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S. 1352

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 SENATE OF THE UNITED STATES

JUNE 25, 2009

Mr. DODD (for himself, Ms. COLLINS, Mr. REED, Mr. LIEBERMAN, Mr. CARDIN, and Mr. WHITEHOUSE) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 Disease Prevention, Education, and Research Act of
6 2009”.

1 **SEC. 2. FINDINGS.**

2 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. Untreated, Lyme disease can lead to
16 severe heart, neurological, eye, and joint problems
17 because the bacteria can affect many different or-
18 gans and organ systems.

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

22 (5) Although Lyme disease accounts for 90 per-
23 cent of all vector-borne infections in the United
24 States, the ticks that spread Lyme disease also
25 spread other diseases, such as anaplasmosis,
26 babesiosis, and tularemia, and carry *Bartonella* and

1 other strains of *Borrelia*. Other tick species, such as
2 the aggressive lone star, spread ehrlichiosis, Rocky
3 Mountain spotted fever, and southern tick-associated
4 rash illness (STARI). Multiple diseases in 1 patient
5 make diagnosis and treatment more difficult.

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

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

16 (8) Persistence of symptomatology in many pa-
17 tients without reliable testing makes treatment of
18 patients more difficult.

19 **SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVI-**
20 **SORY COMMITTEE.**

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

1 Borne Diseases Advisory Committee (referred to in this
2 section as the “Committee”).

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

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

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

12 (3) ensure interagency coordination and com-
13 munication with constituency groups;

14 (4) ensure that a broad spectrum of scientific
15 viewpoints are represented in public health policy de-
16 cisions and that information disseminated to the
17 public and physicians is balanced; and

18 (5) advise relevant Federal agencies on prior-
19 ities related to Lyme and other tick-borne diseases.

20 (c) MEMBERSHIP.—

21 (1) APPOINTED MEMBERS.—

22 (A) IN GENERAL.—From among individ-
23 uals who are not officers or employees of the
24 Federal Government, the Secretary shall ap-

1 point to the Committee, as voting members, the
2 following:

3 (i) Not less than 4 members from the
4 scientific community representing the
5 broad spectrum of viewpoints held within
6 the scientific community related to Lyme
7 and other tick-borne diseases.

8 (ii) Not less than 2 representatives of
9 tick-borne disease voluntary organizations.

10 (iii) Not less than 2 health care pro-
11 viders, including not less than 1 full-time
12 practicing physician, with relevant experi-
13 ence providing care for individuals with a
14 broad range of acute and chronic tick-
15 borne diseases.

16 (iv) Not less than 2 patient represent-
17 atives who are individuals who have been
18 diagnosed with a tick-borne disease or who
19 have had an immediate family member di-
20 agnosed with such a disease.

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

1 (B) DIVERSITY.—In appointing members
2 under this paragraph, the Secretary shall en-
3 sure that such members, as a group, represent
4 a diversity of scientific perspectives relevant to
5 the duties of the Committee.

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

11 (A) The Centers for Disease Control and
12 Prevention.

13 (B) The National Institutes of Health.

14 (C) The Agency for Healthcare Research
15 and Quality.

16 (D) The Food and Drug Administration.

17 (E) The Office of the Assistant Secretary
18 for Health.

19 (F) Such additional Federal agencies as
20 the Secretary determines to be appropriate.

21 (3) CO-CHAIRPERSONS.—The Secretary shall
22 designate the Assistant Secretary of Health as the
23 co-chairperson of the Committee. The appointed
24 members of the Committee shall also elect a public

1 co-chairperson. The public co-chairperson shall serve
2 a 2-year term.

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

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

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

23 (e) REPORT.—Not later than 1 year after the date
24 of enactment of this Act, and annually thereafter, the
25 Committee, acting through the members representing the

1 Centers for Disease Control and Prevention and the Na-
2 tional Institutes of Health, shall submit a report to the
3 Secretary. Each such report shall contain, at a min-
4 imum—

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

6 (2) a list of the Committee's members and their
7 affiliations; and

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

12 (f) AUTHORIZATION OF APPROPRIATIONS.—For the
13 purpose of carrying out this section, there is authorized
14 to be appropriated \$250,000 for each of the fiscal years
15 2010 through 2014. Amounts appropriated under the pre-
16 ceding sentence shall be used for the expenses and per
17 diem costs incurred by the Committee under this section
18 in accordance with the Federal Advisory Committee Act
19 (5 U.S.C. App.), except that no voting member of the
20 Committee shall be a permanent salaried employee.

1 **SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS,**
2 **SURVEILLANCE, PREVENTION, AND RE-**
3 **SEARCH OF LYME AND OTHER TICK-BORNE**
4 **DISEASES.**

5 (a) IN GENERAL.—The Secretary, acting as appro-
6 priate through the Director of the Centers for Disease
7 Control and Prevention, the Director of the National Insti-
8 tutes of Health, the Commissioner of Food and Drugs,
9 and the Director of the Agency for Healthcare Research
10 and Quality, as well as additional Federal agencies as the
11 Secretary determines to be appropriate, and in consulta-
12 tion with the Tick-Borne Diseases Advisory Committee,
13 shall provide for—

14 (1) the conduct or support of the activities de-
15 scribed in subsection (b); and

16 (2) the coordination of all Federal programs
17 and activities related to Lyme disease and other
18 tick-borne diseases.

