106TH CONGRESS
1ST SESSION

S. 1905

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

IN THE SENATE OF THE UNITED STATES

NOVEMBER 10, 1999

Mr. SANTORUM (for himself, Mr. DODD, Mr. TORRICELLI, Mr. LIEBERMAN, Mr. SCHUMER, and Mr. LAUTENBERG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

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

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 Disease Initiative of 1999''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) The incidence of Lyme disease in the United States is increasing rapidly. The Centers for

Disease Control and Prevention (referred to in this Act as the ''CDC'') has determined that, since 1982, there has been a 32-fold increase in reported cases.

(2) In 1998, a total of 15,934 cases of Lyme disease were reported to CDC by 50 States and the District of Columbia (the overall incidence was 6.06 per 100,000), representing a 24 percent increase from the 12,807 cases reported in 1997.

(3) There is no reliable standardized diagnostic test for chronic Lyme disease, and the test for acute Lyme disease should be improved. As a result, the disease is underreported or misreported by as much as 10 or 12 fold, according to some studies, because the symptoms of Lyme disease mimic other health conditions. Thus, precise figures on the incidence of Lyme disease are difficult to develop.

(4) Lyme disease costs our Nation between $1,000,000,000 and $2,000,000,000 in medical costs annually, according to studies. Lost productivity annually per person from Lyme disease has been estimated at 5 to 37 days.

(5) Many health care providers lack the necessary knowledge and expertise—particularly in non-endemic areas—to accurately diagnose and prevent Lyme disease. As a result, patients often visit mul-

tiple doctors before obtaining a diagnosis of the disease, resulting in prolonged pain and suffering, unnecessary tests, and costly, delayed, or futile treatments.

(6) Due to scientific uncertainties about the diagnosis of acute and chronic Lyme disease, and the proper course and length of treatment, many patients have encountered difficulties in obtaining needed insurance coverage for Lyme disease.

(7) Most Lyme disease infections are thought to result from periresidential exposure to infected ticks during property maintenance, recreation, and leisure activities. Thus, individuals who live or work in residential areas surrounded by woods or overgrown brush infested by vector ticks are at risk of Lyme disease. In addition, persons who participate in recreational activities away from home (such as hiking, camping, fishing and hunting in tick habitat) and persons who engage in outdoor occupations (such as landscaping, brush clearing, forestry, military service, and wildlife and parks management in endemic areas) may also be at risk of Lyme disease. Some estimates indicate outdoor workers have a 4-to-4 fold elevation in risk of Lyme disease.

SEC. 3. PUBLIC HEALTH GOALS; 5-YEAR PLAN.

(a) IN GENERAL.—The Secretary of Health and Human Services (acting as appropriate through the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs), the Secretary of Agriculture, the Secretary of the Interior, and the Secretary of Defense (in this Act referred to collectively as the ''Secretaries'') shall collaborate to carry out the following:

(1) The Secretaries shall establish the goals described in subsections (c) through (g) relating to activities to provide for a reduction in the incidence and prevalence of Lyme disease and related tick-borne infectious diseases.

(2) The Secretaries shall carry out activities toward achieving the goals, which may include activities carried out directly by the Secretaries and activities carried out through awards of grants or contracts to public or nonprofit private entities.

(3) In carrying out paragraph (2), the Secretaries shall give priority—

(A) first, to achieving the goal under subsection (c);

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

(C) third, to achieving the goal under subsection (e);

(D) fourth, to achieving the goal under subsection (f); and

(E) fifth, to achieving the goal under subsection (g).

(b) FIVE-YEAR PLAN.—In carrying out subsection (a), the Secretaries shall establish a plan that, for the 5 fiscal years following the date of the enactment of this Act, provides for the activities to be carried out during such fiscal years toward achieving the goals under subsections (c) through (g). The plan shall, as appropriate to such goals, provide for the coordination of programs and activities regarding Lyme disease that are conducted or supported by the Federal Government.

(c) FIRST GOAL: DETECTION TEST.—For purposes of subsection (a), the goal described in this subsection is the development of novel and more sensitive, specific, and reproducible diagnostic tests and procedures (or the improvement or refinement of existing tests) that—

(1) can accurately determine whether an individual has acute or chronic Lyme disease;

(2) can accurately determine the activity of acute or chronic Lyme disease infection or both;

(3) can accurately distinguish acute or chronic Lyme disease or both from other related, tick-borne, coinfectious diseases; and

(4) can accurately measure the responsiveness of acute or chronic Lyme disease infection or both to treatment.

