

109TH CONGRESS  
1ST SESSION

# H. R. 3307

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 HOUSE OF REPRESENTATIVES

JULY 14, 2005

Ms. ROS-LEHTINEN (for herself, Mr. BISHOP of Georgia, Mr. BUTTERFIELD, Mrs. CHRISTENSEN, Mr. CLAY, Mr. CLEAVER, Mr. CONYERS, Mr. DAVIS of Illinois, Mr. AL GREEN of Texas, Mr. HASTINGS of Florida, Ms. JACKSON-LEE of Texas, Mr. JEFFERSON, Mrs. JONES of Ohio, Ms. KILPATRICK of Michigan, Ms. LEE, Mr. MEEKS of New York, Ms. MOORE of Wisconsin, Ms. NORTON, Mr. OWENS, Mr. RANGEL, Mr. RUSH, Mr. SCOTT of Virginia, Mr. THOMPSON of Mississippi, Ms. WATERS, Ms. WATSON, Mr. WYNN, Mr. WEXLER, Mr. ENGEL, Ms. WASSERMAN SCHULTZ, Mr. LYNCH, Mr. MEEK of Florida, Mr. KILDEE, Ms. SCHAKOWSKY, Mr. HINCHEY, Mr. BRADY of Pennsylvania, Mr. TOWNS, Ms. CARSON, and Mr. FORD) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Lupus Research, Edu-  
3 cation, Awareness, Communication, and Healthcare  
4 Amendments of 2005”.

5 **SEC. 2. TABLE OF CONTENTS.**

6 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 edu-  
cation.

7 **SEC. 3. FINDINGS.**

8 Congress makes the following findings:

9 (1) Lupus is a serious, complex, debilitating  
10 autoimmune disease that can cause inflammation  
11 and tissue damage to virtually any organ system in  
12 the body, including the skin, joints, other connective  
13 tissue, blood and blood vessels, heart, lungs, kidney,  
14 and brain.

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

1           (3) Lupus disproportionately affects women of  
2 color; it is 2 to 3 times more common among Afri-  
3 can-Americans, Hispanics, Asians, and Native Amer-  
4 icans and is generally more prevalent in minority  
5 populations, a health disparity that remains unex-  
6 plained. According to the Centers for Disease Con-  
7 trol and Prevention, the rate of lupus mortality has  
8 increased since the late 1970s and is higher among  
9 older African-American women.

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

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

23           (6) The estimated average annual cost of med-  
24 ical treatment for an individual with lupus can range  
25 between \$10,000 and \$30,000; for people who have

1 the most serious form of lupus, medical costs can  
2 greatly exceed this amount, causing a significant  
3 economic, emotional, and social burden to the entire  
4 family and to society.

5 (7) More than  $\frac{1}{2}$  of the people with lupus suf-  
6 fer 4 or more years and visit 3 or more physicians  
7 before obtaining a diagnosis of lupus; early diagnosis  
8 of, and commencement of treatment for, lupus can  
9 prevent or reduce serious organ damage, disability,  
10 and death.

11 (8) Despite the magnitude of lupus and its im-  
12 pact on individuals and families, health professional  
13 and public understanding of lupus remains low; only  
14 1 of 5 Americans can provide even basic information  
15 about lupus, and awareness of lupus is lowest among  
16 adults ages 18 to 34, the age group most likely to  
17 develop symptoms of lupus.

18 (9) Lupus is a significant national health issue  
19 that deserves a comprehensive and coordinated re-  
20 sponse by Federal and State governments with the  
21 involvement of the healthcare provider, patient, and  
22 public health communities.

1 **TITLE I—EXPANDING AND IM-**  
2 **PROVING RESEARCH ON**  
3 **LUPUS**

4 **SEC. 101. EXPANSION OF LUPUS BIOMEDICAL RESEARCH.**

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

7 “EXPANSION OF LUPUS BIOMEDICAL RESEARCH

8 “SEC. 441A. (a) IN GENERAL.—The Secretary, act-  
9 ing through the Director of the Institute, shall expand and  
10 intensify research and related activities of the Institute  
11 with respect to lupus.

12 “(b) COORDINATION WITH OTHER INSTITUTES.—  
13 The Director of the Institute shall coordinate the activities  
14 of the Director under subsection (a) with similar activities  
15 conducted by the other national research institutes and  
16 agencies of the National Institutes of Health to the extent  
17 that such institutes and agencies have responsibilities that  
18 are related to lupus.

19 “(c) PROGRAMS FOR LUPUS.—In carrying out sub-  
20 section (a), the Director of the Institute shall conduct or  
21 support research to expand the understanding of the  
22 causes of, and to find a cure for, lupus. Activities under  
23 such subsection shall include conducting and supporting  
24 the following:

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

3           “(2) Research to determine the reasons under-  
4           lying the disproportionate prevalence of lupus in Af-  
5           rican-American, Hispanic, Native American, and  
6           Asian women.

7           “(3) Epidemiological studies to address the fre-  
8           quency and natural history of the disease and the  
9           differences between the sexes and among racial and  
10          ethnic groups with respect to the disease.

11          “(4) Clinical research for the development and  
12          evaluation of new treatments, including new biologi-  
13          cal agents.

14          “(5) Research to validate lupus biomarkers.