19 (b) ACTIVITIES.—The activities described in this sub-
20 section are the following:

21 (1) DEVELOPMENT OF DIAGNOSTIC TESTS.—

22 Such activities include—

23 (A) the development of sensitive and more
24 accurate diagnostic tools and tests, including a
25 direct detection test for Lyme disease capable

1 of distinguishing active infection from past in-
2 fection;

3 (B) improving the efficient utilization of
4 diagnostic testing currently available to account
5 for the multiple clinical manifestations of both
6 acute and chronic Lyme disease; and

7 (C) providing for the timely evaluation of
8 promising emerging diagnostic methods.

9 (2) SURVEILLANCE AND REPORTING.—Such ac-
10 tivities include surveillance and reporting of Lyme
11 and other tick-borne diseases—

12 (A) to accurately determine the prevalence
13 of Lyme and other tick-borne diseases;

14 (B) to evaluate the feasibility of developing
15 a reporting system for the collection of data on
16 physician-diagnosed cases of Lyme disease that
17 do not meet the surveillance criteria of the Cen-
18 ters for Disease Control and Prevention in
19 order to more accurately gauge disease inci-
20 dence; and

21 (C) to evaluate the feasibility of creating a
22 national uniform reporting system including re-
23 quired reporting by laboratories in each State.

24 (3) PREVENTION.—Such activities include—

1 (A) the provision and promotion of access
2 to a comprehensive, up-to-date clearinghouse of
3 peer-reviewed information on Lyme and other
4 tick-borne diseases;

5 (B) increased public education related to
6 Lyme and other tick-borne diseases through the
7 expansion of the Community Based Education
8 Programs of the Centers for Disease Control
9 and Prevention to include expansion of informa-
10 tion access points to the public;

11 (C) the creation of a physician education
12 program that includes the full spectrum of sci-
13 entific research related to Lyme and other tick-
14 borne diseases; and

15 (D) the sponsoring of scientific conferences
16 on Lyme and other tick-borne diseases, includ-
17 ing reporting and consideration of the full spec-
18 trum of clinically based knowledge, with the
19 first of such conferences to be held not later
20 than 24 months after the date of enactment of
21 this Act.

22 (4) CLINICAL OUTCOMES RESEARCH.—Such ac-
23 tivities include—

1 (A) the establishment of epidemiological
2 research objectives to determine the long term
3 course of illness for Lyme disease; and

4 (B) determination of the effectiveness of
5 different treatment modalities by establishing
6 treatment outcome objectives.

7 (c) AUTHORIZATION OF APPROPRIATIONS.—

8 (1) IN GENERAL.—For the purposes of carrying
9 out this section, and for the purposes of providing
10 for additional research, prevention, and educational
11 activities for Lyme and other tick-borne diseases,
12 there is authorized to be appropriated \$20,000,000
13 for each of the fiscal years 2010 through 2014.

14 (2) CDC ACTIVITIES.—Of the amounts author-
15 ized to be appropriated under paragraph (1)—

16 (A) for fiscal year 2010, not less than
17 \$7,500,000 shall be for activities of the Centers
18 for Disease Control and Prevention that sup-
19 port the purposes described in such paragraph;
20 and

21 (B) for each of fiscal years 2011 through
22 2014, not less than \$5,000,000 shall be for
23 such activities of the Centers for Disease Con-
24 trol and Prevention.

1 (3) ADDITIONAL AMOUNTS.—The authorization
2 of appropriations under this subsection is in addition
3 to any other authorization of appropriations avail-
4 able for the purposes described in paragraph (1).

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

7 (a) IN GENERAL.—Not later than 18 months after
8 the date of enactment of this Act, and annually thereafter,
9 the Secretary shall submit to Congress a report on the
10 activities carried out under this Act.

11 (b) CONTENT.—Reports under subsection (a) shall
12 contain—

13 (1) significant activities or developments related
14 to the surveillance, diagnosis, treatment, education,
15 or prevention of Lyme or other tick-borne diseases,
16 including suggestions for further research and edu-
17 cation;

18 (2) a scientifically qualified assessment of Lyme
19 and other tick-borne diseases, including both acute
20 and chronic instances, related to the broad spectrum
21 of empirical evidence of treating physicians, as well
22 as published peer reviewed data, that shall include
23 recommendations for addressing research gaps in di-
24 agnosis and treatment of Lyme and other tick-borne

1 diseases and an evaluation of treatment guidelines
2 and their utilization;

3 (3) progress in the development of accurate di-
4 agnostic tools that are more useful in the clinical
5 setting for both acute and chronic disease;

6 (4) the promotion of public awareness and phy-
7 sician education initiatives to improve the knowledge
8 of health care providers and the public regarding
9 clinical and surveillance practices for Lyme disease
10 and other tick-borne diseases; and

11 (5) a copy of the most recent annual report
12 issued by the Tick-Borne Diseases Advisory Com-
13 mittee established under section 3 and an assess-
14 ment of progress in achieving the recommendations
15 included in the Committee's report.

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