(d) SECOND GOAL: IMPROVED SURVEILLANCE AND REPORTING SYSTEM.—

(1) IN GENERAL.—For purposes of subsection (a), the goal described in this subsection is to assess the medical, social, and economic burden of Lyme disease in the United States. This assessment shall include a review of the system in the United States for surveillance and reporting with respect to Lyme disease and a determination of whether and in what manner the system can be improved.

(2) CERTAIN ACTIVITIES.—In carrying out activities toward the goal described in paragraph (1), the Secretaries shall—

(A) consult with the States, the Conference of State and Territorial Epidemiologists, units of local government, physicians and health providers, patients with Lyme disease, and organizations representing such patients;

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

(C) with respect to health conditions that are reported by physicians as cases of Lyme disease but do not meet the surveillance criteria established by the Director of the Centers for Disease Control and Prevention to be counted as such cases, consider whether data on such health conditions should be maintained and analyzed to assist in understanding the circumstances in which Lyme disease is being diagnosed and the manner in which it is being treated.

(e) THIRD GOAL: LYME DISEASE PREVENTION; DEVELOPMENT OF INDICATORS.—For purposes of subsection (a), the goal described in this subsection is to reduce, through the use of effective public health education, prevention, and tick population reduction techniques, the incidence of Lyme disease in the 10 highest endemic States by 33 percent by the date that is 5 years after the date of the enactment of this Act. In carrying out activities toward such goal, the Secretaries shall carry out each of the following:

(1) Establish a baseline incidence rate of Lyme disease in the 10 highest endemic States. The establishment of this baseline must take into consideration the surveillance criteria review specified in subsection (d).

(2) Encourage the use of natural and nonpesticidal methods to control and reduce tick populations, where appropriate.

(3) Reduce the risks of Lyme disease at all federally owned lands located in endemic States and regions, as well as at locations known or suspected to pose a risk of Lyme disease to patrons and employees, through the following:

(A) The development of standardized, periodic (not less than 1 per year) Lyme disease risk assessments that test and then categorize the overall level of risk of Lyme disease at federally owned lands in endemic States and regions. The Lyme disease risk assessments shall be made available to the public in appropriate forms, and may include such factors as—

(i) whether any human cases of Lyme disease have been diagnosed and treated on, or in areas adjacent to, the federally owned lands;

(ii) whether vectors capable of transmitting Lyme disease to humans are known to inhabit the federally owned land;

(iii) whether any such vectors present on the federally owned land are known to actually be infected with Lyme disease; and

(iv) the geographic distribution of Lyme disease risk within the federally owned land.

(B) The development and coordination of public awareness programs to educate patrons, employees, and health professionals at federally owned lands about the risks of Lyme disease, all appropriate prevention methods that can be used to reduce these risks, and information about the symptoms and nature of the disease.

(C) The use of appropriate habitat management and integrated pest-control techniques to reduce the number of tick-borne Lyme disease vectors in areas where humans work or recreate.

(f) FOURTH GOAL: PREVENTION OF TICK-BORNE DISEASES OTHER THAN LYME.—For purposes of subsection (a), the goal described in this subsection is to de-

velop the capabilities at the Centers for Disease Control and Prevention, within the Department of Defense, and in State and local health departments to implement adequate surveillance, improved diagnosis, and effective strategies for the prevention and control of tick-borne diseases other than Lyme disease. Such diseases may include Lyme-like illness, ehrlichiosis, babesiosis, other bacterial, viral and rickettsial diseases such as tularemia, tick-borne encephalitis, and Rocky Mountain Spotted Fever, respectively.

(g) FIFTH GOAL: IMPROVED PUBLIC AND PHYSICIAN EDUCATION.—For purposes of subsection (a), the goal described in this subsection is to improve the knowledge of physicians, health care providers, and the public regarding the best and most effective methods to prevent, diagnose, and treat Lyme disease and related tick-borne diseases.

SEC. 4. LYME DISEASE TASKFORCE.

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

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

section (b) of such section. Nothing in this section may be construed as interfering with or undermining the peer review process for research programs and grants, and the Task Force shall take care that its activities complement existing interagency relationships and interdepartmental working groups to the maximum extent practicable.

(c) MEMBERSHIP.—

(1) EX OFFICIO MEMBERS.—The following officials (or their designees) shall serve as ex officio members of the Task Force:

(A) The Director of the National Institute of Allergy and Infectious Diseases.

(B) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

(C) The Director of the National Institute of Neurological Disorders and Stroke.

(D) The Director of the National Center for Infectious Diseases.

(E) The Director of the Epidemiology Program Office.

(F) The Director of the Public Health Practice Program Office.

(G) The Commander of the United States Army Medical Command.

