

110TH CONGRESS  
1ST SESSION

# H. R. 2295

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## 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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