

110TH CONGRESS  
1ST SESSION

# S. 1382

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

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IN THE SENATE OF THE UNITED STATES

MAY 14, 2007

Mr. REID introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## 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.

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

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

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

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

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

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

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

18          (9) Several ALS disease registries and data-  
19 bases exist in the United States and throughout the  
20 world, including the SOD1 database, the National  
21 Institute of Neurological Disorders and Stroke re-  
22 pository, and the Department of Veterans Affairs  
23 ALS Registry.

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

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

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

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

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

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

19                 (C) to promote a better understanding of  
20 ALS;

21                 (D) to collect information that is impor-  
22 tant for research into the genetic and environ-  
23 mental factors that cause ALS;

24                 (E) to strengthen the ability of a clearing-  
25 house—

1 (i) to collect and disseminate research  
 2 findings on environmental, genetic and  
 3 other causes of ALS and other motor neu-  
 4 ron disorders that can be confused with  
 5 ALS, misdiagnosed as ALS, and in some  
 6 cases progress to ALS;

7 (ii) make available information to pa-  
 8 tients about research studies for which  
 9 they may be eligible; and

10 (iii) maintain information about clin-  
 11 ical specialists and clinical trials on thera-  
 12 pies; and

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

15 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**  
 16 **ACT.**

17 Part P of title III of the Public Health Service Act  
 18 (42 U.S.C. 280g et seq.) is amended by adding at the end  
 19 the following:

20 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REG-**  
 21 **ISTRY.**

22 “(a) ESTABLISHMENT.—

23 “(1) IN GENERAL.—Not later than 1 year after  
 24 the receipt of the report described in subsection  
 25 (b)(2)(A), the Secretary, acting through the Director

1 of the Centers for Disease Control and Prevention  
2 and in consultation with a national voluntary health  
3 organization with experience serving the population  
4 of individuals with amyotrophic lateral sclerosis (re-  
5 ferred to in this section as ‘ALS’), shall—

6 “(A) develop a system to collect data on  
7 ALS and other motor neuron disorders that can  
8 be confused with ALS, misdiagnosed as ALS,  
9 and in some cases progress to ALS, including  
10 information with respect to the incidence and  
11 prevalence of the disease in the United States;  
12 and

13 “(B) establish a national registry for the  
14 collection and storage of such data to include a  
15 population-based registry of cases in the United  
16 States of ALS and other motor neuron dis-  
17 orders that can be confused with ALS,  
18 misdiagnosed as ALS, and in some cases  
19 progress to ALS.

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

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

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

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

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

9           “(E) other matters as recommended by the  
10 Advisory Committee established under sub-  
11 section (b).

12       “(b) ADVISORY COMMITTEE.—

13           “(1) ESTABLISHMENT.—Not later than 90 days  
14 after the date of the enactment of this section, the  
15 Secretary, acting through the Director of the Cen-  
16 ters for Disease Control and Prevention, shall estab-  
17 lish a committee to be known as the Advisory Com-  
18 mittee on the National ALS Registry (referred to in  
19 this section as the ‘Advisory Committee’). The Advi-  
20 sory Committee shall be composed of at least one  
21 member, to be appointed by the Secretary, acting  
22 through the Director of the Centers for Disease  
23 Control and Prevention, representing each of the fol-  
24 lowing:

1           “(A) National voluntary health associa-  
2           tions that focus solely on ALS and have dem-  
3           onstrated experience in ALS research, care, and  
4           patient services, as well as other voluntary asso-  
5           ciations focusing on neurodegenerative diseases  
6           that represent and advocate on behalf of pa-  
7           tients with ALS and patients with other motor  
8           neuron disorders that can be confused with  
9           ALS, misdiagnosed as ALS, and in some cases  
10          progress to ALS.

11          “(B) The National Institutes of Health, to  
12          include, upon the recommendation of the Direc-  
13          tor of the National Institutes of Health, rep-  
14          resentatives from the National Institute of Neu-  
15          rological Disorders and Stroke and the National  
16          Institute of Environmental Health Sciences.

