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1ST SESSION

S. 1503

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

IN THE SENATE OF THE UNITED STATES

JUNE 4, 2015

Mr. BLUMENTHAL (for himself, Ms. AYOTTE, Mrs. GILLIBRAND, Mr. REED, Ms. KLOBUCHAR, Mr. COONS, Mr. WHITEHOUSE, Mr. CASEY, 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 enhanced Federal efforts concerning the prevention, education, treatment, and research activities related to Lyme disease 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 2015”.

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 spirochaetes, and is transmitted to humans by the
9 bite of infected ticks. Early signs of infection may
10 include a rash and flu-like symptoms, such as fever,
11 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, and joint problems be-
17 cause the bacteria can affect many different organs
18 and organ systems.

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

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

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

6 (6) The Centers for Disease Control and Pre-
7 vention reported over 36,000 confirmed or probable
8 Lyme disease cases in 2013 and has estimated that
9 the total number of people diagnosed with Lyme dis-
10 ease annually is roughly 10 times higher than the
11 number of cases 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 5 to 14 years of age.

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

19 (9) In the absence of a safe and effective
20 human vaccine, reducing exposure to ticks is the
21 best defense against Lyme disease, Rocky Mountain
22 spotted fever, and other tick-borne diseases. Ento-
23 mology-based approaches to prevent tick-borne dis-
24 eases include the use and development of insect re-

1 health policy decisions and that information dis-
2 seminated to the public and physicians is based
3 on the best available science and is appro-
4 priately balanced; and

5 (E) advise relevant Federal agencies on
6 priorities related to Lyme disease and other
7 tick-borne diseases; and

8 (2) in coordination with relevant agencies with-
9 in the Department of Health and Human Services,
10 regularly review published public and private treat-
11 ment guidelines and evaluate such guidelines for ef-
12 fective representation of a wide diversity of views.

13 (c) MEMBERSHIP.—

14 (1) APPOINTED MEMBERS.—

15 (A) IN GENERAL.—From among individ-
16 uals who are not officers or employees of the
17 Federal Government, the Secretary shall ap-
18 point to the Committee, as voting members, the
19 following:

20 (i) Not fewer than 4 members from
21 the scientific community representing the
22 broad spectrum of viewpoints held within
23 the scientific community related to Lyme
24 disease and other tick-borne diseases, in-
25 cluding experts in the areas of—

1 (I) medicine, epidemiology, and
2 public health;

3 (II) veterinary medicine and ani-
4 mal health;

5 (III) entomology and pest man-
6 agement; and

7 (IV) microbiology.

8 (ii) Not fewer than 2 representatives
9 of tick-borne disease voluntary advocacy
10 organizations, which may include 1 rep-
11 resentative of a patient-supported tick-
12 borne disease advocacy organization.

13 (iii) Not fewer than 2 health care pro-
14 viders, including not fewer than 1 physi-
15 cian involved in direct patient care, with
16 relevant experience providing care for indi-
17 viduals with a broad range of acute and
18 chronic Lyme disease and other tick-borne
19 diseases.

20 (iv) Not fewer than 2 patient rep-
21 resentatives who are individuals who have
22 been diagnosed with Lyme disease or an-
23 other tick-borne disease or who have had
24 an immediate family member diagnosed
25 with such a disease.

1 (v) Not fewer than 2 representatives
2 of State and local health departments and
3 national organizations that represent State
4 and local health professionals who inves-
5 tigate or treat patients with Lyme disease
6 or other tick-borne diseases.

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

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

17 (A) The Centers for Disease Control and
18 Prevention.

19 (B) The National Institutes of Health.

20 (C) The Agency for Healthcare Research
21 and Quality.

22 (D) The Food and Drug Administration.

23 (E) The Office of the Assistant Secretary
24 for Health.

25 (F) The Department of Agriculture.

1 (G) Such additional Federal departments
2 and agencies as the Secretary determines ap-
3 propriate.

