

110TH CONGRESS
1ST SESSION

H. R. 2295

AN ACT

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

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 “ALS Registry Act”.

3 **SEC. 2. FINDINGS.**

4 Congress makes the following findings:

5 (1) Amyotrophic lateral sclerosis (referred to in
6 this section as “ALS”) is a fatal, progressive
7 neurodegenerative disease that affects motor nerve
8 cells in the brain and the spinal cord.

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

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

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

16 (5) There is no known cure for ALS.

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

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

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

1 (9) Several ALS disease registries and data-
2 bases exist in the United States and throughout the
3 world, including the SOD1 database, the National
4 Institute of Neurological Disorders and Stroke re-
5 pository, and the Department of Veterans Affairs
6 ALS Registry.

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

10 (11) In each of fiscal years 2006 and 2007,
11 Congress directed \$887,000 to the Centers for Dis-
12 ease Control and Prevention to begin a nationwide
13 ALS registry.

14 (12) The Centers for Disease Control and Pre-
15 vention and the Agency for Toxic Substances and
16 Disease Registry have established three pilot
17 projects, beginning in fiscal year 2006, to evaluate
18 the science to guide the creation of a national ALS
19 registry.

20 (13) The establishment of a national registry
21 will help—

22 (A) to identify the incidence and preva-
23 lence of ALS in the United States;

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

1 (C) to promote a better understanding of
2 ALS;

3 (D) to collect information that is impor-
4 tant for research into the genetic and environ-
5 mental factors that cause ALS;

6 (E) to strengthen the ability of a clearing-
7 house—

8 (i) to collect and disseminate research
9 findings on environmental, genetic, and
10 other causes of ALS and other motor neu-
11 ron disorders that can be confused with
12 ALS, misdiagnosed as ALS, and in some
13 cases progress to ALS;

14 (ii) to make available information to
15 patients about research studies for which
16 they may be eligible; and

17 (iii) to maintain information about
18 clinical specialists and clinical trials on
19 therapies; and

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

1 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
2 **ACT.**

3 Part P of title III of the Public Health Service Act
4 (42 U.S.C. 280g et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REG-**
7 **ISTRY.**

8 “(a) ESTABLISHMENT.—

9 “(1) IN GENERAL.—Not later than 1 year after
10 the receipt of the report described in subsection
11 (b)(3), the Secretary, acting through the Director of
12 the Centers for Disease Control and Prevention and
13 in consultation with a national voluntary health or-
14 ganization with experience serving the population of
15 individuals with amyotrophic lateral sclerosis (re-
16 ferred to in this section as ‘ALS’), shall—

17 “(A) develop a system to collect data on
18 ALS and other motor neuron disorders that can
19 be confused with ALS, misdiagnosed as ALS,
20 and in some cases progress to ALS, including
21 information with respect to the incidence and
22 prevalence of the disease in the United States;
23 and

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

1 States of ALS and other motor neuron dis-
2 orders that can be confused with ALS,
3 misdiagnosed as ALS, and in some cases
4 progress to ALS.

5 “(2) PURPOSE.—It is the purpose of the reg-
6 istry established under paragraph (1)(B) to gather
7 available data concerning—

8 “(A) ALS, including the incidence and
9 prevalence of ALS in the United States;

10 “(B) the environmental and occupational
11 factors that may be associated with the disease;

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

15 “(D) other motor neuron disorders that
16 can be confused with ALS, misdiagnosed as
17 ALS, and in some cases progress to ALS; and

18 “(E) other matters as recommended by the
19 Advisory Committee established under sub-
20 section (b).

21 “(b) ADVISORY COMMITTEE.—

22 “(1) ESTABLISHMENT.—Not later than 90 days
23 after the date of the enactment of this section, the
24 Secretary, acting through the Director of the Cen-
25 ters for Disease Control and Prevention, shall estab-

1 lish a committee to be known as the Advisory Com-
2 mittee on the National ALS Registry (referred to in
3 this section as the ‘Advisory Committee’). The Advi-
4 sory Committee shall be composed of at least one
5 member, to be appointed by the Secretary, acting
6 through the Director of the Centers for Disease
7 Control and Prevention, representing each of the fol-
8 lowing:

9 “(A) National voluntary health associa-
10 tions that focus solely on ALS and have dem-
11 onstrated experience in ALS research, care, and
12 patient services, as well as other voluntary asso-
13 ciations focusing on neurodegenerative diseases
14 that represent and advocate on behalf of pa-
15 tients with ALS and patients with other motor
16 neuron disorders that can be confused with
17 ALS, misdiagnosed as ALS, and in some cases
18 progress to ALS.