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

17 **SEC. 102. STRENGTHENING LUPUS EPIDEMIOLOGY; LUPUS**  
18 **STUDY.**

19          Part B of title III of the Public Health Service Act  
20          (42 U.S.C. 243 et seq.) is amended by inserting after sec-  
21          tion 318B the following:

22                 “STRENGTHENING LUPUS EPIDEMIOLOGY

23                 “SEC. 318C. (a) IN GENERAL.—The Secretary, act-  
24                 ing through the Director of the Centers for Disease Con-  
25                 trol and Prevention, shall work with a consortium of lead-  
26                 ing United States academic health institutions that have

1 expertise in the epidemiology of lupus to undertake a na-  
2 tional scale lupus epidemiological study to determine the  
3 true prevalence and incidence of lupus in the United  
4 States.

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

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

13 “(2) the enhancement of the 2 study sites in-  
14 volved in the existing lupus patient registry of the  
15 Centers for Disease Control and Prevention on the  
16 day before the date of enactment of the Lupus Re-  
17 search, Education, Awareness, Communication, and  
18 Healthcare Amendments of 2005.

19 “(c) GEOGRAPHIC REPRESENTATION.—The Director  
20 of the Centers for Disease Control and Prevention shall  
21 ensure that the consortium described in subsection (a)  
22 represents different geographic regions of the United  
23 States that have a sufficient number of individuals of all  
24 racial and ethnic backgrounds disproportionately affected

1 by lupus, including Hispanics, Asians, Native Americans,  
2 and African-Americans.

3 “(d) CERTAIN ACTIVITIES.—In carrying out sub-  
4 sections (a) and (b), the consortium described in sub-  
5 section (a) shall capture data related to all affected popu-  
6 lations on all forms of lupus, including lupus related dis-  
7 orders.

8 “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
9 are authorized to be appropriated to carry out this section  
10 \$3,500,000 for each of the fiscal years 2006, 2007, 2008,  
11 and 2009.

12 “LUPUS STUDY AND REPORT BY THE INSTITUTE OF  
13 MEDICINE

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

17 “(1) to evaluate the Federal and State activities  
18 related to lupus research, education, and awareness  
19 programs and activities and make recommendations  
20 for ways in which these initiatives could be ex-  
21 panded;

22 “(2) to identify the gaps in Federal research re-  
23 lated to—

24 “(A) the causes of lupus;

25 “(B) lupus detection and diagnosis;

26 “(C) lupus treatment; and

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

2           “(3) to make recommendations for building and  
3 supporting the lupus research enterprise, including  
4 recommendations for strategies for future basic, clin-  
5 ical, social, and behavioral research—

6           “(A) to determine the pathophysiology and  
7 pathogenesis of the disease; and

8           “(B) to secure the development of new and  
9 improved lupus therapies and ways to diagnose  
10 the disease;

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

15          “(A) improve public and health profes-  
16 sional awareness of lupus; and

17          “(B) partner and support nonprofit vol-  
18 untary health agencies (such as the Lupus  
19 Foundation of America, Inc.) and academic in-  
20 stitutions and other interested stakeholders  
21 whose primary purposes are to increase public  
22 awareness of lupus and to improve the diag-  
23 nosis and treatment of lupus;

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

1           “(6) to summarize the clinical and biological  
2 features of lupus and the characteristics and man-  
3 agement of major symptoms and make recommenda-  
4 tions for disease management and measurement; and

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

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

14           **TITLE II—ENHANCING LUPUS**  
15           **AWARENESS AND EDUCATION**

16           **SEC. 201. INCREASING PUBLIC AWARENESS AND IMPROV-**  
17           **ING HEALTH PROFESSIONAL EDUCATION.**

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

22           “INCREASING PUBLIC AWARENESS OF LUPUS AND  
23           IMPROVING HEALTH PROFESSIONAL EDUCATION

24           “SEC. 318E. (a) IN GENERAL.—The Secretary, act-  
25 ing through the Director of the Office on Women’s Health  
26 and in collaboration with the Lupus Foundation of Amer-

1 ica, Inc. and the National Center on Minority Health and  
2 Health Disparities of the National Institutes of Health,  
3 shall conduct and support a sustained national lupus pub-  
4 lic awareness and health professional education campaign,  
5 with an emphasis on reaching populations at highest risk  
6 for the disease.

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

11 “(1) promote increased awareness of early  
12 intervention and treatment so as to significantly im-  
13 prove the diagnosis, treatment, and quality of life for  
14 people with lupus;

15 “(2) direct communication and education ef-  
16 forts toward minority communities that may be un-  
17 derserved or disproportionately affected by lupus;  
18 and

19 “(3) target at-risk women and health profes-  
20 sionals likely to see women with lupus, including pri-  
21 mary care physicians and specialists such as  
22 rheumatologists, nephrologists, dermatologists, and  
23 immunologists, so as to help reduce the amount of  
24 time taken to achieve a correct diagnosis of lupus.

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

6       “(d) INTEGRATION WITH OTHER PROGRAMS.—To  
7 the extent practicable and appropriate, the Secretary shall  
8 integrate efforts under this section with other programs  
9 carried out by the Secretary.

10       “(e) AUTHORIZATION OF APPROPRIATIONS.—There  
11 are authorized to be appropriated to carry out this section  
12 \$1,000,000 for each of the fiscal years 2006 through  
13 2010.”.

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