

109TH CONGRESS  
1ST SESSION

# S. 756

To amend the Public Health Service Act to enhance public and health professional awareness and understanding of lupus and to strengthen the Nation's research efforts to identify the causes and cure of lupus.

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## IN THE SENATE OF THE UNITED STATES

APRIL 11, 2005

Mr. BENNETT (for himself, Mrs. MURRAY, Mr. SHELBY, and Mr. HATCH) 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 amend the Public Health Service Act to enhance public and health professional awareness and understanding of lupus and to strengthen the Nation's research efforts to identify the causes and cure of lupus.

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 “Lupus Research, Edu-  
5       cation, Awareness, Communication, and Healthcare  
6       Amendments of 2005”.

### 7   **SEC. 2. TABLE OF CONTENTS.**

8       The table of contents for this Act is as follows:

- Sec. 1. Short title.  
 Sec. 2. Table of contents.  
 Sec. 3. Findings.

TITLE I—EXPANDING AND IMPROVING RESEARCH ON LUPUS

- Sec. 101. Expansion of lupus biomedical research.  
 Sec. 102. Strengthening lupus epidemiology; lupus study.

TITLE II—ENHANCING LUPUS AWARENESS AND EDUCATION

- Sec. 201. Increasing public awareness and improving health professional education.

1 **SEC. 3. FINDINGS.**

2 Congress makes the following findings:

3 (1) Lupus is a serious, complex, debilitating  
 4 autoimmune disease that can cause inflammation  
 5 and tissue damage to virtually any organ system in  
 6 the body, including the skin, joints, other connective  
 7 tissue, blood and blood vessels, heart, lungs, kidney,  
 8 and brain.

9 (2) The Lupus Foundation of America, Inc. es-  
 10 timates that approximately 1,500,000 to 2,000,000  
 11 Americans live with some form of lupus; lupus af-  
 12 fects women 9 times more often than men and 80  
 13 percent of newly diagnosed cases of lupus develop  
 14 among women of child-bearing age.

15 (3) Lupus disproportionately affects women of  
 16 color; it is 2 to 3 times more common among Afri-  
 17 can-Americans, Hispanics, Asians, and Native Amer-  
 18 icans and is generally more prevalent in minority  
 19 populations, a health disparity that remains unex-  
 20 plained. According to the Centers for Disease Con-

1        trol and Prevention, the rate of lupus mortality has  
2        increased since the late 1970s and is higher among  
3        older African-American women.

4            (4) There have been no new drugs approved by  
5        the Food and Drug Administration specifically for  
6        lupus in nearly 40 years and while current treat-  
7        ments for the disease can be effective, they can lead  
8        to damaging side effects.

9            (5) The pain and fatigue associated with lupus  
10       can threaten people's ability to live independently  
11       and make it difficult to maintain employment and  
12       lead normal lives. One in 5 people with lupus is dis-  
13       abled by the disease, and consequently receives sup-  
14       port from government programs, including medicare,  
15       medicaid, social security disability, and social secu-  
16       rity supplemental income.

17           (6) The estimated average annual cost of med-  
18       ical treatment for an individual with lupus can range  
19       between \$10,000 and \$30,000; for people who have  
20       the most serious form of lupus, medical costs can  
21       greatly exceed this amount, causing a significant  
22       economic, emotional, and social burden to the entire  
23       family and to society.

24           (7) More than 1/2 of the people with lupus suf-  
25       fer 4 or more years and visit 3 or more physicians

1 before obtaining a diagnosis of lupus; early diagnosis  
 2 of, and commencement of treatment for, lupus can  
 3 prevent or reduce serious organ damage, disability,  
 4 and death.

5 (8) Despite the magnitude of lupus and its im-  
 6 pact on individuals and families, health professional  
 7 and public understanding of lupus remains low; only  
 8 1 of 5 Americans can provide even basic information  
 9 about lupus, and awareness of lupus is lowest among  
 10 adults ages 18 to 34, the age group most likely to  
 11 develop symptoms of lupus.

12 (9) Lupus is a significant national health issue  
 13 that deserves a comprehensive and coordinated re-  
 14 sponse by Federal and State governments with the  
 15 involvement of the healthcare provider, patient, and  
 16 public health communities.

