

110TH CONGRESS
1ST SESSION

S. 1359

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.

IN THE SENATE OF THE UNITED STATES

MAY 10, 2007

Mrs. MURRAY (for herself, Mr. BENNETT, Mr. BROWN, and Mr. AKAKA) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2007”.

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 biological
3 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 2007.

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 2008, 2009, 2010,
2 and 2011.

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 2007, 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 ferts 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 2008 through
6 2012.”.

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