4 (3) CO-CHAIRPERSONS.—The Committee shall
5 be headed by the following co-chairpersons:

6 (A) The Assistant Secretary of Health.

7 (B) A public chairperson appointed by the
8 members of the Committee, who shall serve a 2-
9 year term.

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

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

20 (d) MEETINGS.—The Committee shall hold public
21 meetings after providing notice to the public of such meet-
22 ings, and shall meet at least twice a year with additional
23 meetings subject to the call of the co-chairpersons. Agenda
24 items with respect to such meetings may be added at the
25 request of the members of the Committee, including the

1 co-chairpersons. Meetings shall be conducted, and records
2 of the proceedings shall be maintained, as required by ap-
3 plicable law and by regulations of the Secretary.

4 (e) REPORT.—Not later than 1 year after the date
5 of enactment of this Act and annually thereafter, the Com-
6 mittee, acting through the members representing the Cen-
7 ters for Disease Control and Prevention and the National
8 Institutes of Health, shall submit a report to the Sec-
9 retary. Each such report shall contain, at a minimum—

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

21 (a) IN GENERAL.—The Secretary, acting, as appro-
22 priate, through the Director of the Centers for Disease
23 Control and Prevention, the Director of the National Insti-
24 tutes of Health, the Commissioner of Food and Drugs,
25 the Director of the Agency for Healthcare Research and

1 Quality, the Chief of the Forest Service, or other Federal
2 agencies as the Secretary determines appropriate, and in
3 consultation with the Tick-Borne Diseases Advisory Com-
4 mittee, shall—

5 (1) conduct or support the activities described
6 in subsection (b); and

7 (2) coordinate all Federal programs and activi-
8 ties related to Lyme disease and other tick-borne
9 diseases.

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

12 (1) The development of diagnostic tests, includ-
13 ing—

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

19 (B) improving the efficient utilization of
20 diagnostic tests that have been adequately vali-
21 dated clinically available to account for the mul-
22 tiple clinical manifestations of both acute and
23 chronic Lyme disease;

24 (C) providing for the timely evaluation of
25 promising emerging diagnostic methods; and

1 (D) the development of quantitative assays
2 for the detection of tick-borne pathogens in
3 ticks.

4 (2) Surveillance and reporting of Lyme disease
5 and other tick-borne diseases—

6 (A) to accurately determine the incidence
7 of Lyme disease and other tick-borne diseases;

8 (B) to evaluate the feasibility of developing
9 a reporting system for the collection of data on
10 cases of Lyme disease that do not meet the sur-
11 veillance criteria of the Centers for Disease
12 Control and Prevention in order to more accu-
13 rately gauge disease incidence;

14 (C) to evaluate the feasibility of creating a
15 national uniform reporting system including re-
16 quired reporting by laboratories in each State;
17 and

18 (D) to evaluate the feasibility of creating a
19 national monitoring system for tick populations.

20 (3) Prevention activities, including—

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

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

7 (C) the creation of a physician education
8 program that includes the full spectrum of sci-
9 entific research related to the identification of
10 symptoms associated with, and the diagnosis of,
11 Lyme disease and other tick-borne diseases,
12 and, in coordination with the Tick-Borne Dis-
13 eases Advisory Committee established under
14 section 3, the publication of an annual report
15 that evaluates published guidelines and current
16 research available on Lyme disease, in order to
17 best educate health professionals on the latest
18 research and diversity of treatment options for
19 Lyme disease;

20 (D) research to understand mechanisms of
21 tick repellents and to develop new chemical and
22 non-chemical strategies for the control of ticks;
23 and

24 (E) exploring the utility and potential for
25 the development of a safe and effective vaccine

1 against Lyme disease and other tick-borne dis-
2 eases.

3 (4) Sponsoring scientific conferences on Lyme
4 disease and other tick-borne diseases, including re-
5 porting in accordance with subsection (c) and con-
6 sideration of the full spectrum of clinically based
7 knowledge, with the first of such conferences to be
8 held not later than 2 years after the date of enact-
9 ment of this Act.

