

LUPUS RESEARCH AND CARE AMENDMENTS OF 2000

OCTOBER 10, 2000.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BLILEY, from the Committee on Commerce, submitted the following

R E P O R T

[To accompany H.R. 762]

The Committee on Commerce, to whom was referred the bill (H.R. 762) to amend the Public Health Service Act to provide for research and services with respect to lupus, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Lupus Research and Care Amendments of 2000”.

**SEC. 2. FINDINGS.**

The Congress finds that—

- (1) lupus is a serious, complex, inflammatory, autoimmune disease of particular concern to women;
- (2) lupus affects women 9 times more often than men;
- (3) there are 3 main types of lupus: systemic lupus, a serious form of the disease that affects many parts of the body; discoid lupus, a form of the disease that affects mainly the skin; and drug-induced lupus caused by certain medications;
- (4) lupus can be fatal if not detected and treated early;
- (5) the disease can simultaneously affect various areas of the body, such as the skin, joints, kidneys, and brain, and can be difficult to diagnose because the symptoms of lupus are similar to those of many other diseases;
- (6) lupus disproportionately affects African-American women, as the prevalence of the disease among such women is 3 times the prevalence among white women, and an estimated 1 in 250 African-American women between the ages of 15 and 65 develops the disease;
- (7) it has been estimated that between 1,400,000 and 2,000,000 Americans have been diagnosed with the disease, and that many more have undiagnosed cases;
- (8) current treatments for the disease can be effective, but may lead to damaging side effects;
- (9) many victims of the disease suffer debilitating pain and fatigue, making it difficult to maintain employment and lead normal lives; and
- (10) in fiscal year 1996, the amount allocated by the National Institutes of Health for research on lupus was \$33,000,000, which is less than ½ of 1 percent of the budget for such Institutes.

## **TITLE I—RESEARCH ON LUPUS**

**SEC. 101. EXPANSION AND INTENSIFICATION OF ACTIVITIES.**

Subpart 4 of part C of title IV of the Public Health Service Act (42 U.S.C. 285d et seq.) is amended by inserting after section 441 the following section:

“LUPUS

“SEC. 441A. (a) IN GENERAL.—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) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.

“(2) Basic research concerning the etiology and causes of the disease.

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

“(4) The development of improved diagnostic techniques.

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

“(6) Information and education programs for health care professionals and the public.

“(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.”.

## TITLE II—DELIVERY OF SERVICES REGARDING LUPUS

### SEC. 201. ESTABLISHMENT OF PROGRAM OF GRANTS.

(a) **IN GENERAL.**—The Secretary of Health and Human Services shall in accordance with this title make grants to provide for projects for the establishment, operation, and coordination of effective and cost-efficient systems for the delivery of essential services to individuals with lupus and their families.

(b) **RECIPIENTS OF GRANTS.**—A grant under subsection (a) may be made to an entity only if the entity is a public or nonprofit private entity, which may include a State or local government; a public or nonprofit private hospital, community-based organization, hospice, ambulatory care facility, community health center, migrant health center, or homeless health center; or other appropriate public or nonprofit private entity.

(c) **CERTAIN ACTIVITIES.**—To the extent practicable and appropriate, the Secretary shall ensure that projects under subsection (a) provide services for the diagnosis and disease management of lupus. Activities that the Secretary may authorize for such projects may also include the following:

(1) Delivering or enhancing outpatient, ambulatory, and home-based health and support services, including case management and comprehensive treatment services, for individuals with lupus; and delivering or enhancing support services for their families.

(2) Delivering or enhancing inpatient care management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities of individuals with lupus.

(3) Improving the quality, availability, and organization of health care and support services (including transportation services, attendant care, homemaker services, day or respite care, and providing counseling on financial assistance and insurance) for individuals with lupus and support services for their families.

(d) **INTEGRATION WITH OTHER PROGRAMS.**—To the extent practicable and appropriate, the Secretary shall integrate the program under this title with other grant programs carried out by the Secretary, including the program under section 330 of the Public Health Service Act.

### SEC. 202. CERTAIN REQUIREMENTS.

A grant may be made under section 201 only if the applicant involved makes the following agreements:

(1) Not more than 5 percent of the grant will be used for administration, accounting, reporting, and program oversight functions.

(2) The grant will be used to supplement and not supplant funds from other sources related to the treatment of lupus.

(3) The applicant will abide by any limitations deemed appropriate by the Secretary on any charges to individuals receiving services pursuant to the grant. As deemed appropriate by the Secretary, such limitations on charges may vary based on the financial circumstances of the individual receiving services.

(4) The grant will not be expended to make payment for services authorized under section 201(a) to the extent that payment has been made, or can reasonably be expected to be made, with respect to such services—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(5) The applicant will, at each site at which the applicant provides services under section 201(a), post a conspicuous notice informing individuals who receive the services of any Federal policies that apply to the applicant with respect to the imposition of charges on such individuals.

### SEC. 203. TECHNICAL ASSISTANCE.

The Secretary may provide technical assistance to assist entities in complying with the requirements of this title in order to make such entities eligible to receive grants under section 201.

### SEC. 204. DEFINITIONS.

For purposes of this title:

(1) The term “official poverty line” means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981.

(2) The term "Secretary" means the Secretary of Health and Human Services.

**SEC. 205. AUTHORIZATION OF APPROPRIATIONS.**

For the purpose of carrying out this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.

