4 (A) Accurately determining the prevalence
5 of Lyme and other tick-borne disease.

6 (B) Evaluating the feasibility of developing
7 a reporting system for the collection of data on
8 physician-diagnosed cases of Lyme disease that
9 do not meet the surveillance criteria of the Cen-
10 ters for Disease Control and Prevention in
11 order to more accurately gauge disease inci-
12 dence.

13 (C) Evaluating the feasibility of creating a
14 national uniform reporting system including re-
15 quired reporting by laboratories in each State.

16 (3) PREVENTION.—

17 (A) The provision and promotion of access
18 to a comprehensive, up-to-date clearinghouse of
19 peer-reviewed information on Lyme and other
20 tick-borne disease.

21 (B) Increased public education related to
22 Lyme and other tick-borne diseases through the
23 expansion of the community-based education
24 programs of the Centers for Disease Control

1 and Prevention to include expansion of informa-
2 tion access points to the public.

3 (C) The creation of a physician education
4 program that includes the full spectrum of sci-
5 entific research related to Lyme and other tick-
6 borne diseases.

7 (D) The sponsoring of scientific con-
8 ferences on Lyme and other tick-borne diseases,
9 including reporting and consideration of the full
10 spectrum of clinically based knowledge, with the
11 first of such conferences to be held not later
12 than 24 months after the date of the enactment
13 of this Act.

14 (4) CLINICAL OUTCOMES RESEARCH.—

15 (A) The establishment of epidemiological
16 research objectives to determine the long-term
17 course of illness for Lyme disease.

18 (B) Determination of the effectiveness of
19 different treatment modalities by establishing
20 treatment outcome objectives.

21 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
22 purposes of carrying out this section and providing for ad-
23 ditional research, prevention, and educational activities for
24 Lyme and other tick-borne diseases, there is authorized
25 to be appropriated \$20,000,000 for each of fiscal years

1 2010 through 2014. Such authorization of appropriations
2 is in addition to any other authorization of appropriations
3 available for such purpose. Of the amounts authorized to
4 be appropriated under this subsection—

5 (1) for fiscal year 2010, at least \$7,500,000
6 shall be for activities of the Centers for Disease Con-
7 trol and Prevention; and

8 (2) for each of fiscal years 2011 through 2014,
9 at least \$5,000,000 shall be for activities of the Cen-
10 ters for Disease Control and Prevention.

11 **SEC. 5. REPORTS ON LYME AND OTHER TICK-BORNE DIS-**
12 **EASES.**

13 (a) IN GENERAL.—Not later than 18 months after
14 the date of the enactment of this Act, and annually there-
15 after, the Secretary shall submit to the Congress a report
16 on the activities carried out under this Act.

17 (b) CONTENT.—Reports under subsection (a) shall
18 contain—

19 (1) a description of significant activities or de-
20 velopments related to the surveillance, diagnosis,
21 treatment, education, or prevention of Lyme or other
22 tick-borne diseases, including suggestions for further
23 research and education;

24 (2) a scientifically qualified assessment of Lyme
25 and other tick-borne diseases, including both acute

1 and chronic instances, related to the broad spectrum
2 of empirical evidence of treating physicians, as well
3 as published peer-reviewed data, that shall include
4 recommendations for addressing research gaps in di-
5 agnosis and treatment of Lyme and other tick-borne
6 diseases and an evaluation of treatment guidelines
7 and their utilization;

8 (3) a description of progress in the development
9 of accurate diagnostic tools that are more useful in
10 the clinical setting for both acute and chronic dis-
11 ease;

12 (4) a description of activities for the promotion
13 of public awareness and physician education initia-
14 tives to improve the knowledge of health care pro-
15 viders and the public regarding clinical and surveil-
16 lance practices for Lyme disease and other tick-
17 borne diseases; and

18 (5) a copy of the most recent annual report
19 issued by the Tick-Borne Diseases Advisory Com-
20 mittee established in section 3 and an assessment of
21 progress in achieving recommendations of that Com-
22 mittee.

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