

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 2877

To provide for the expansion and intensification of efforts for prevention, education, and research activities with respect to Lyme and other tick-borne diseases, including the establishment of a Tick-Borne Diseases Advisory Committee.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 2005

Mr. SMITH of New Jersey (for himself, Mr. GILCHREST, and Mr. PLATTS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To provide for the expansion and intensification of efforts for prevention, education, and research activities with respect 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 “Act for Lyme Edu-  
5       cation and Research and Tick-Borne Diseases” or the  
6       “ALERT Act”.

1 **SEC. 2. FINDINGS.**

2 The Congress finds as follows:

3 (1) The United States alone has 82 species of  
4 ticks causing at least 10 major diseases, which are  
5 Lyme disease, anaplasmosis, human monocytic  
6 ehrlichiosis, babesiosis, tick paralysis, relapsing fever,  
7 tularemia, Rocky Mountain spotted fever, Colorado  
8 tick fever, and southern tick-associated rash illness  
9 (STARI) (also known as Masters' disease). New tick  
10 species continue to be classified, and new diseases  
11 continue to emerge.

12 (2) Lyme disease is the most prevalent vector-  
13 borne disease in the United States today.

14 (3) According to the Centers for Disease Con-  
15 trol and Prevention, only 10 percent of cases that  
16 meet its surveillance criteria are reported; thus, an  
17 estimated 200,000 to 240,000 new cases occur each  
18 year.

19 (4) Tests to detect serum antibodies for Lyme  
20 disease can yield a high number of false-positive and  
21 false-negative results. False-negative results may  
22 delay diagnosis and treatment, which may lead to  
23 chronic, more debilitating, persistent and costly dis-  
24 ease.

25 (5) The diagnosis and treatment picture of  
26 Lyme disease and other tick-borne diseases can be

1 complicated because more than one tick-borne dis-  
2 ease can be acquired by the bite of the same tick.

3 (6) If it is not diagnosed and treated early,  
4 Lyme disease can lead to chronic illness and can af-  
5 fect every system in the body, including the central  
6 nervous system. Diagnosis is complicated because  
7 Lyme disease can mimic diseases such as meningitis,  
8 multiple sclerosis, brain tumor, Alzheimer's disease,  
9 Parkinson's disease, ALS, and psychiatric illness.

10 (7) According to a study by the National Insti-  
11 tutes of Health, patients with persistent Lyme dis-  
12 ease suffer physical disability equivalent to that of  
13 congestive heart failure, severe pain equivalent to  
14 post-operative pain, and profound fatigue similar to  
15 multiple sclerosis.

16 **SEC. 3. GOALS.**

17 (a) FIVE-YEAR PLAN.—The Secretary of Health and  
18 Human Services, acting as appropriate through the Direc-  
19 tor of the Agency for Healthcare Research and Quality,  
20 the Director of the Centers for Disease Control and Pre-  
21 vention, and the Director of the National Institutes of  
22 Health, shall establish a plan that, for the five fiscal years  
23 following the date of the enactment of this Act, provides  
24 for activities to be carried out during such fiscal years to-  
25 ward achieving the goals described in paragraphs (1)

1 through (4) of subsection (b). The plan shall, as appropriate to such goals, provide for the coordination of programs and activities regarding Lyme disease and other tick-borne diseases that are conducted or supported by the Federal Government.

6 (b) GOALS.—

7 (1) FIRST GOAL: DIAGNOSTIC TEST.—The first  
8 goal under subsection (a) shall be—

9 (A) to develop a sensitive and definitive  
10 test for the diagnosis of Lyme disease capable  
11 of distinguishing active infection from past in-  
12 fection;

13 (B) to improve efficient utilization of diag-  
14 nostic testing currently available to account for  
15 the multiple clinical manifestations of both  
16 acute and chronic Lyme disease; and

17 (C) to provide for the rapid evaluation and  
18 adoption of emerging test methods.

19 (2) SECOND GOAL: SURVEILLANCE AND RE-  
20 PORTING OF LYME DISEASE AND OTHER TICK-  
21 BORNE DISEASES.—The second goal under sub-  
22 section (a) shall be—

23 (A) to accurately determine the prevalence  
24 of Lyme disease and other tick-borne diseases  
25 in the United States;

1 (B) to evaluate the feasibility of developing  
2 a reporting system for collecting data on physi-  
3 cian-diagnosed cases that do not meet the sur-  
4 veillance criteria of the Centers for Disease  
5 Control and Prevention in order to more accu-  
6 rately gauge disease outbreaks and incidence;  
7 and

8 (C) to evaluate the feasibility of creating a  
9 national uniform reporting system to include  
10 mandatory reporting by laboratories in each  
11 State.