(H) The Commander of the United States Army Center for Health Promotion and Preventative Medicine.

(I) The Director of the Center for Biologics Evaluation and Research.

(J) The Administrator of the Agricultural Research Service.

(K) The Director of the National Park Service.

(L) The Director of the Fish and Wildlife Service.

(M) The Director of the Indian Health Service.

(N) The Chief Biologist of the Biological Resources Division, United States Geological Survey.

(2) APPOINTED MEMBERS.—Appointments to the Task Force shall be made in accordance with the following:

(A) Two members shall be research scientists with demonstrated achievements in research related to Lyme disease and related tick-borne diseases. The scientists shall be appointed by the Secretary of Health and Human Services (in this paragraph referred to as the ''Sec-

retary'') in consultation with the National Academy of Sciences.

(B) Four members shall be representatives of organizations whose primary emphasis is on research and public education into Lyme disease and related tick-borne diseases. One representative from each of such organizations shall be appointed by the Secretary in consultation with the National Academy of Sciences.

(C) Two members shall be clinicians with extensive experience in the treatment of individuals with chronic Lyme disease and related tick-borne diseases. The clinicians shall be appointed by the Secretary in consultation with the Institute of Medicine and the National Academy of Sciences.

(D) Two members shall be individuals who are the parents, spouse, or legal guardians of a person or persons that have contracted Lyme disease or a related tick-borne disease. The individuals shall be appointed by the Secretary in consultation with the ex officio members under paragraph (1) and the four organizations referred to in subparagraph (B).

(E) One member shall be a representative of the Council of State and Territorial Epidemiologists.

(F) One member shall be a representative of the National Association of County and City Health Officials.

(G) One member shall be an epidemiologist of demonstrated achievements in the field of epidemiology. The epidemiologist shall be appointed by the Secretary in consultation with the National Academy of Sciences.

(d) ADMINISTRATIVE SUPPORT; TERMS OF SERVICE; OTHER PROVISIONS.—The following apply with respect to the Task Force:

(1) The Task Force shall receive necessary and appropriate administrative support from the Department of Health and Human Services.

(2) Members of the Task Force shall be appointed for the duration of the Task Force.

(3) From among the members appointed under subsection (c)(2), the Task Force shall designate an individual to serve as the chairperson of the Task Force.

(4) The Task Force shall meet no less than 2 times per year.

(5) Members of the Task Force shall not receive additional compensation for their service. Such members may receive reimbursement for appropriate and additional expenses that are incurred through service on the Task Force which would not have incurred had they not been a member of the Task Force.

(6) Any vacancy in the membership of the Task Force shall be filled in the manner in which the original appointment was made and does not affect the power of the remaining members to carry out the duties of the Task Force.

SEC. 5. ANNUAL REPORTS.

The Secretaries shall submit to the Congress periodic reports on the activities carried out under this Act and the extent of progress being made toward the goals established under section 3. The first such report shall be submitted not later than 18 months after the date of the enactment of this Act, and subsequent reports shall be submitted annually thereafter until the goals are met.

SEC. 6. AUTHORIZATION OF APPROPRIATIONS.

(a) NATIONAL INSTITUTES OF HEALTH.—In addition to other authorizations of appropriations that are available for carrying out the purposes described in this Act and that are established for the National Institutes

of Health, there are authorized to be appropriated to the Director of such Institutes for such purposes $8,000,000 for each of the fiscal years 2000 through 2004.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION.—In addition to other authorizations of appropriations that are available for carrying out the purposes described in this Act and that are established for the Centers for Disease Control and Prevention, there are authorized to be appropriated to the Director of such Centers for such purposes $8,000,000 for each of the fiscal years 2000 through 2004.

(c) DEPARTMENT OF DEFENSE.—In addition to other authorizations of appropriations that are available for carrying out the purposes described in this Act and that are established for the Department of Defense, there are authorized to be appropriated to the Secretary of Defense for such purposes $6,000,000 for each of the fiscal years 2000 through 2004.

(d) DEPARTMENT OF AGRICULTURE.—In addition to other authorizations of appropriations that are available for carrying out the purposes described in this Act and that are established for the Department of Agriculture, there are authorized to be appropriated to the Secretary of Agriculture for such purposes $1,500,000 for each of the fiscal years 2000 through 2004.

(e) DEPARTMENT OF INTERIOR.—In addition to other authorizations of appropriations that are available for carrying out the purposes described in this Act and that are established for the Department of Interior, there are authorized to be appropriated to the Secretary of Interior for such purposes $1,500,000 million for each of the fiscal years 2000 through 2004.

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