19 “(B) The National Institutes of Health, to
20 include, upon the recommendation of the Direc-
21 tor of the National Institutes of Health, rep-
22 resentatives from the National Institute of Neu-
23 rological Disorders and Stroke and the National
24 Institute of Environmental Health Sciences.

25 “(C) The Department of Veterans Affairs.

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

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

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

7 “(G) Clinicians with expertise on ALS and
8 related diseases.

9 “(H) Epidemiologists with experience in
10 data registries.

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

14 “(J) Statisticians.

15 “(K) Ethicists.

16 “(L) Attorneys.

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

20 “(2) DUTIES.—The Advisory Committee shall
21 review information and make recommendations to
22 the Secretary concerning—

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

1 “(B) the type of information to be col-
2 lected and stored in the Registry;

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

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

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

11 “(3) REPORT.—Not later than 1 year after the
12 date on which the Advisory Committee is estab-
13 lished, the Advisory Committee shall submit a report
14 concerning the review conducted under paragraph
15 (2) that contains the recommendations of the Advi-
16 sory Committee with respect to the results of such
17 review.

18 “(c) GRANTS.—Notwithstanding the recommenda-
19 tions of the Advisory Committee under subsection (b), the
20 Secretary, acting through the Director of the Centers for
21 Disease Control and Prevention, may award grants to, and
22 enter into contracts and cooperative agreements with, pub-
23 lic or private nonprofit entities for the collection, analysis,
24 and reporting of data on ALS and other motor neuron

1 disorders that can be confused with ALS, misdiagnosed
2 as ALS, and in some cases progress to ALS.

3 “(d) COORDINATION WITH STATE, LOCAL, AND FED-
4 ERAL REGISTRIES.—

5 “(1) IN GENERAL.—In establishing the Na-
6 tional ALS Registry under subsection (a), the Sec-
7 retary, acting through the Director of the Centers
8 for Disease Control and Prevention, shall—

9 “(A) identify, build upon, expand, and co-
10 ordinate among existing data and surveillance
11 systems, surveys, registries, and other Federal
12 public health and environmental infrastructure
13 wherever possible, including—

14 “(i) the 3 ALS registry pilot projects
15 initiated in fiscal year 2006 by the Centers
16 for Disease Control and Prevention and
17 the Agency for Toxic Substances and Dis-
18 ease Registry at the South Carolina Office
19 of Research & Statistics; the Mayo Clinic
20 in Rochester, Minnesota; and Emory Uni-
21 versity in Atlanta, Georgia;

22 “(ii) the Department of Veterans Af-
23 fairs ALS Registry;

24 “(iii) the DNA and Cell Line Reposi-
25 tory of the National Institute of Neuro-

1 logical Disorders and Stroke Human Ge-
2 netics Resource Center;

3 “ (iv) the Agency for Toxic Substances
4 and Disease Registry studies, including
5 studies conducted in Illinois, Missouri, El
6 Paso and San Antonio, Texas, and Massa-
7 chusetts;

8 “ (v) State-based ALS registries, in-
9 cluding the Massachusetts ALS Registry;

10 “ (vi) the National Vital Statistics Sys-
11 tem; and

12 “ (vii) any other existing or relevant
13 databases that collect or maintain informa-
14 tion on those motor neuron diseases rec-
15 ommended by the Advisory Committee es-
16 tablished in subsection (b); and

17 “ (B) provide for research access to ALS
18 data as recommended by the Advisory Com-
19 mittee established in subsection (b) to the ex-
20 tent permitted by applicable statutes and regu-
21 lations and in a manner that protects personal
22 privacy consistent with applicable privacy stat-
23 utes and regulations.

24 “ (2) COORDINATION WITH NIH AND DEPART-
25 MENT OF VETERANS AFFAIRS.—Notwithstanding the

1 recommendations of the Advisory Committee estab-
2 lished in subsection (b), and consistent with applica-
3 ble privacy statutes and regulations, the Secretary
4 shall ensure that epidemiological and other types of
5 information obtained under subsection (a) is made
6 available to the National Institutes of Health and
7 the Department of Veterans Affairs.

8 “(e) DEFINITION.—For the purposes of this section,
9 the term ‘national voluntary health association’ means a
10 national non-profit organization with chapters or other af-
11 filiated organizations in States throughout the United
12 States.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
14 are authorized to be appropriated to carry out this section,
15 \$25,000,000 for fiscal year 2008, and \$16,000,000 for
16 each of the fiscal years 2009 through 2012.”.

Passed the House of Representatives October 16,
2007.

Attest:

Clerk.

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