## 17 **TITLE I—EXPANDING AND IM-** 18 **PROVING RESEARCH ON** 19 **LUPUS**

### 20 **SEC. 101. EXPANSION OF LUPUS BIOMEDICAL RESEARCH.**

21 Section 441A of the Public Health Service Act (42  
 22 U.S.C. 285d–6a) is amended to read as follows:

23 “EXPANSION OF LUPUS BIOMEDICAL RESEARCH

24 “SEC. 441A. (a) IN GENERAL.—The Secretary, act-  
 25 ing through the Director of the Institute, shall expand and

1 intensify research and related activities of the Institute  
2 with respect to lupus.

3 “(b) COORDINATION WITH OTHER INSTITUTES.—

4 The Director of the Institute shall coordinate the activities  
5 of the Director under subsection (a) with similar activities  
6 conducted by the other national research institutes and  
7 agencies of the National Institutes of Health to the extent  
8 that such institutes and agencies have responsibilities that  
9 are related to lupus.

10 “(c) PROGRAMS FOR LUPUS.—In carrying out sub-  
11 section (a), the Director of the Institute shall conduct or  
12 support research to expand the understanding of the  
13 causes of, and to find a cure for, lupus. Activities under  
14 such subsection shall include conducting and supporting  
15 the following:

16 “(1) Basic research to discover the pathogenesis  
17 and pathophysiology of the disease.

18 “(2) Research to determine the reasons under-  
19 lying the disproportionate prevalence of lupus in Af-  
20 rican-American, Hispanic, Native American, and  
21 Asian women.

22 “(3) Epidemiological studies to address the fre-  
23 quency and natural history of the disease and the  
24 differences between the sexes and among racial and  
25 ethnic groups with respect to the disease.

1           “(4) Clinical research for the development and  
2           evaluation of new treatments, including new biologi-  
3           cal agents.

4           “(5) Research to validate lupus biomarkers.

5           “(6) Research to develop improved diagnostic  
6           tests.”.

7   **SEC. 102. STRENGTHENING LUPUS EPIDEMIOLOGY; LUPUS**  
8           **STUDY.**

9           Part B of title III of the Public Health Service Act  
10          (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
11          tion 318B the following:

12               “STRENGTHENING LUPUS EPIDEMIOLOGY

13           “SEC. 318C. (a) IN GENERAL.—The Secretary, act-  
14          ing through the Director of the Centers for Disease Con-  
15          trol and Prevention, shall work with a consortium of lead-  
16          ing United States academic health institutions that have  
17          expertise in the epidemiology of lupus to undertake a na-  
18          tional scale lupus epidemiological study to determine the  
19          true prevalence and incidence of lupus in the United  
20          States.

21           “(b) USE OF FUNDS.—The Director of the Centers  
22          for Disease Control and Prevention shall enter into a coop-  
23          erative agreement with the consortium described in sub-  
24          section (a) to develop, implement, and manage a system  
25          for lupus data collection and analysis, including—

1           “(1) the creation and use of a common data  
2           entry and management system across all study sites;  
3           and

4           “(2) the enhancement of the 2 study sites in-  
5           volved in the existing lupus patient registry of the  
6           Centers for Disease Control and Prevention on the  
7           day before the date of enactment of the Lupus Re-  
8           search, Education, Awareness, Communication, and  
9           Healthcare Amendments of 2005.

10          “(c) GEOGRAPHIC REPRESENTATION.—The Director  
11       of the Centers for Disease Control and Prevention shall  
12       ensure that the consortium described in subsection (a)  
13       represents different geographic regions of the United  
14       States that have a sufficient number of individuals of all  
15       racial and ethnic backgrounds disproportionately affected  
16       by lupus, including Hispanics, Asians, Native Americans,  
17       and African-Americans.

18          “(d) CERTAIN ACTIVITIES.—In carrying out sub-  
19       sections (a) and (b), the consortium described in sub-  
20       section (a) shall capture data related to all affected popu-  
21       lations on all forms of lupus, including lupus related dis-  
22       orders.

23          “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
24       are authorized to be appropriated to carry out this section

1 \$3,500,000 for each of the fiscal years 2006, 2007, 2008,  
2 and 2009.

