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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Lyme and Tick-Borne Disease Prevention, Education, and Research Act of 2015”.

SEC. 2. FINDINGS.

Congress makes the following findings:

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

(2) Lyme disease is caused by the bacterium Borrelia burgdorferi, which belongs to the class of spirochaetes, and is transmitted to humans by the bite of infected ticks. Early signs of infection may include a rash and flu-like symptoms, such as fever, muscle aches, headaches, and fatigue.

(3) Although Lyme disease can be treated with antibiotics if caught early, the disease often goes undetected because it mimics other illnesses or may be misdiagnosed. Untreated, Lyme disease can lead to severe heart, neurological, and joint problems because the bacteria can affect many different organs and organ systems.

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

(5) Although Lyme disease accounts for 90 percent of all vector-borne disease in the United States, the ticks that spread Lyme disease also spread other diseases, such as anaplasmosis and babesiosis, and carry other strains of Borrelia burgdorferi. Other
tick species, such as the aggressive lone star tick, spread ehrlichiosis, Rocky Mountain spotted fever, and southern tick-associated rash illness (STARI). Multiple diseases in 1 patient make diagnosis and treatment more difficult.

(6) The Centers for Disease Control and Prevention reported over 36,000 confirmed or probable Lyme disease cases in 2013 and has estimated that the total number of people diagnosed with Lyme disease annually is roughly 10 times higher than the number of cases reported.

(7) According to the Centers for Disease Control and Prevention, from 1992 to 2006, the incidence of Lyme disease was highest among children 5 to 14 years of age.

(8) Persistence of symptomatology in many patients without reliable testing makes diagnosis and treatment of patients more difficult.

(9) In the absence of a safe and effective human vaccine, reducing exposure to ticks is the best defense against Lyme disease, Rocky Mountain spotted fever, and other tick-borne diseases. Entomology-based approaches to prevent tick-borne diseases include the use and development of insect re-
pellent, prompt tick removal, application of pesticides, and reduction of tick habitat.

SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVISORY COMMITTEE.

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

(b) Duties.—The Committee shall—

(1) advise the Secretary and the Assistant Secretary for Health regarding the manner in which such officials can—

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

(B) identify opportunities to coordinate efforts with other Federal agencies and private organizations addressing such diseases;

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

(D) ensure that a broad spectrum of scientific viewpoints are considered in public
health policy decisions and that information dis-
seminated to the public and physicians is based
on the best available science and is appro-
priately balanced; and

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

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

(c) Membership.—

(1) Appointed Members.—

(A) In General.—From among individ-
uals who are not officers or employees of the
Federal Government, the Secretary shall ap-
point to the Committee, as voting members, the
following:

(i) Not fewer than 4 members from
the scientific community representing the
broad spectrum of viewpoints held within
the scientific community related to Lyme
disease and other tick-borne diseases, in-
cluding experts in the areas of—
(I) medicine, epidemiology, and public health;

(II) veterinary medicine and animal health;

(III) entomology and pest management; and

(IV) microbiology.

(ii) Not fewer than 2 representatives of tick-borne disease voluntary advocacy organizations, which may include 1 representative of a patient-supported tick-borne disease advocacy organization.

(iii) Not fewer than 2 health care providers, including not fewer than 1 physician involved in direct patient care, with relevant experience providing care for individuals with a broad range of acute and chronic Lyme disease and other tick-borne diseases.

(iv) Not fewer than 2 patient representatives who are individuals who have been diagnosed with Lyme disease or another tick-borne disease or who have had an immediate family member diagnosed with such a disease.
(v) Not fewer than 2 representatives of State and local health departments and national organizations that represent State and local health professionals who investigate or treat patients with Lyme disease or other tick-borne diseases.

(B) DIVERSITY.—In appointing members under this paragraph, the Secretary shall ensure that such members, as a group, represent a diversity of scientific perspectives relevant to the duties of the Committee.

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

(A) The Centers for Disease Control and Prevention.

(B) The National Institutes of Health.

(C) The Agency for Healthcare Research and Quality.

(D) The Food and Drug Administration.

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

(F) The Department of Agriculture.
(G) Such additional Federal departments
and agencies as the Secretary determines ap-
propriate.

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

(A) The Assistant Secretary of Health.

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

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

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

(d) MEETINGS.—The Committee shall hold public
meetings after providing notice to the public of such meet-
ings, and shall meet at least twice a year with additional
meetings subject to the call of the co-chairpersons. Agenda
items with respect to such meetings may be added at the
request of the members of the Committee, including the
co-chairpersons. Meetings shall be conducted, and records of the proceedings shall be maintained, as required by applicable law and by regulations of the Secretary.

(e) REPORT.—Not later than 1 year after the date of enactment of this Act and annually thereafter, the Committee, acting through the members representing the Centers for Disease Control and Prevention and the National Institutes of Health, shall submit a report to the Secretary. Each such report shall contain, at a minimum—

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

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

(3) a summary of the Committee’s activities and recommendations during the previous year, including any significant issues regarding the functioning of the Committee.

SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS, SURVEILLANCE, PREVENTION, AND RESEARCH OF LYME DISEASE AND OTHER TICK-BORNE DISEASES.

(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, the Director of the Agency for Healthcare Research and
Quality, the Chief of the Forest Service, or other Federal agencies as the Secretary determines appropriate, and in consultation with the Tick-Borne Diseases Advisory Committee, shall—

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

(2) coordinate all Federal programs and activities related to Lyme disease and other tick-borne diseases.

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

(1) The development of diagnostic tests, including—

(A) the development of sensitive and more accurate diagnostic tools and tests, including a direct detection test for Lyme disease capable of distinguishing active infection from past infection;

(B) improving the efficient utilization of diagnostic tests that have been adequately validated clinically available to account for the multiple clinical manifestations of both acute and chronic Lyme disease;

(C) providing for the timely evaluation of promising emerging diagnostic methods; and
(D) the development of quantitative assays for the detection of tick-borne pathogens in ticks.

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

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

(B) to evaluate the feasibility of developing a reporting system for the collection of data on cases of Lyme disease that do not meet the surveillance criteria of the Centers for Disease Control and Prevention in order to more accurately gauge disease incidence;

(C) to evaluate the feasibility of creating a national uniform reporting system including required reporting by laboratories in each State; and

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

(3) Prevention activities, including—

(A) the provision and promotion of access to a comprehensive, up-to-date clearinghouse of peer-reviewed information on Lyme disease and other tick-borne diseases;
(B) increased public education related to Lyme disease 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 the identification of symptoms associated with, and the diagnosis of, Lyme disease and other tick-borne diseases, and, in coordination with the Tick-Borne Diseases Advisory Committee established under section 3, the publication of an annual report that evaluates published guidelines and current research available on Lyme disease, in order to best educate health professionals on the latest research and diversity of treatment options for Lyme disease;

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

(E) exploring the utility and potential for the development of a safe and effective vaccine
against Lyme disease and other tick-borne diseases.

(4) Sponsoring scientific conferences on Lyme disease and other tick-borne diseases, including reporting in accordance with subsection (c) and consideration of the full spectrum of clinically based knowledge, with the first of such conferences to be held not later than 2 years after the date of enactment of this Act.

(5) Clinical outcomes research, including—

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

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

(c) SCIENTIFIC CONFERENCES.—

(1) Sense of Congress.—It is the sense of Congress that participation in or sponsorship of scientific conferences and meetings is essential to the mission of the Department of Health and Human Services in addressing Lyme disease and other tick-borne diseases.

(2) Conference reporting.—
(A) **IN GENERAL.**—The Secretary shall submit to Congress an annual report regarding the costs and contracting procedures related to conferences with respect to addressing Lyme disease and other tick-borne diseases that are organized by the Federal Government or attended by representatives of the Federal Government, for which the cost to the Federal Government was more than $100,000.

(B) **CONTENTs.**—Each report submitted under subparagraph (A) shall include, with respect to each such conference held during the applicable period—

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

(ii) the number of participants attending;

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

(I) the cost of any food or beverages;

(II) the cost of any audio-visual services;
(III) the cost of employee or contractor travel to and from the conference; and

(IV) a discussion of the methodology used to determine which costs relate to the conference; and

(iv) a description of the contracting procedures used in coordinating the conference, including—

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

(II) a discussion of any cost comparison conducted by the departmental component or office in evaluating potential contractors for the conference.

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

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

(b) Content.—Reports under subsection (a) shall include—
(1) information relating to significant activities or developments related to the surveillance, diagnosis, treatment, education, or prevention of Lyme disease or other tick-borne diseases, including suggestions for further research and education;

(2) a scientifically qualified assessment of Lyme disease and other tick-borne diseases, including both acute and chronic instances, related to the broad spectrum of clinical evidence of treating physicians involved in direct patient care, as well as published peer reviewed data, that shall include recommendations for addressing interagency research gaps in tick biology and tick management, and the diagnosis, transmission, and treatment of Lyme disease and other tick-borne diseases, and an evaluation of treatment guidelines and the utilization of such guidelines;

(3) details regarding progress in the development of accurate diagnostic tools that are more useful in the clinical setting for both acute and chronic disease;

(4) information relating to the promotion of public awareness and physician education initiatives to improve the knowledge of health care providers and the public regarding clinical and surveillance
practices for Lyme disease and other tick-borne diseases; and

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

SEC. 6. APPROPRIATIONS.

Funds for the purpose of carrying out this Act may be derived from amounts appropriated to the Department of Health and Human Services and otherwise available for obligation and expenditure for each of the fiscal years 2016 through 2020. Amounts appropriated under the preceding sentence shall be used for the expenses and per diem costs incurred by the Tick-Borne Diseases Advisory Committee established under section 3 in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), except that no voting member of the Tick-Borne Diseases Advisory Committee shall be a permanent salaried employee.