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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

APRIL 11, 2013

Mr. BLUMENTHAL (for himself, Mrs. GILLIBRAND, Mr. REED, Mr. LAUTENBERG, Mr. WHITEHOUSE, Mr. FRANKEN, Ms. KLOBUCHAR, and Mr. SCHUMER) 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 2013”.

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 over 33,000 confirmed or probable
8 Lyme Disease cases in 2011.

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 diagnosis and
15 treatment of 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”).

25 (b) DUTIES.—The Committee shall—

1 (1) advise the Secretary and the Assistant Sec-
2 retary for Health regarding the manner in which
3 such officials can—

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

7 (B) identify opportunities to coordinate ef-
8 forts with other Federal agencies and private
9 organizations addressing such diseases;

10 (C) ensure interagency coordination and
11 communication with constituency groups;

12 (D) ensure that a broad spectrum of sci-
13 entific viewpoints are represented in public
14 health policy decisions and that information dis-
15 seminated to the public and physicians is bal-
16 anced; and

17 (E) advise relevant Federal agencies on
18 priorities related to Lyme and other tick-borne
19 diseases; and

20 (2) in coordination with relevant agencies with-
21 in the Department of Health and Human Services,
22 regularly review published public and private treat-
23 ment guidelines and evaluate such guidelines for ef-
24 fective representation of a wide diversity of views.

25 (c) MEMBERSHIP.—

(1) APPOINTED MEMBERS.—

(A) IN GENERAL.—From among individuals who are not officers or employees of the Federal Government, the Secretary shall appoint to the Committee, as voting members, the following:

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

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

(iii) Not less than 2 health care providers, including not less than 1 full-time practicing physician, with relevant experience providing care for individuals with a broad range of acute and chronic tick-borne diseases.

(iv) Not less than 2 patient representatives who are individuals who have been diagnosed with a tick-borne disease or who have had an immediate family member diagnosed with such a disease.

1 (v) At least 2 representatives of State
2 and local health departments and national
3 organizations that represent State and
4 local health professionals.

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

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

15 (A) The Centers for Disease Control and
16 Prevention.

17 (B) The National Institutes of Health.

18 (C) The Agency for Healthcare Research
19 and Quality.

20 (D) The Food and Drug Administration.

21 (E) The Office of the Assistant Secretary
22 for Health.

23 (F) Such additional Federal agencies as
24 the Secretary determines to be appropriate.

1 (3) CO-CHAIRPERSONS.—The Secretary shall
2 designate the Assistant Secretary of Health as the
3 co-chairperson of the Committee. The appointed
4 members of the Committee shall also elect a public
5 co-chairperson. The public co-chairperson shall serve
6 a 2-year term.

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

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

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

1 of the proceedings shall be maintained, as required by ap-
2 plicable law and by regulations of the Secretary.

3 (e) REPORT.—Not later than 1 year after the date
4 of enactment of this Act, and annually thereafter, the
5 Committee, acting through the members representing the
6 Centers for Disease Control and Prevention and the Na-
7 tional Institutes of Health, shall submit a report to the
8 Secretary. Each such report shall contain, at a min-
9 imum—

10 (1) a description of the Committee’s functions;

11 (2) a list of the Committee’s members and their
12 affiliations; and

13 (3) a summary of the Committee’s activities
14 and recommendations during the previous year, in-
15 cluding any significant issues regarding the func-
16 tioning of the Committee.

17 (f) AUTHORIZATION OF APPROPRIATIONS.—For the
18 purpose of carrying out this section, there is authorized
19 to be appropriated such sums as may be necessary for
20 each of the fiscal years 2014 through 2018. Amounts ap-
21 propriated under the preceding sentence shall be used for
22 the expenses and per diem costs incurred by the Com-
23 mittee under this section in accordance with the Federal
24 Advisory Committee Act (5 U.S.C. App.), except that no

1 voting member of the Committee shall be a permanent sal-
 2 aried employee.

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

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

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

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

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

23 (1) DEVELOPMENT OF DIAGNOSTIC TESTS.—
 24 Such activities include—

1 (A) the development of sensitive and more
2 accurate diagnostic tools and tests, including a
3 direct detection test for Lyme disease capable
4 of distinguishing active infection from past in-
5 fection;

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

10 (C) providing for the timely evaluation of
11 promising emerging diagnostic methods.

12 (2) SURVEILLANCE AND REPORTING.—Such ac-
13 tivities include surveillance and reporting of Lyme
14 and other tick-borne diseases—

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

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

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

4 (3) PREVENTION.—Such activities include—

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

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

15 (C) the creation of a physician education
16 program that includes the full spectrum of sci-
17 entific research related to Lyme and other tick-
18 borne diseases, and, in coordination with the
19 Advisory Committee established under section
20 3, the publication of an annual report that eval-
21 uates published guidelines and current research
22 available on Lyme disease, in order to best edu-
23 cate health professionals on the latest research
24 and diversity of treatment options for Lyme
25 disease; and

1 (D) the sponsoring of scientific conferences
 2 on Lyme and other tick-borne diseases, includ-
 3 ing reporting and consideration of the full spec-
 4 trum of clinically based knowledge, with the
 5 first of such conferences to be held not later
 6 than 24 months after the date of enactment of
 7 this Act.

8 (4) CLINICAL OUTCOMES RESEARCH.—Such ac-
 9 tivities include—

10 (A) the establishment of epidemiological
 11 research objectives to determine the long-term
 12 course of illness for Lyme disease; and

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

16 (c) AUTHORIZATION OF APPROPRIATIONS.—

17 (1) IN GENERAL.—For the purposes of carrying
 18 out this section, and for the purposes of providing
 19 for additional research, prevention, and educational
 20 activities for Lyme and other tick-borne diseases,
 21 there is authorized to be appropriated such sums as
 22 may be necessary for each of the fiscal years 2014
 23 through 2018.

24 (2) ADDITIONAL AMOUNTS.—The authorization
 25 of appropriations under this subsection is in addition

1 to any other authorization of appropriations avail-
2 able for the purposes described in paragraph (1).

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

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

9 (b) CONTENT.—Reports under subsection (a) shall
10 contain—

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

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

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

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

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

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