3 “LUPUS STUDY AND REPORT BY THE INSTITUTE OF  
4 MEDICINE

5 “SEC. 318D. (a) CONTRACT.—The Secretary shall  
6 enter into a contract with the Institute of Medicine to con-  
7 duct a study—

8 “(1) to evaluate the Federal and State activities  
9 related to lupus research, education, and awareness  
10 programs and activities and make recommendations  
11 for ways in which these initiatives could be ex-  
12 panded;

13 “(2) to identify the gaps in Federal research re-  
14 lated to—

15 “(A) the causes of lupus;

16 “(B) lupus detection and diagnosis;

17 “(C) lupus treatment; and

18 “(D) lupus quality-of-life concerns;

19 “(3) to make recommendations for building and  
20 supporting the lupus research enterprise, including  
21 recommendations for strategies for future basic, clin-  
22 ical, social, and behavioral research—

23 “(A) to determine the pathophysiology and  
24 pathogenesis of the disease; and

1 “(B) to secure the development of new and  
2 improved lupus therapies and ways to diagnose  
3 the disease;

4 “(4) to determine the gaps in lupus health pro-  
5 fessional education programs and public awareness  
6 efforts and make recommendations for ways in  
7 which the Federal Government can—

8 “(A) improve public and health profes-  
9 sional awareness of lupus; and

10 “(B) partner and support nonprofit vol-  
11 untary health agencies (such as the Lupus  
12 Foundation of America, Inc.) and academic in-  
13 stitutions and other interested stakeholders  
14 whose primary purposes are to increase public  
15 awareness of lupus and to improve the diag-  
16 nosis and treatment of lupus;

17 “(5) to make recommendations regarding ways  
18 to improve the quality of life for people with lupus;

19 “(6) to summarize the clinical and biological  
20 features of lupus and the characteristics and man-  
21 agement of major symptoms and make recommenda-  
22 tions for disease management and measurement; and

23 “(7) to make recommendations for epidemiolog-  
24 ical studies in the various population groups affected  
25 by lupus in the United States.

1 “(b) REPORT.—Not later than 18 months after the  
 2 date of enactment of the Lupus Research, Education,  
 3 Awareness, Communication, and Healthcare Amendments  
 4 of 2005, the Institute of Medicine shall submit to the Sec-  
 5 retary a report containing the information described in  
 6 paragraphs (1) through (7) of subsection (a).”.

## 7 **TITLE II—ENHANCING LUPUS** 8 **AWARENESS AND EDUCATION**

### 9 **SEC. 201. INCREASING PUBLIC AWARENESS AND IMPROV-** 10 **ING HEALTH PROFESSIONAL EDUCATION.**

11 Part B of title III of the Public Health Service Act  
 12 (as amended by section 102) (42 U.S.C. 243 et seq.) is  
 13 further amended by inserting after section 318D the fol-  
 14 lowing:

15 “INCREASING PUBLIC AWARENESS OF LUPUS AND  
 16 IMPROVING HEALTH PROFESSIONAL EDUCATION

17 “SEC. 318E. (a) IN GENERAL.—The Secretary, act-  
 18 ing through the Director of the Office on Women’s Health  
 19 and in collaboration with the Lupus Foundation of Amer-  
 20 ica, Inc. and the National Center on Minority Health and  
 21 Health Disparities of the National Institutes of Health,  
 22 shall conduct and support a sustained national lupus pub-  
 23 lic awareness and health professional education campaign,  
 24 with an emphasis on reaching populations at highest risk  
 25 for the disease.

1       “(b) USE OF FUNDS.—In conducting the sustained  
2 national lupus public awareness and health professional  
3 educational campaign, the Director of the Office on Wom-  
4 en’s Health shall—

5           “(1) promote increased awareness of early  
6 intervention and treatment so as to significantly im-  
7 prove the diagnosis, treatment, and quality of life for  
8 people with lupus;

9           “(2) direct communication and education ef-  
10 forts toward minority communities that may be un-  
11 derserved or disproportionately affected by lupus;  
12 and

13           “(3) target at-risk women and health profes-  
14 sionals likely to see women with lupus, including pri-  
15 mary care physicians and specialists such as  
16 rheumatologists, nephrologists, dermatologists, and  
17 immunologists, so as to help reduce the amount of  
18 time taken to achieve a correct diagnosis of lupus.

19       “(c) CERTAIN ACTIVITIES.—To the extent prac-  
20 ticable and appropriate, the Secretary shall ensure that  
21 communications under subsections (a) and (b) provide the  
22 latest medically sound information related to the signs,  
23 symptoms, diagnosis, and disease management of lupus.

24       “(d) INTEGRATION WITH OTHER PROGRAMS.—To  
25 the extent practicable and appropriate, the Secretary shall

1 integrate efforts under this section with other programs  
2 carried out by the Secretary.

3 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
4 are authorized to be appropriated to carry out this section  
5 \$1,000,000 for each of the fiscal years 2006 through  
6 2010.”.

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