

**[COMMITTEE PRINT]**

(SHOWING H.R. 2295 AS REPORTED BY THE SUBCOMMITTEE ON HEALTH  
ON JULY 19, 2007)

110TH CONGRESS  
1ST SESSION

**H. R. 2295**

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

---

IN THE HOUSE OF REPRESENTATIVES

MAY 14, 2007

Mr. ENGEL (for himself, Mr. TERRY, Mr. WAXMAN, Mr. UPTON, Mr. MARKEY, Mr. WHITFIELD, Mr. TOWNS, Mr. SHIMKUS, Mr. RUSH, Mr. FOSSELLA, Mr. WYNN, Mrs. BONO, Mr. GENE GREEN of Texas, Mr. FERGUSON, Mrs. CAPPS, Mrs. MYRICK, Mr. DOYLE, Mr. ALLEN, Ms. SCHAKOWSKY, Ms. SOLIS, Mr. GONZALEZ, Mr. INSLEE, Ms. BALDWIN, Mr. ROSS, Mr. WEINER, Mr. MATHESON, Mr. BUTTERFIELD, Mr. BARROW, Ms. ROS-LEHTINEN, Mr. RANGEL, Mr. MCCRERY, Mr. STARK, Mr. GOODE, Mr. KENNEDY, Mr. GERLACH, Mr. ROTHMAN, Mr. BURTON of Indiana, Mr. EMANUEL, Mr. SHAYS, Mr. HIGGINS, Ms. FALLIN, Mr. COHEN, Mr. BOUSTANY, Mr. PATRICK J. MURPHY of Pennsylvania, Mr. SMITH of New Jersey, Mr. McDERMOTT, Mr. BROWN of South Carolina, Ms. NORTON, Mrs. McMORRIS RODGERS, Mr. PRICE of North Carolina, Mr. MCHUGH, Mr. ABERCROMBIE, Mr. EHLERS, Mr. McNULTY, Mr. GALLEGLY, Mr. MCINTYRE, Mr. PEARCE, Mr. NADLER, Ms. CARSON, Mr. OLVER, Mr. TIERNEY, Mr. KANJORSKI, Mr. BISHOP of New York, Mr. MCGOVERN, Mr. CROWLEY, Mr. GRIJALVA, Mrs. LOWEY, Mr. SHERMAN, Ms. LORETTA SANCHEZ of California, Mr. MURTHA, Mr. ETHERIDGE, Mr. CAPUANO, Ms. KAPTUR, Mr. VAN HOLLEN, Mrs. MCCARTHY of New York, Ms. MCCOLLUM of Minnesota, Mr. BERMAN, Mr. SIRES, Ms. ROYBAL-ALLARD, Mr. CRAMER, Ms. HIRONO, Ms. BORDALLO, Mr. BOSWELL, and Mr. KIND) introduced the following bill; which was referred to the Committee on Energy and Commerce

# A BILL

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,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “ALS Registry Act”.

5       **SEC. 2. FINDINGS.**

6       Congress makes the following findings:

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

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

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

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

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

19              (6) More than 5,000 individuals in the United  
20      States are diagnosed with ALS annually and as

1 many as 30,000 individuals may be living with ALS  
2 in the United States today.

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

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

8 (9) Several ALS disease registries and data-  
9 bases exist in the United States and throughout the  
10 world, including the SOD1 database, the National  
11 Institute of Neurological Disorders and Stroke re-  
12 pository, and the Department of Veterans Affairs  
13 ALS Registry.

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

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

21 (12) The Centers for Disease Control and Pre-  
22 vention and the Agency for Toxic Substances and  
23 Disease Registry has established three pilot projects,  
24 beginning in fiscal year 2006, to evaluate the science  
25 to guide the creation of a national ALS registry.

1           (13) The establishment of a national registry  
2 will help—

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

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

7           (C) to promote a better understanding of  
8 ALS;

9           (D) to collect information that is impor-  
10 tant for research into the genetic and environ-  
11 mental factors that cause ALS;

12           (E) to strengthen the ability of a clearing-  
13 house—

14           (i) to collect and disseminate research  
15 findings on environmental, genetic, and  
16 other causes of ALS and other motor neu-  
17 ron disorders that can be confused with  
18 ALS, misdiagnosed as ALS, and in some  
19 cases progress to ALS;

20           (ii) make available information to pa-  
21 tients about research studies for which  
22 they may be eligible; and

23           (iii) maintain information about clin-  
24 ical specialists and clinical trials on thera-  
25 pies; and

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

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

5 Part P of title III of the Public Health Service Act  
6 (42 U.S.C. 280g et seq.) is amended by adding at the end  
7 the following:

