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109TH CONGRESS
1ST SESSION

H. R. 4033

To amend the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis Registry.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 7, 2005

Mr. ENGEL (for himself, Mr. TERRY, Mr. SHIMKUS, Mr. WAXMAN, Mr. WHITFIELD, Mr. BROWN of Ohio, Ms. ESHOO, Mr. TOWNS, Mr. RUSH, Mrs. CAPPS, Mr. ALLEN, Mr. RANGEL, Mr. FOLEY, Mr. MCNULTY, Mr. MCHUGH, Ms. ROS-LEHTINEN, Mr. MCDERMOTT, Ms. DELAURO, Mr. SHAYS, Mr. JEFFERSON, Mr. GOODE, Mr. LANTOS, Ms. BERKLEY, Mr. CALVERT, Ms. BORDALLO, Mr. BRADY of Pennsylvania, Mr. MOORE of Kansas, Ms. JACKSON-LEE of Texas, Mr. ABERCROMBIE, Ms. CARSON, Mr. CROWLEY, Mr. FILNER, Mr. GRIJALVA, Mr. HIGGINS, Mr. HINCHEY, Mr. KUCINICH, Mr. LYNCH, Mr. RUPPERSBERGER, Mr. SANDERS, Mr. SCHIFF, Mr. SCOTT of Georgia, Mr. VAN HOLLEN, Ms. WASSERMAN SCHULTZ, Mr. WEINER, Mr. WEXLER, Mr. CAPUANO, and Mr. OWENS) 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 provide for the establishment of an Amyotrophic Lateral Sclerosis Registry.

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 "ALS Registry Act".

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Amyotrophic Lateral Sclerosis (referred to in this section as "ALS") is a fatal, progressive neurodegenerative disease that affects motor nerve cells in the brain and the spinal cord.

(2) The average life expectancy for a person with ALS is 2 to 5 years from the time of diagnosis.

(3) The cause of ALS is not well understood.

(4) There is only one drug currently approved by the Food and Drug Administration for the treatment of ALS, which has thus far shown only modest effects, prolonging life by just a few months.

(5) There is no known cure for ALS.

(6) More than 5,000 individuals in the United States are diagnosed with ALS annually and as many as 30,000 individuals may be living with ALS in the United States today.

(7) Studies have found relationships between ALS and environmental and genetic factors, but those relationships are not well understood.

(8) Scientists believe that there are significant ties between ALS and any motor neuron diseases.

(9) Several ALS disease registries and databases exist in the United States and throughout the world, including the SOD1 database, the National

Institute of Neurological Disorders and Stroke repository, and the Department of Veterans Affairs ALS Registry.

(10) A single national system to collect and store information on the prevalence and incidence of ALS in the United States does not exist.

(11) The establishment of a national registry will help—

(A) identify the incidence and prevalence of ALS in the United States;

(B) collect data important to the study of ALS;

(C) promote a better understanding of ALS;

(D) promote research into the genetic and environmental factors that cause ALS;

(E) provide a means for patients to contact scientists researching the environmental and genetic factors that cause ALS as well as those engaged in clinical trials; and

(F) enhance efforts to find treatments and a cure for ALS.

SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

“SEC. 399O. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.

“(a) ESTABLISHMENT.—

“(1) IN GENERAL.—Not later than 6 months after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with a national voluntary health organization with experience serving the population of individuals with amyotrophic lateral sclerosis (referred to in this section as ‘ALS’), shall—

“(A) develop a system to collect data on ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

“(B) establish a national registry for the collection and storage of such data to include a population-based registry of cases of ALS in the United States.

“(2) PURPOSE.—It is the purpose of the registry established under paragraph (1)(B) to—

“(A) gather data concerning—

“(i) ALS, including the incidence and prevalence of ALS in the United States;

“(ii) the environmental and occupational factors that may be associated with the disease;

“(iii) the age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease; and

“(iv) other matters as recommended by the Advisory Committee established under subsection (b); and

“(B) establish a secure method to put patients in contact with scientists studying the environmental, and genetic causes of motor neuron disease or conducting clinical trials on therapies for motor neuron disease.

“(b) ADVISORY COMMITTEE.—

“(1) ESTABLISHMENT.—Not later than 60 days after the date of the enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the ‘Advisory Committee’). The Advisory Committee shall be composed of at least one member, to be appointed by the Secretary, acting through the Director of the Centers for Disease Control and Prevention, representing each of the following:

“(A) National voluntary health associations that focus solely on ALS that have a demonstrated experience in ALS research, care, and patient services.

“(B) The National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences.

“(C) The Department of Veterans Affairs.

“(D) The Agency for Toxic Substances and Disease Registry.

“(E) The Centers for Disease Control and Prevention.

“(F) Patients with ALS or their family members.

“(G) Clinicians who have worked with data registries.

“(H) Epidemiologists with experience in data registries.

“(I) Geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases.

“(J) Statisticians.

“(K) Ethicists.

“(L) Attorneys.

“(M) Other individuals with an interest in developing and maintaining the National ALS Registry.

“(2) DUTIES.—The Advisory Committee shall conduct a study and make recommendations to the Secretary concerning—

“(A) the development and maintenance of the National ALS Registry;

“(B) the type of information to be collected and stored in the Registry;

“(C) the manner in which such data is to be collected;

“(D) the use and availability of such data including guidelines for such use; and

“(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

''(3) REPORT.—Not later than 6 months after the date on which the Advisory Committee is established, the Advisory Committee shall submit a report concerning the study conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such study.

''(c) GRANTS.—Notwithstanding the recommendations of the Advisory Committee under subsection (b), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS.

''(d) COORDINATION WITH STATE, LOCAL, AND FEDERAL REGISTRIES.—

''(1) IN GENERAL.—In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

''(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, including—

"(i) the Department of Veterans Affairs ALS Registry;

"(ii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center;

"(iii) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio Texas, and Massachusetts;

"(iv) State-based ALS registries, including the Massachusetts ALS Registry;

"(v) the National Vital Statistics System; and

"(vi) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

"(B) provide for public access to an electronic national database that accepts data from State-based registries, health care professionals, and others as recommended by the Advisory Committee established in subsection (b) in a manner that protects personal privacy consistent with medical privacy regulations.

"(2) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Notwithstanding the recommendations of the Advisory Committee established in subsection (b), the Secretary shall ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

"(e) DEFINITION.—For the purposes of this section, the term 'national voluntary health association' means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $25,000,000 for fiscal year 2006, and such sums as may be necessary for each of fiscal years 2007 through 2010.".

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