110TH CONGRESS
1ST SESSION

H. R. 1192

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 HOUSE OF REPRESENTATIVES

FEBRUARY 27, 2007

Mr. MEEK of Florida (for himself, Ms. ROS-LEHTINEN, Mr. LEWIS of Georgia, Mr. BRADY of Pennsylvania, Ms. JACKSON-LEE of Texas, and Mr. ORTIZ) 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.

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 ''Lupus Research, Education, Awareness, Communication, and Healthcare Amendments of 2007''.

SEC. 2. TABLE OF CONTENTS.

The table of contents for this Act is as follows:

SEC. 3. FINDINGS.

Congress makes the following findings:

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

(2) The Lupus Foundation of America, Inc. estimates that approximately 1,500,000 to 2,000,000 Americans live with some form of lupus; lupus affects women 9 times more often than men and 80 percent of newly diagnosed cases of lupus develop among women of child-bearing age.

(3) Lupus disproportionately affects women of color; it is 2 to 3 times more common among African-Americans, Hispanics, Asians, and Native Americans and is generally more prevalent in minority

populations, a health disparity that remains unexplained. According to the Centers for Disease Control and Prevention, the rate of lupus mortality has increased since the late 1970s and is higher among older African-American women.

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

(5) The pain and fatigue associated with lupus can threaten people's ability to live independently and make it difficult to maintain employment and lead normal lives. One in 5 people with lupus is disabled by the disease, and consequently receives support from government programs, including medicare, medicaid, social security disability, and social security supplemental income.

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

(7) More than ½ of the people with lupus suffer 4 or more years and visit 3 or more physicians before obtaining a diagnosis of lupus; early diagnosis of, and commencement of treatment for, lupus can prevent or reduce serious organ damage, disability, and death.

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

(9) Lupus is a significant national health issue that deserves a comprehensive and coordinated response by Federal and State governments with the involvement of the healthcare provider, patient, and public health communities.

TITLE I—EXPANDING AND IMPROVING RESEARCH ON LUPUS

SEC. 101. EXPANSION OF LUPUS BIOMEDICAL RESEARCH.

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

''EXPANSION OF LUPUS BIOMEDICAL RESEARCH

''SEC. 441A. (a) IN GENERAL.—The Secretary, acting through the Director of the Institute, shall expand and intensify research and related activities of the Institute with respect to lupus.

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

''(c) PROGRAMS FOR LUPUS.—In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:

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

''(2) Research to determine the reasons underlying the disproportionate prevalence of lupus in African-American, Hispanic, Native American, and Asian women.

"(3) Epidemiological studies to address the frequency and natural history of the disease and the differences between the sexes and among racial and ethnic groups with respect to the disease.

"(4) Clinical research for the development and evaluation of new treatments, including new biological agents.

"(5) Research to validate lupus biomarkers.

"(6) Research to develop improved diagnostic tests.".

SEC. 102. STRENGTHENING LUPUS EPIDEMIOLOGY; LUPUS STUDY.

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

"STRENGTHENING LUPUS EPIDEMIOLOGY

"SEC. 318C. (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall work with a consortium of leading United States academic health institutions that have expertise in the epidemiology of lupus to undertake a national scale lupus epidemiological study to determine the true prevalence and incidence of lupus in the United States.

"(b) USE OF FUNDS.—The Director of the Centers for Disease Control and Prevention shall enter into a cooperative agreement with the consortium described in subsection (a) to develop, implement, and manage a system for lupus data collection and analysis, including—

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

"(2) the enhancement of the 2 study sites involved in the existing lupus patient registry of the Centers for Disease Control and Prevention on the day before the date of enactment of the Lupus Research, Education, Awareness, Communication, and Healthcare Amendments of 2007.

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

"(d) CERTAIN ACTIVITIES.—In carrying out subsections (a) and (b), the consortium described in subsection (a) shall capture data related to all affected populations on all forms of lupus, including lupus related disorders.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $3,500,000 for each of the fiscal years 2008, 2009, 2010, and 2011.

“LUPUS STUDY AND REPORT BY THE INSTITUTE OF MEDICINE

“SEC. 318D. (a) CONTRACT.—The Secretary shall enter into a contract with the Institute of Medicine to conduct a study—

“(1) to evaluate the Federal and State activities related to lupus research, education, and awareness programs and activities and make recommendations for ways in which these initiatives could be expanded;

“(2) to identify the gaps in Federal research related to—

“(A) the causes of lupus;

“(B) lupus detection and diagnosis;

“(C) lupus treatment; and

“(D) lupus quality-of-life concerns;

“(3) to make recommendations for building and supporting the lupus research enterprise, including recommendations for strategies for future basic, clinical, social, and behavioral research—

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

''(B) to secure the development of new and improved lupus therapies and ways to diagnose the disease;

''(4) to determine the gaps in lupus health professional education programs and public awareness efforts and make recommendations for ways in which the Federal Government can—

''(A) improve public and health professional awareness of lupus; and

''(B) partner and support nonprofit voluntary health agencies (such as the Lupus Foundation of America, Inc.) and academic institutions and other interested stakeholders whose primary purposes are to increase public awareness of lupus and to improve the diagnosis and treatment of lupus;

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

''(6) to summarize the clinical and biological features of lupus and the characteristics and management of major symptoms and make recommendations for disease management and measurement; and

''(7) to make recommendations for epidemiological studies in the various population groups affected by lupus in the United States.

"(b) REPORT.—Not later than 18 months after the date of enactment of the Lupus Research, Education, Awareness, Communication, and Healthcare Amendments of 2007, the Institute of Medicine shall submit to the Secretary a report containing the information described in paragraphs (1) through (7) of subsection (a).".

TITLE II—ENHANCING LUPUS AWARENESS AND EDUCATION

SEC. 201. INCREASING PUBLIC AWARENESS AND IMPROVING HEALTH PROFESSIONAL EDUCATION.

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

"INCREASING PUBLIC AWARENESS OF LUPUS AND IMPROVING HEALTH PROFESSIONAL EDUCATION

"SEC. 318E. (a) IN GENERAL.—The Secretary, acting through the Director of the Office on Women's Health and in collaboration with the Lupus Foundation of America, Inc. and the National Center on Minority Health and Health Disparities of the National Institutes of Health, shall conduct and support a sustained national lupus public awareness and health professional education campaign, with an emphasis on reaching populations at highest risk for the disease.

‘‘(b) USE OF FUNDS.—In conducting the sustained national lupus public awareness and health professional educational campaign, the Director of the Office on Women's Health shall—

‘‘(1) promote increased awareness of early intervention and treatment so as to significantly improve the diagnosis, treatment, and quality of life for people with lupus;

‘‘(2) direct communication and education efforts toward minority communities that may be underserved or disproportionately affected by lupus; and

‘‘(3) target at-risk women and health professionals likely to see women with lupus, including primary care physicians and specialists such as rheumatologists, nephrologists, dermatologists, and immunologists, so as to help reduce the amount of time taken to achieve a correct diagnosis of lupus.

‘‘(c) CERTAIN ACTIVITIES.—To the extent practicable and appropriate, the Secretary shall ensure that communications under subsections (a) and (b) provide the latest medically sound information related to the signs, symptoms, diagnosis, and disease management of lupus.

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

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $1,000,000 for each of the fiscal years 2008 through 2012.”.

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