

105TH CONGRESS
2D SESSION

S. 2034

To establish a program to provide for a reduction in the incidence and prevalence of Lyme disease.

IN THE SENATE OF THE UNITED STATES

MAY 5, 1998

Mr. DODD introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

A BILL

To establish a program to provide for a reduction in the incidence and prevalence of Lyme disease.

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 Disease Initia-
5 tive Act of 1998”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) The incidence of Lyme disease in the
9 United States is increasing more rapidly than most
10 other diseases. The Centers for Disease Control and

1 Prevention has determined that, since 1982, there
2 has been a 32-fold increase in reported cases.

3 (2) For 1996, such Centers determined that
4 16,455 cases of the disease were reported.

5 (3) There is no reliable standardized diagnostic
6 test for Lyme disease, and it is therefore likely that
7 the disease is severely underreported. The disease is
8 often misdiagnosed because the symptoms of the dis-
9 ease mimic other health conditions.

10 (4) Lyme disease costs our Nation at least
11 \$60,000,000 a year in direct medical costs for early,
12 acute cases. The costs of chronic cases of the dis-
13 ease, as well as the costs of lost wages and produc-
14 tivity, are many times higher.

15 (5) Many health care providers lack the nec-
16 essary knowledge and expertise—particularly in non-
17 endemic areas—to accurately diagnose Lyme dis-
18 ease. As a result, patients often visit multiple doc-
19 tors before obtaining a diagnosis of the disease, re-
20 sulting in prolonged pain and suffering, unnecessary
21 tests, and costly and futile treatments.

22 **SEC. 3. PUBLIC HEALTH GOALS; FIVE-YEAR PLAN.**

23 (a) IN GENERAL.—The Secretary of Health and
24 Human Services (acting as appropriate through the Direc-
25 tor of the Centers for Disease Control and Prevention and

1 the Director of the National Institutes of Health) and the
 2 Secretary of Defense shall collaborate to carry out the fol-
 3 lowing:

4 (1) The Secretaries shall establish the goals de-
 5 scribed in subsections (c) through (f) (relating to ac-
 6 tivities to provide for a reduction in the incidence
 7 and prevalence of Lyme disease).

8 (2) The Secretaries shall carry out activities to-
 9 ward achieving the goals, which may include activi-
 10 ties carried out directly by the Secretaries and ac-
 11 tivities carried out through awards of grants or con-
 12 tracts to public or nonprofit private entities.

13 (3) In carrying out paragraph (2), the Secretar-
 14 ies shall give priority—

15 (A) first, to achieving the goal under sub-
 16 section (c);

17 (B) second, to achieving the goal under
 18 subsection (d);

19 (C) third, to achieving the goal under sub-
 20 section (e); and

21 (D) fourth, to achieving the goal under
 22 subsection (f).

23 (b) FIVE-YEAR PLAN.—In carrying out subsection
 24 (a), the Secretaries shall establish a plan that, for the 5
 25 fiscal years following the date of the enactment of this

1 Act, provides for the activities to be carried out during
 2 such fiscal years toward achieving the goals under sub-
 3 sections (c) through section (f). The plan shall, as appro-
 4 priate to such goals, provide for the coordination of pro-
 5 grams and activities regarding Lyme disease that are con-
 6 ducted or supported by the Federal Government.

7 (c) FIRST GOAL: DETECTION TEST.—

8 (1) IN GENERAL.—For purposes of subsection
 9 (a), the goal described in this subsection is the de-
 10 velopment, by the expiration of the 18-year period
 11 beginning on the date of the enactment of this Act,
 12 of—

13 (A) a test for accurately determining
 14 whether an individual who has been bitten by a
 15 tick has Lyme disease; and

16 (B) a test for accurately determining
 17 whether a patient with such disease has been
 18 cured of the disease.

19 (d) SECOND GOAL: IMPROVED SURVEILLANCE AND
 20 REPORTING SYSTEM.—For purposes of subsection (a), the
 21 goal described in this subsection is to review the system
 22 in the United States for surveillance and reporting with
 23 respect to Lyme disease and to determine whether and in
 24 what manner the system can be improved (relative to the

1 date of the enactment of this Act). In carrying out activi-
2 ties toward such goal, the Secretaries shall—

3 (1) consult with the States, units of local gov-
4 ernment, physicians, patients with Lyme disease,
5 and organizations representing such patients;

6 (2) consider whether uniform formats should be
7 developed for the reporting by physicians of cases of
8 Lyme disease to public health officials; and

9 (3) with respect to health conditions that are
10 reported by physicians as cases of Lyme disease but
11 do not meet the criteria established by the Director
12 of the Centers for Disease Control and Prevention to
13 be counted as such cases, consider whether data on
14 such health conditions should be maintained and
15 analyzed to assist in understanding the cir-
16 cumstances in which Lyme disease is being diag-
17 nosed and the manner in which it is being treated.

18 (e) THIRD GOAL: INDICATOR REGARDING ACCURATE
19 DIAGNOSIS.—For purposes of subsection (a), the goal de-
20 scribed in this subsection is to determine the average num-
21 ber of visits to physicians that are made by patients with
22 Lyme disease before a diagnosis of such disease is made.
23 In carrying out activities toward such goal, the Secretaries
24 shall conduct a study of patients and physicians in 2 or

1 more geographic areas in which there is a significant inci-
 2 dence or prevalence of cases of Lyme disease.