10 (5) Clinical outcomes research, including—

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

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

17 (c) SCIENTIFIC CONFERENCES.—

18 (1) SENSE OF CONGRESS.—It is the sense of
19 Congress that participation in or sponsorship of sci-
20 entific conferences and meetings is essential to the
21 mission of the Department of Health and Human
22 Services in addressing Lyme disease and other tick-
23 borne diseases.

24 (2) CONFERENCE REPORTING.—

1 (A) IN GENERAL.—The Secretary shall
2 submit to Congress an annual report regarding
3 the costs and contracting procedures related to
4 conferences with respect to addressing Lyme
5 disease and other tick-borne diseases that are
6 organized by the Federal Government or at-
7 tended by representatives of the Federal Gov-
8 ernment, for which the cost to the Federal Gov-
9 ernment was more than \$100,000.

10 (B) CONTENTS.—Each report submitted
11 under subparagraph (A) shall include, with re-
12 spect to each such conference held during the
13 applicable period—

14 (i) a description of the purpose of the
15 conference;

16 (ii) the number of participants attend-
17 ing;

18 (iii) a detailed statement of the costs
19 to the Federal Government, including—

20 (I) the cost of any food or bev-
21 erages;

22 (II) the cost of any audio-visual
23 services;

1 (III) the cost of employee or con-
2 tractor travel to and from the con-
3 ference; and

4 (IV) a discussion of the method-
5 ology used to determine which costs
6 relate to the conference; and

7 (iv) a description of the contracting
8 procedures used in coordinating the con-
9 ference, including—

10 (I) whether contracts were
11 awarded on a competitive basis; and

12 (II) a discussion of any cost com-
13 parison conducted by the depart-
14 mental component or office in evalu-
15 ating potential contractors for the
16 conference.

17 **SEC. 5. REPORTS ON LYME DISEASE AND OTHER TICK-**
18 **BORNE DISEASES.**

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

23 (b) CONTENT.—Reports under subsection (a) shall
24 include—

1 (1) information relating to significant activities
2 or developments related to the surveillance, diag-
3 nosis, treatment, education, or prevention of Lyme
4 disease or other tick-borne diseases, including sug-
5 gestions for further research and education;

6 (2) a scientifically qualified assessment of Lyme
7 disease and other tick-borne diseases, including both
8 acute and chronic instances, related to the broad
9 spectrum of clinical evidence of treating physicians
10 involved in direct patient care, as well as published
11 peer reviewed data, that shall include recommenda-
12 tions for addressing interagency research gaps in
13 tick biology and tick management, and the diag-
14 nosis, transmission, and treatment of Lyme disease
15 and other tick-borne diseases, and an evaluation of
16 treatment guidelines and the utilization of such
17 guidelines;

18 (3) details regarding progress in the develop-
19 ment of accurate diagnostic tools that are more use-
20 ful in the clinical setting for both acute and chronic
21 disease;

22 (4) information relating to the promotion of
23 public awareness and physician education initiatives
24 to improve the knowledge of health care providers
25 and the public regarding clinical and surveillance

1 practices for Lyme disease and other tick-borne dis-
2 eases; and

3 (5) a copy of the most recent annual report of
4 the Tick-Borne Diseases Advisory Committee issued
5 under section 3(e), and an assessment of progress in
6 achieving the recommendations included in such re-
7 port.

8 **SEC. 6. APPROPRIATIONS.**

9 Funds for the purpose of carrying out this Act may
10 be derived from amounts appropriated to the Department
11 of Health and Human Services and otherwise available for
12 obligation and expenditure for each of the fiscal years
13 2016 through 2020. Amounts appropriated under the pre-
14 ceding sentence shall be used for the expenses and per
15 diem costs incurred by the Tick-Borne Diseases Advisory
16 Committee established under section 3 in accordance with
17 the Federal Advisory Committee Act (5 U.S.C. App.), ex-
18 cept that no voting member of the Tick-Borne Diseases
19 Advisory Committee shall be a permanent salaried em-
20 ployee.

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