12 (3) THIRD GOAL: PREVENTION OF LYME DIS-  
13 EASE AND OTHER TICK-BORNE DISEASES AND COM-  
14 PPLICATIONS DUE TO DELAYED DIAGNOSIS AND  
15 TREATMENT.—The third goal under subsection (a)  
16 shall be—

17 (A) for the Director of the Agency for  
18 Healthcare Research and Quality, in coordina-  
19 tion with the Director of the Centers for Dis-  
20 ease Control and Prevention and the Director  
21 of the National Institutes of Health, to provide  
22 and promote access to a comprehensive, up-to-  
23 date clearinghouse of peer-reviewed information  
24 on Lyme and other tick-borne diseases;

1 (B) to provide for public education by ex-  
2 panding the Community Based Education Pro-  
3 grams of the Centers for Disease Control and  
4 Prevention to include expansion of information  
5 access points available to the public;

6 (C) to create a physician education pro-  
7 gram that includes the full spectrum of sci-  
8 entific research on Lyme and other tick-borne  
9 diseases; and

10 (D) for the Secretary to sponsor scientific  
11 conferences on Lyme and other tick-borne dis-  
12 eases, including reporting and consideration of  
13 the full spectrum of clinically-based knowledge,  
14 with the first of such conferences held within  
15 24 months after the date of the enactment of  
16 this Act and with further conferences held as  
17 determined appropriate by the Secretary.

18 (4) FOURTH GOAL: CLINICAL OUTCOMES RE-  
19 SEARCH.—The fourth goal under subsection (a)  
20 shall be—

21 (A) to establish epidemiological research  
22 goals to determine the long term course of ill-  
23 ness for Lyme disease; and

1 (B) to establish treatment outcomes re-  
2 search goals to determine the effectiveness of  
3 different treatment modalities.

4 **SEC. 4. STUDY BY INSTITUTE OF MEDICINE.**

5 (a) IN GENERAL.—Not later than 90 days after the  
6 date of the enactment of this Act, the Secretary shall re-  
7 quest the Institute of Medicine, National Academies of  
8 Sciences, to enter into an agreement with the Secretary  
9 for the conduct of a study of chronic Lyme disease. Such  
10 study shall include a systematic assessment of empirical  
11 evidence of treating physicians, as well as published peer-  
12 reviewed data, and shall include recommendations for ad-  
13 dressing research gaps in diagnosis and treatment of  
14 chronic Lyme disease and an assessment of treatment  
15 guidelines, such as those of the Infectious Diseases Society  
16 of America and those of the International Lyme and Asso-  
17 ciated Diseases Society, and their utilization.

18 (b) REPORT.—The Secretary shall ensure that, not  
19 later than one year after the Secretary enters into the  
20 agreement under subsection (a), a report providing the re-  
21 sults of the study under such subsection is submitted to  
22 the Secretary and the Tick-Borne Diseases Advisory Com-  
23 mittee under section 6.

1 **SEC. 5. INCREASED FUNDING FOR RESEARCH AND EDU-**  
2 **CATION.**

3 (a) IN GENERAL.—For the purpose of providing for  
4 research and educational activities for Lyme and other  
5 tick-borne diseases, and for carrying out efforts to prevent  
6 Lyme and other tick-borne diseases, there is authorized  
7 to be appropriated \$20,000,000 for each of the fiscal years  
8 2006 through 2010. Such authorization is in addition to  
9 other authorizations of appropriations that are available  
10 for such purpose.

11 (b) STUDY.—Of the amounts appropriated under  
12 subsection (a), the Secretary shall reserve not more than  
13 \$500,000 for conducting the study under section 4.

14 **SEC. 6. ESTABLISHMENT OF TICK-BORNE DISEASES ADVI-**  
15 **SORY COMMITTEE.**

16 (a) ESTABLISHMENT.—Not later than 180 days after  
17 the date of the enactment of this Act, the Secretary shall  
18 establish within the Office of the Secretary an advisory  
19 committee to be known as the Tick-Borne Diseases Advi-  
20 sory Committee (referred to in this section as the “Com-  
21 mittee”).

