

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.

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 2005”.

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 a bacterial infection that is
7 transmitted by a tick bite. Early signs of infection
8 may include a rash and flu-like symptoms such as
9 fever, muscle aches, headaches, and fatigue.

10 (3) Although Lyme disease can be treated with
11 antibiotics if caught early, the disease often goes un-
12 detected because it mimics other illnesses or may be
13 misdiagnosed. Untreated, Lyme disease can lead to
14 severe heart, neurological, eye, and joint problems
15 because the bacteria can affect many different or-
16 gans and organ systems.

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

20 (5) Although Lyme disease accounts for 90 per-
21 cent of all vector-borne infections in the United
22 States, the ticks that spread Lyme disease also
23 spread other diseases, such as ehrlichiosis,
24 babesiosis, and other strains of *Borrelia*. All of these
25 diseases in 1 patient makes diagnosis and treatment
26 more difficult.

1 (6) Studies indicate that the actual number of
2 tick-borne disease cases are approximately 10 times
3 the amount reported.

4 (7) Persistence of symptomatology in many pa-
5 tients without reliable testing makes treatment of
6 patients more difficult.

7 **SEC. 3. ESTABLISHMENT OF A TICK-BORNE DISEASES ADVI-**
8 **SORY COMMITTEE.**

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

16 (b) DUTIES.—The Committee shall advise the Sec-
17 retary and the Assistant Secretary for Health regarding
18 the manner in which such officials can—

19 (1) ensure interagency coordination and com-
20 munication and minimize overlap regarding efforts
21 to address tick-borne diseases;

22 (2) identify opportunities to coordinate efforts
23 with other Federal agencies and private organiza-
24 tions addressing such diseases;

1 (3) ensure interagency coordination and com-
2 munication with constituency groups;

3 (4) ensure that a broad spectrum of scientific
4 viewpoints are represented in public health policy de-
5 cisions and that information disseminated to the
6 public and physicians is balanced; and

7 (5) advise relevant Federal agencies on prior-
8 ities related to the Lyme and tick-borne diseases.

9 (c) MEMBERSHIP.—

10 (1) APPOINTED MEMBERS.—

11 (A) IN GENERAL.—From among individ-
12 uals who are not officers or employees of the
13 Federal Government, the Secretary shall ap-
14 point to the Committee, as voting members, an
15 equal number of individuals from each of the
16 groups described in clauses (i) through (v) of
17 subparagraph (B).

18 (B) GROUPS.—The groups described in
19 this subparagraph include the following:

20 (i) Scientific community members rep-
21 resenting the broad spectrum of viewpoints
22 held within the scientific community re-
23 lated to Lyme and other tick-borne dis-
24 eases.

1 (ii) Representatives of tick-borne dis-
2 ease voluntary organizations.

3 (iii) Health care providers, including
4 at least 1 full-time practicing physician,
5 with relevant experience providing care for
6 individuals with a broad range of acute
7 and chronic tick-borne diseases.

8 (iv) Patient representatives who are
9 individuals who have been diagnosed with a
10 tick-borne disease or who have had an im-
11 mediate family member diagnosed with
12 such a disease.

13 (v) Representatives of State and local
14 health departments and national organiza-
15 tions that represent State and local health
16 professionals.

17 (C) DIVERSITY.—In appointing members
18 under this paragraph, the Secretary shall en-
19 sure that such members, as a group, represent
20 a diversity of scientific perspectives relevant to
21 the duties of the Committee.

22 (2) EX OFFICIO MEMBERS.—The Secretary
23 shall designate, as nonvoting, ex officio members of
24 the Committee, representatives overseeing tick-borne

1 disease activities from each of the following Federal
2 agencies:

3 (A) The Centers for Disease Control and
4 Prevention.

5 (B) The National Institutes of Health.

6 (C) The Agency for Healthcare Research
7 and Quality.

8 (D) The Food and Drug Administration.

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

11 (F) Such additional Federal agencies as
12 the Secretary determines to be appropriate.

13 (3) CO-CHAIRPERSONS.—The Secretary shall
14 designate the Assistant Secretary of Health as the
15 co-chairperson of the Committee. The appointed
16 members of the Committee shall also elect a public
17 co-chairperson. The public co-chairperson shall serve
18 a 2-year term.