8 **“SEC. 3990. AMYOTROPHIC LATERAL SCLEROSIS REG-**  
9 **ISTRY.**

10 “(a) ESTABLISHMENT.—

11 “(1) IN GENERAL.—Not later than 1 year after  
12 the receipt of the report described in subsection  
13 (b)(2)(A), the Secretary, acting through the Director  
14 of the Centers for Disease Control and Prevention  
15 and in consultation with a national voluntary health  
16 organization with experience serving the population  
17 of individuals with amyotrophic lateral sclerosis (re-  
18 ferred to in this section as ‘ALS’), shall—

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

1           “(B) establish a national registry for the  
2           collection and storage of such data to include a  
3           population-based registry of cases in the United  
4           States of ALS and other motor neuron dis-  
5           orders that can be confused with ALS,  
6           misdiagnosed as ALS, and in some cases  
7           progress to ALS.

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

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

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

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

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

21           “(E) other matters as recommended by the  
22          Advisory Committee established under sub-  
23          section (b).

24          “(b) ADVISORY COMMITTEE.—

1           “(1) ESTABLISHMENT.—Not later than 90 days  
2 after the date of the enactment of this section, the  
3 Secretary, acting through the Director of the Cen-  
4 ters for Disease Control and Prevention, shall estab-  
5 lish a committee to be known as the Advisory Com-  
6 mittee on the National ALS Registry (referred to in  
7 this section as the ‘Advisory Committee’). The Advi-  
8 sory Committee shall be composed of at least one  
9 member, to be appointed by the Secretary, acting  
10 through the Director of the Centers for Disease  
11 Control and Prevention, representing each of the fol-  
12 lowing:

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

23           “(B) The National Institutes of Health, to  
24 include, upon the recommendation of the Direc-  
25 tor of the National Institutes of Health, rep-

1           representatives from the National Institute of Neu-  
2           rological Disorders and Stroke and the National  
3           Institute of Environmental Health Sciences.

4           “(C) The Department of Veterans Affairs.

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

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

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

11          “(G) Clinicians with expertise on ALS and  
12          related diseases.

13          “(H) Epidemiologists with experience in  
14          data registries.

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

18          “(J) Statisticians.

19          “(K) Ethicists.

20          “(L) Attorneys.

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

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

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

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

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

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

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

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

23           “(c) GRANTS.—Notwithstanding the recommenda-  
24 tions of the Advisory Committee under subsection (b), the  
25 Secretary, acting through the Director of the Centers for

1 Disease Control and Prevention, may award grants to, and  
2 enter into contracts and cooperative agreements with, pub-  
3 lic or private nonprofit entities for the collection, analysis,  
4 and reporting of data on ALS and other motor neuron  
5 disorders that can be confused with ALS, misdiagnosed  
6 as ALS, and in some cases progress to ALS.

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

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

13 “(A) identify, build upon, expand, and co-  
14 ordinate among existing data and surveillance  
15 systems, surveys, registries, and other Federal  
16 public health and environmental infrastructure  
17 wherever possible, including—

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

1                   “(ii) the Department of Veterans Af-  
2                   fairs ALS Registry;

3                   “(iii) the DNA and Cell Line Reposi-  
4                   tory of the National Institute of Neuro-  
5                   logical Disorders and Stroke Human Ge-  
6                   netics Resource Center;

7                   “(iv) Agency for Toxic Substances  
8                   and Disease Registry studies, including  
9                   studies conducted in Illinois, Missouri, El  
10                  Paso and San Antonio, Texas, and Massa-  
11                  chusetts;

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

14                  “(vi) the National Vital Statistics Sys-  
15                  tem; and

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

21                  “(B) provide for research access to ALS  
22                  data as recommended by the Advisory Com-  
23                  mittee established in subsection (b) to the ex-  
24                  tent permitted by applicable statutes and regu-  
25                  lations and in a manner that protects personal

1           privacy consistent with applicable privacy stat-  
2           utes and regulations.

3           “(2) COORDINATION WITH NIH AND DEPART-  
4           MENT OF VETERANS AFFAIRS.—Notwithstanding the  
5           recommendations of the Advisory Committee estab-  
6           lished in subsection (b), and consistent with applica-  
7           ble privacy statutes and regulations, the Secretary  
8           shall ensure that epidemiological and other types of  
9           information obtained under subsection (a) is made  
10          available to the National Institutes of Health and  
11          the Department of Veterans Affairs.

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

17          “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
18          are authorized to be appropriated to carry out this section,  
19          \$25,000,000 for fiscal year 2008, and \$16,000,000 for  
20          each of the fiscal years 2009 through 2012.”.