17          “(C) The Department of Veterans Affairs.

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

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

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

24          “(G) Clinicians with expertise on ALS and  
25          related diseases.

1           “(H) Epidemiologists with experience in  
2 data registries.

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

6           “(J) Statisticians.

7           “(K) Ethicists.

8           “(L) Attorneys.

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

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

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

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

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

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

23           “(E) the collection of information about  
24 diseases and disorders that primarily affect

1           motor neurons that are considered essential to  
2           furthering the study and cure of ALS.

3           “(3) REPORT.—Not later than 1 years after the  
4           date on which the Advisory Committee is estab-  
5           lished, the Advisory Committee shall submit a report  
6           concerning the review conducted under paragraph  
7           (2) that contains the recommendations of the Advi-  
8           sory Committee with respect to the results of such  
9           review.

10          “(c) GRANTS.—Notwithstanding the recommenda-  
11         tions of the Advisory Committee under subsection (b), the  
12         Secretary, acting through the Director of the Centers for  
13         Disease Control and Prevention, may award grants to, and  
14         enter into contracts and cooperative agreements with, pub-  
15         lic or private nonprofit entities for the collection, analysis,  
16         and reporting of data on ALS and other motor neuron  
17         disorders that can be confused with ALS, misdiagnosed  
18         as ALS, and in some cases progress to ALS.

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

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

1           “(A) identify, build upon, expand, and co-  
2           ordinate among existing data and surveillance  
3           systems, surveys, registries, and other Federal  
4           public health and environmental infrastructure  
5           wherever possible, including—

6                   “(i) the 3 ALS registry pilot projects  
7                   initiated in fiscal year 2006 by the Centers  
8                   for Disease Control and Prevention and  
9                   the Agency for Toxic Substances and Dis-  
10                  ease Registry at the South Carolina Office  
11                  of Research & Statistics; the Mayo Clinic  
12                  in Rochester, Minnesota; and Emory Uni-  
13                  versity in Atlanta, Georgia;

14                   “(ii) the Department of Veterans Af-  
15                  fairs ALS Registry;

16                   “(iii) the DNA and Cell Line Reposi-  
17                  tory of the National Institute of Neuro-  
18                  logical Disorders and Stroke Human Ge-  
19                  netics Resource Center;

20                   “(iv) Agency for Toxic Substances  
21                  and Disease Registry studies, including  
22                  studies conducted in Illinois, Missouri, El  
23                  Paso and San Antonio, Texas, and Massa-  
24                  chusetts;

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

3           “(vi) the National Vital Statistics Sys-  
4           tem; and

5           “(vii) any other existing or relevant  
6           databases that collect or maintain informa-  
7           tion on those motor neuron diseases rec-  
8           ommended by the Advisory Committee es-  
9           tablished in subsection (b); and

10          “(B) provide for research access to ALS  
11          data as recommended by the Advisory Com-  
12          mittee established in subsection (b) to the ex-  
13          tent permitted by applicable statutes and regu-  
14          lations and in a manner that protects personal  
15          privacy consistent with applicable privacy stat-  
16          utes and regulations.

17          “(2) COORDINATION WITH NIH AND DEPART-  
18          MENT OF VETERANS AFFAIRS.—Notwithstanding the  
19          recommendations of the Advisory Committee estab-  
20          lished in subsection (b), and consistent with applica-  
21          ble privacy statutes and regulations, the Secretary  
22          shall ensure that epidemiological and other types of  
23          information obtained under subsection (a) is made  
24          available to the National Institutes of Health and  
25          the Department of Veterans Affairs.

1       “(e) DEFINITION.—For the purposes of this section,  
2 the term ‘national voluntary health association’ means a  
3 national non-profit organization with chapters or other af-  
4 filiated organizations in States throughout the United  
5 States.

6       “(f) AUTHORIZATION OF APPROPRIATIONS.—There  
7 are authorized to be appropriated to carry out this section,  
8 \$25,000,000 for fiscal year 2008, and such sums as may  
9 be necessary for each of fiscal years 2009 through 2012.”.

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