**PURPOSE AND SUMMARY**

H.R. 762 expands Federal lupus research activities through the National Institutes of Health. The bill also authorizes the Secretary of Health and Human Services to make grants to projects for the delivery of essential services to individuals with lupus and their families.

**BACKGROUND AND NEED FOR LEGISLATION**

Over 1.4 million Americans have lupus erythematosus, a devastating disease that causes the immune system to attack the body's own cells and organs. Lupus causes debilitating health effects including extreme joint pain and swelling, constant fevers, overwhelming fatigue, horrible skin rashes, organ failure, and a host of other devastating symptoms. Lupus destroys the quality of life for many of its victims. The disease can severely damage the kidneys, heart, lungs, and other vital organs. Lupus disables one in five of its victims, often at a very young age. Tragically, every year thousands of lupus victims die from complications of the disease.

Ninety percent of the victims of lupus are women, and it is more common among women of color. Lupus is two to three times more likely to affect African-Americans, Hispanics, Asians and Native-Americans than women of European ancestry. Lupus tends to strike women in their child-bearing years, between the ages of 15 and 44, yet is difficult to diagnose. By the time some lupus patients are diagnosed, especially in poor or rural communities, irreversible damage to vital organs may already have occurred. This increases the need for expensive treatments, such as kidney dialysis or organ transplantation.

Lupus is a complicated and mysterious disease that needs extensive study. Presently there is no cure for lupus, nor do researchers fully understand what causes the disease. Medical science has not discovered why lupus alternates between periods of remission and periods of disease activity, called flares, nor why the disease can remain mild in some individuals and become life-threatening in others.

Lupus is an expensive disease to treat. The cost to provide medical care for a person with lupus averages between six and ten thousand dollars annually. The Lupus Foundation of America estimates the economic impact of lupus on the Federal treasury to be several billion dollars every year. These costs include disability income payments to the tens of thousands of lupus victims disabled every year by the disease. They also include the cost of government-sponsored medical care provided through the Medicare and Medicaid programs, and uncollected tax revenue due to lost wages when individuals with lupus are unable to work.

Current research on lupus must be enhanced in hopes of addressing the disease. Moreover, it is important to try new ways of providing for care to get to patients for early diagnosis and disease management. H.R. 762 will provide for enhanced research and

allow for projects to reach out to lupus victims and improve patient care among low-income populations. The Committee expects these projects to provide examples that can be followed in other private and public programs to help victims of lupus.

#### HEARINGS

The Subcommittee on Health and Environment held a hearing on H.R. 762 on September 13, 2000. The Subcommittee received testimony from Ms. Tomiko Fraser, National Spokesperson, Lupus Foundation of America, Inc.

#### COMMITTEE CONSIDERATION

On September 26, 2000, the Subcommittee on Health and Environment was discharged from the further consideration of H.R. 762. On September 26, 2000, the Full Committee met in open markup session and ordered H.R. 762 reported, with an amendment, by a voice vote.

#### COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 762 reported. A motion by Mr. Bliley to order H.R. 762 reported to the House, with an amendment, was agreed to by a voice vote.

The following amendment was agreed to by a voice vote:

An amendment in the nature of a substitute by Mr. Bilirakis, No. 1, creating flexibility for the Secretary's authority to provide grants.

#### COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a legislative hearing and made findings that are reflected in this report.

#### COMMITTEE ON GOVERNMENT REFORM OVERSIGHT FINDINGS

Pursuant to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, no oversight findings have been submitted to the Committee by the Committee on Government Reform.

#### NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 762, the Lupus Research and Care Amendments of 2000, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

#### COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

The cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not timely received by the Committee. The Committee will submit such estimate to the House upon its receipt.

## FEDERAL MANDATES STATEMENT

The estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act was not timely received by the Committee. The Committee will submit such statement to the House upon its receipt.

## ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

## CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

## APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

## SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

*Section 1. Short title*

Section 1 of H.R. 762 provides the short title of the bill, the "Lupus Research and Care Amendments of 2000".

*Section 2. Findings*

Section 2 provides findings on the serious nature of the lupus problem in America.

## TITLE I—RESEARCH ON LUPUS

*Section 101. Expansion and intensification of activities*

Title I of the bill amends subpart 4 of part C of title IV of the Public Health Services Act and expands Federal lupus medical research activities supported through the National Institutes of Health. The provision authorizes such sums as may be necessary for these activities for each of the fiscal years 2001 through 2003.

## TITLE II—DELIVERY OF SERVICES REGARDING LUPUS

### *Section 201. Establishment of program of grants*

Section 201 authorizes the Secretary of Health and Human Services to make grants to projects for the delivery of essential services to individuals with lupus and their families.

### *Section 202. Certain requirements*

Section 202 provides for certain requirements on grant recipients.

### *Section 203. Technical assistance*

Section 203 provides for technical assistance to grant applicants.

### *Section 204. Definitions*

Section 204 provides certain definitions.

### *Section 205. Authorization of appropriations*

Section 205 authorizes such sums as may be necessary for each of the fiscal years 2001 through 2003.

### CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

## **SECTION 441A OF THE PUBLIC HEALTH SERVICE ACT**

### *LUPUS*

*SEC. 441A. (a) IN GENERAL.—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) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.*

*(2) Basic research concerning the etiology and causes of the disease.*

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

*(4) The development of improved diagnostic techniques.*

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

(6) *Information and education programs for health care professionals and the public.*

(d) *AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.*