

111TH CONGRESS  
1ST SESSION

# 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.

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## 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

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# 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.

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

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 appropriate through the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the Director of the Agency for Healthcare Research and Quality, as well as additional Federal agencies as the Secretary determines to be appropriate, and in consultation with the Tick-Borne Diseases Advisory Committee, shall provide for—

14                 (1) the conduct or support of the activities described in subsection (b); and

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

19         (b) **ACTIVITIES.**—The activities described in this subsection are the following:

21                 (1) **DEVELOPMENT OF DIAGNOSTIC TESTS.**—  
22         Such activities include—

23                 (A) the development of sensitive and more accurate diagnostic tools and tests, including a 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—

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

(B) increased public education related to Lyme and other tick-borne diseases through the expansion of the Community Based Education Programs of the Centers for Disease Control and Prevention to include expansion of information access points to the public;

(C) the creation of a physician education program that includes the full spectrum of scientific research related to Lyme and other tick-borne diseases; and

(D) the sponsoring of scientific conferences on Lyme and other tick-borne diseases, including reporting and consideration of the full spectrum of clinically based knowledge, with the first of such conferences to be held not later than 24 months after the date of enactment of 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

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

7 (c) AUTHORIZATION OF APPROPRIATIONS.—

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.

## 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—

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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