3 (f) **FOURTH GOAL: PHYSICIAN KNOWLEDGE.**—For
 4 purposes of subsection (a), the goals described in this sub-
 5 section are to make a significant increase in the number
 6 of physicians who have an appropriate level of knowledge
 7 regarding Lyme disease, and to develop and apply an ob-
 8 jective method of determining the number of physicians
 9 who have such knowledge.

10 **SEC. 4. LYME DISEASE TASK FORCE.**

11 (a) **IN GENERAL.**—Not later than 120 days after the
 12 date of enactment of this Act, there shall be established
 13 in accordance with this section an advisory committee to
 14 be known as the Lyme Disease Task Force (in this section
 15 referred to as the Task Force).

16 (b) **DUTIES.**—The Task Force shall provide advice
 17 to the Secretaries with respect to achieving the goals
 18 under section 3, including advice on the plan under sub-
 19 section (b) of such section.

20 (c) **COMPOSITION.**—The Task Force shall be com-
 21 posed of 9 members with appropriate knowledge or experi-
 22 ence regarding Lyme disease. Of such members—

23 (1) 2 shall be appointed by the Secretary of
 24 Health and Human Services, after consultation with

1 the Director of the Centers for Disease Control and
2 Prevention;

3 (2) 2 shall be appointed by the Secretary of
4 Health and Human Services, after consultation with
5 the Director of the National Institutes of Health;

6 (3) 1 shall be appointed by the Secretary of De-
7 fense;

8 (4) 2 shall be appointed by the Speaker of the
9 House of Representatives, after consultation with
10 the Minority Leader of the House; and

11 (5) 2 shall be appointed by the President Pro
12 Tempore of the Senate, after consultation with the
13 Minority Leader of the Senate.

14 (d) CHAIR.—The Task Force shall, from among the
15 members of the Task Force, designate an individual to
16 serve as the chair of the Task Force.

17 (e) MEETINGS.—The Task Force shall meet at the
18 call of the Chair or a majority of the members.

19 (f) TERM OF SERVICE.—The term of service of a
20 member of the Task Force is the duration of the Task
21 Force.

22 (g) VACANCIES.—Any vacancy in the membership of
23 the Task Force shall be filled in the manner in which the
24 original appointment was made and shall not affect the

1 power of the remaining members to carry out the duties
2 of the Task Force.

3 (h) COMPENSATION; REIMBURSEMENT OF EX-
4 PENSES.—Members of the Task Force may not receive
5 compensation for service on the Task Force. Such mem-
6 bers may, in accordance with chapter 57 of title 5, United
7 States Code, be reimbursed for travel, subsistence, and
8 other necessary expenses incurred in carrying out the du-
9 ties of the Task Force.

10 (i) STAFF; ADMINISTRATIVE SUPPORT.—The Sec-
11 retary of Health and Human Services shall, on a reim-
12 bursable basis, provide to the Task Force such staff, ad-
13 ministrative support, and other assistance as may be nec-
14 essary for the Task Force to effectively carry out the du-
15 ties under subsection (b).

16 (j) TERMINATION.—The Task Force shall terminate
17 on the date that is 90 days after the end of the fifth fiscal
18 year that begins after the date of the enactment of this
19 Act.

20 **SEC. 5. ANNUAL REPORTS.**

21 The Secretaries shall submit to the Congress periodic
22 reports on the activities carried out under this Act and
23 the extent of progress being made toward the goals estab-
24 lished under section 3. The first such report shall be sub-
25 mitted not later than 18 months after the date of the en-

1 actment of this Act, and subsequent reports shall be sub-
2 mitted annually thereafter until the goals are met.

3 **SEC. 6. DEFINITION.**

4 For purposes of this Act, the term “Secretaries”
5 means—

6 (1) the Secretary of Health and Human Serv-
7 ices, acting as appropriate through the Director of
8 the Centers for Disease Control and Prevention and
9 the Director of the National Institutes of Health;
10 and

11 (2) the Secretary of Defense.

12 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

13 (a) NATIONAL INSTITUTES OF HEALTH.—In addi-
14 tion to other authorizations of appropriations that are
15 available for carrying out the purposes described in this
16 Act and that are established for the National Institutes
17 of Health, there are authorized to be appropriated to the
18 Director of such Institutes for such purposes \$9,000,000
19 for each of the fiscal years 1999 through 2003.

20 (b) CENTERS FOR DISEASE CONTROL AND PREVEN-
21 TION.—In addition to other authorizations of appropria-
22 tions that are available for carrying out the purposes de-
23 scribed in this Act and that are established for the Centers
24 for Disease Control and Prevention, there are authorized
25 to be appropriated to the Director of such Centers for such

1 purposes \$8,000,000 for each of the fiscal years 1999
2 through 2003.

3 (c) DEPARTMENT OF DEFENSE.—In addition to
4 other authorizations of appropriations that are available
5 for carrying out the purposes described in this Act and
6 that are established for the Department of Defense, there
7 are authorized to be appropriated to the Secretary of De-
8 fense for such purposes \$3,000,000 for each of the fiscal
9 years 1999 through 2003.

10 **SEC. 8. SENSE OF THE CONGRESS.**

11 It is the sense of the Congress that the Food and
12 Drug Administration should—

13 (1) conduct a rapid and thorough review of new
14 drug applications for drugs to immunize individuals
15 against Lyme disease; and

16 (2) ensure that the labeling approved for such
17 drugs specifically indicate the particular strains of
18 Lyme disease for which the drugs provide immuniza-
19 tion, the duration of the period of immunization,
20 and the reliability rate of the drugs.

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