

**Lyme and Tick-borne Disease Prevention, Education, and Research Act of 2005
(Introduced in Senate)**

S 1479 IS

109th CONGRESS

1st Session

S. 1479

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

July 25, 2005

Mr. DODD (for himself and Mr. SANTORUM) 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.

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 2005'.

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 a bacterial infection that is transmitted by a tick bite. 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, eye, 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, eye, and joint problems.
- (5) Although Lyme disease accounts for 90 percent of all vector-borne infections in the United States, the ticks that spread Lyme disease also spread other diseases, such as ehrlichiosis, babesiosis, and other strains of Borrelia. All of these diseases in 1 patient makes diagnosis and treatment more difficult.

- (6) Studies indicate that the actual number of tick-borne disease cases are approximately 10 times the amount reported.
- (7) Persistence of symptomatology in many patients without reliable testing makes treatment of patients more difficult.

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 advise the Secretary and the Assistant Secretary for Health regarding the manner in which such officials can--

- (1) ensure interagency coordination and communication and minimize overlap regarding efforts to address tick-borne diseases;
- (2) identify opportunities to coordinate efforts with other Federal agencies and private organizations addressing such diseases;
- (3) ensure interagency coordination and communication with constituency groups;
- (4) ensure that a broad spectrum of scientific viewpoints are represented in public health policy decisions and that information disseminated to the public and physicians is balanced; and
- (5) advise relevant Federal agencies on priorities related to the Lyme and tick-borne diseases.

(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, an equal number of individuals from each of the groups described in clauses (i) through (v) of subparagraph (B).

(B) GROUPS- The groups described in this subparagraph include the following:

- (i) Scientific community members representing the broad spectrum of viewpoints held within the scientific community related to Lyme and other tick-borne diseases.
- (ii) Representatives of tick-borne disease voluntary organizations.
- (iii) Health care providers, including at least 1 full-time practicing physician, with relevant experience providing care for individuals with a broad range of acute and chronic tick-borne diseases.
- (iv) 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.
- (v) Representatives of State and local health departments and national organizations that represent State and local health professionals.

(C) 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) Such additional Federal agencies as the Secretary determines to be appropriate.

(3) CO-CHAIRPERSONS- The Secretary shall designate the Assistant Secretary of Health as the co-chairperson of the Committee. The appointed members of the Committee shall also elect a public co-chairperson. The public co-chairperson 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 appointed 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, except as otherwise determined by the Secretary, after providing notice to the public of such meetings, 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) Authorization of Appropriations- For the purpose of carrying out this section, there is authorized to be appropriated \$250,000 for each of the fiscal years 2006 through 2009. Amounts appropriated under the preceding sentence shall be used for the expenses and per diem costs incurred by the Committee under this section in accordance with the Federal Advisory Committee Act, except that no voting member of the Committee shall be a permanent salaried employee.

SEC. 4. FEDERAL ACTIVITIES RELATED TO THE DIAGNOSIS, SURVEILLANCE, PREVENTION, AND RESEARCH OF LYME 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, 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 the coordination of all Federal programs and activities related to Lyme and other tick-borne diseases, including the activities described in paragraphs (1) through (4) of subsection (a).

(b) Activities- The activities described in this subsection are the following:

(1) DEVELOPMENT OF DIAGNOSTIC TESTS- Such activities include--

(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 testing currently available to account for the multiple clinical manifestations of both acute and chronic Lyme disease; and

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

(2) SURVEILLANCE AND REPORTING- Such activities include surveillance and reporting of Lyme and other tick-borne diseases--

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

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

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

(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 disease;

(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.

(4) CLINICAL OUTCOMES RESEARCH- Such activities include--

(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) Authorization of Appropriations- For the purposes of carrying out this section, and for the purposes of providing for additional research, prevention, and educational activities for Lyme and other tick-borne diseases, there is authorized to be appropriated

\$20,000,000 for each of the fiscal years 2006 through 2010. Such authorization is in addition to any other authorization of appropriations available for such purpose.

SEC. 5. REPORTS ON LYME 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 contain--

- (1) significant activities or developments related to the surveillance, diagnosis, treatment, education, or prevention of Lyme or other tick-borne diseases, including suggestions for further research and education;
- (2) a scientifically qualified assessment of Lyme and other tick-borne diseases, including both acute and chronic instances, related to the broad spectrum of empirical evidence of treating physicians, as well as published peer reviewed data, that shall include recommendations for addressing research gaps in diagnosis and treatment of Lyme and other tick-borne diseases and an evaluation of treatment guidelines and their utilization;
- (3) progress in the development of accurate diagnostic tools that are more useful in the clinical setting for both acute and chronic disease; and
- (4) 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.