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

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

4           (2) identify opportunities to coordinate efforts  
5           with other Federal agencies and private organiza-  
6           tions addressing such diseases;

7           (3) ensure interagency coordination and com-  
8           munication with constituency groups;

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

13          (5) advise relevant Federal agencies on prior-  
14          ities.

15          (c) MEMBERSHIP.—

16                (1) APPOINTED MEMBERS.—

17                    (A) IN GENERAL.—From among individ-  
18                    uals who are not officers or employees of the  
19                    Federal Government, the Secretary shall ap-  
20                    point to the Committee, as voting members, an  
21                    equal number of individuals from each of the  
22                    groups described in clauses (i) through (v), as  
23                    follows:

24                            (i) Scientific community members rep-  
25                            resenting the broad spectrum of viewpoints

1 held within the scientific community, such  
2 as members of the International Lyme and  
3 Associated Diseases Society.

4 (ii) Representatives of tick-borne dis-  
5 ease voluntary organizations.

6 (iii) Health care providers who are  
7 full-time practicing physicians providing  
8 care for acute and chronic tick-borne dis-  
9 eases.

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

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

19 (B) CERTAIN REQUIREMENT.—In appoint-  
20 ing members under subparagraph (A), the Sec-  
21 retary shall ensure that such members, as a  
22 group, represent a diversity of scientific per-  
23 spectives relevant to the duties of the Com-  
24 mittee.

1           (2) EX OFFICIO MEMBERS.—The Secretary  
2 shall designate the Assistant Secretary for Health as  
3 a nonvoting, ex officio member of the Committee. In  
4 addition, the Secretary shall designate, as nonvoting  
5 members of the Committee, representatives from  
6 each of the following Federal agencies:

7           (A) The Agency for Healthcare Research  
8 and Quality.

9           (B) The National Institutes of Health.

10          (C) The Centers for Disease Control and  
11 Prevention.

12          (D) The Food and Drug Administration.

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

15          (F) Such additional Federal agencies as  
16 the Secretary determines to be appropriate.

17          (3) CHAIR.—The members of the Committee  
18 appointed under paragraph (1) shall select an indi-  
19 vidual from among such members to serve as the  
20 chair of the Committee. The term for serving as the  
21 chair shall be two years.

22          (4) TERM OF APPOINTMENT.—The term of  
23 service for each member of the Committee, other  
24 than the Assistant Secretary for Health, shall be  
25 four years.

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

8           (d) MEETINGS.—The Committee shall hold public  
9           meetings, except as otherwise determined by the Sec-  
10          retary, giving notice to the public of such, and meet at  
11          least twice a year with additional meetings subject to the  
12          call of the Chair. Agenda items may be added at the re-  
13          quest of members of the Committee, including the Chairs.  
14          Meetings shall be conducted, and records of the pro-  
15          ceedings shall be maintained, as required by applicable law  
16          and by regulations of the Secretary.

17          (e) AUTHORIZATION OF APPROPRIATIONS.—For the  
18          purpose of carrying out this section, there is authorized  
19          to be appropriated \$250,000 for each of the fiscal years  
20          2006 and 2007. Amounts appropriated under the pre-  
21          ceding sentence shall be used for the expenses and per  
22          diem costs incurred by the Committee under this section  
23          in accordance with the Federal Advisory Committee Act,  
24          except that no voting member of the Committee shall be  
25          a permanent salaried employee.

1 **SEC. 7. REPORTS.**

2 (a) IN GENERAL.—Not later than 24 months after  
3 the date of the enactment of this Act, and annually there-  
4 after, the Secretary shall submit to the Congress a report  
5 on the activities carried out under this Act.

6 (b) CONTENT.—Reports under subsection (a) shall  
7 describe—

8 (1) progress in the development of accurate di-  
9 agnostic tools and treatment modalities and their  
10 use in clinical settings;

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

16 (3) other significant activities relating to sur-  
17 veillance, diagnosis, treatment, or prevention of  
18 Lyme and other tick-borne diseases.

19 **SEC. 8. DEFINITION.**

20 For purposes of this Act, the “Secretary” means the  
21 Secretary of Health and Human Services.

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