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

22 (5) VACANCY.—A vacancy in the membership of
23 the Committee shall be filled in the same manner as
24 the original appointment. Any member appointed to
25 fill a vacancy for an unexpired term shall be ap-

1 pointed for the remainder of that term. Members
2 may serve after the expiration of their terms until
3 their successors have taken office.

4 (d) MEETINGS.—The Committee shall hold public
5 meetings, except as otherwise determined by the Sec-
6 retary, after providing notice to the public of such meet-
7 ings, and shall meet at least twice a year with additional
8 meetings subject to the call of the co-chairpersons. Agenda
9 items with respect to such meetings may be added at the
10 request of the members of the Committee, including the
11 co-chairpersons. Meetings shall be conducted, and records
12 of the proceedings shall be maintained, as required by ap-
13 plicable law and by regulations of the Secretary.

14 (e) AUTHORIZATION OF APPROPRIATIONS.—For the
15 purpose of carrying out this section, there is authorized
16 to be appropriated \$250,000 for each of the fiscal years
17 2006 through 2009. Amounts appropriated under the pre-
18 ceding sentence shall be used for the expenses and per
19 diem costs incurred by the Committee under this section
20 in accordance with the Federal Advisory Committee Act,
21 except that no voting member of the Committee shall be
22 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 appro-
6 priate through the Director of the Centers for Disease
7 Control and Prevention, the Director of the National Insti-
8 tutes of Health, the Commissioner of Food and Drugs,
9 and the Director of the Agency for Healthcare Research
10 and Quality, as well as additional Federal agencies as the
11 Secretary determines to be appropriate, and in consulta-
12 tion with the Tick-Borne Diseases Advisory Committee,
13 shall provide for the coordination of all Federal programs
14 and activities related to Lyme and other tick-borne dis-
15 eases, including the activities described in paragraphs (1)
16 through (4) of subsection (a).

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

19 (1) DEVELOPMENT OF DIAGNOSTIC TESTS.—

20 Such activities include—

21 (A) the development of sensitive and more
22 accurate diagnostic tools and tests, including a
23 direct detection test for Lyme disease capable
24 of distinguishing active infection from past in-
25 fection;

1 (B) improving the efficient utilization of
2 diagnostic testing currently available to account
3 for the multiple clinical manifestations of both
4 acute and chronic Lyme disease; and

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

7 (2) SURVEILLANCE AND REPORTING.—Such ac-
8 tivities include surveillance and reporting of Lyme
9 and other tick-borne diseases—

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

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

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

21 (3) PREVENTION.—Such activities include—

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

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

11 (D) the sponsoring of scientific conferences
12 on Lyme and other tick-borne diseases, includ-
13 ing reporting and consideration of the full spec-
14 trum of clinically-based knowledge, with the
15 first of such conferences to be held not later
16 than 24 months after the date of enactment of
17 this Act.

18 (4) CLINICAL OUTCOMES RESEARCH.—Such ac-
19 tivities include—

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

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

1 (c) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purposes of carrying out this section, and for the purposes
3 of providing for additional research, prevention, and edu-
4 cational activities for Lyme and other tick-borne diseases,
5 there is authorized to be appropriated \$20,000,000 for
6 each of the fiscal years 2006 through 2010. Such author-
7 ization is in addition to any other authorization of appro-
8 priations available for such purpose.

9 **SEC. 5. REPORTS ON LYME AND OTHER TICK-BORNE DIS-**
10 **EASES .**

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

15 (b) CONTENT.—Reports under subsection (a) shall
16 contain—

17 (1) significant activities or developments related
18 to the surveillance, diagnosis, treatment, education,
19 or prevention of Lyme or other tick-borne diseases,
20 including suggestions for further research and edu-
21 cation;

22 (2) a scientifically qualified assessment of Lyme
23 and other tick-borne diseases, including both acute
24 and chronic instances, related to the broad spectrum
25 of empirical evidence of treating physicians, as well

1 as published peer reviewed data, that shall include
2 recommendations for addressing research gaps in di-
3 gnosis and treatment of Lyme and other tick-borne
4 diseases and an evaluation of treatment guidelines
5 and their utilization;

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

9 (4) the promotion of public awareness and phy-
10 sician education initiatives to improve the knowledge
11 of health care providers and the public regarding
12 clinical and surveillance practices for Lyme disease
13 and other tick-borne diseases.

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