

Calendar No. 518

110TH CONGRESS
1ST SESSION

S. 1382

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

IN THE SENATE OF THE UNITED STATES

MAY 14, 2007

Mr. REID (for himself, Mrs. MURRAY, Mrs. BOXER, Mr. HARKIN, Mr. BROWN, Mr. ISAKSON, Mr. INOUE, Mr. DURBIN, Mr. SANDERS, Mr. CRAIG, Mr. BAUCUS, Mr. REED, Mrs. FEINSTEIN, Mr. COLEMAN, Mr. COCHRAN, Mr. CONRAD, Mrs. CLINTON, Mr. MENENDEZ, Mr. THUNE, Mr. BUNNING, Ms. MURKOWSKI, Mrs. DOLE, Mr. JOHNSON, Ms. KLOBUCHAR, Mr. BURR, Mr. DODD, Mr. NELSON of Florida, Mr. BAYH, Mr. HAGEL, Mr. LAUTENBERG, Mr. VITTER, Mr. WARNER, Mr. SCHUMER, Mr. BINGAMAN, Mr. LOTT, Mr. DEMINT, Mr. BENNETT, Ms. SNOWE, Mr. DORGAN, Ms. STABENOW, Mr. MARTINEZ, Mr. CASEY, Mr. GRAHAM, Mr. TESTER, Mr. SMITH, Mr. LIEBERMAN, Mr. WHITEHOUSE, Mr. CARDIN, Mr. AKAKA, Mr. GRASSLEY, Ms. CANTWELL, Ms. COLLINS, Ms. LANDRIEU, Mr. WYDEN, Ms. MIKULSKI, Mr. BROWNBACK, Mr. SESSIONS, Mr. BIDEN, Mr. KERRY, Mr. LEAHY, Mr. CHAMBLISS, Mrs. MCCASKILL, Mr. LEVIN, Mr. CARPER, Mr. PRYOR, Mr. SUNUNU, and Mrs. LINCOLN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 4, 2007

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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

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

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

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

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

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

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

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

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

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

5 (C) to promote a better understanding of
6 ALS;

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

10 (E) to strengthen the ability of a clearing-
11 house—

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

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

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

24 (F) to enhance efforts to find treatments
25 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)(2)(A), the Secretary, acting through the Director
12 of the Centers for Disease Control and Prevention
13 and in consultation with a national voluntary health
14 organization with experience serving the population
15 of 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 years 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 “(e) 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) 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 such sums as may
 16 be necessary for each of fiscal years 2009 through 2012.”.

17 **SECTION 1. SHORT TITLE.**

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

19 **SEC. 2. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.**

20 *Part P of title III of the Public Health Service Act*
 21 *(42 U.S.C. 280g et seq.) is amended by adding at the end*
 22 *the following:*

23 **“SEC. 399R. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY.**

24 “(a) ESTABLISHMENT.—

1 “(1) *IN GENERAL.*—Not later than 1 year after
2 the receipt of the report described in subsection
3 (b)(2)(A), the Secretary, acting through the Director
4 of the Centers for Disease Control and Prevention,
5 shall—

6 “(A) develop a system to collect data on
7 amyotrophic lateral sclerosis (referred to in this
8 section as ‘ALS’) and other motor neuron dis-
9 orders that can be confused with ALS,
10 misdiagnosed as ALS, and in some cases
11 progress to ALS, including information with re-
12 spect to the incidence and prevalence of the dis-
13 ease in the United States; and

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

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

22 “(A) better describe the incidence and prev-
23 alence of ALS in the United States;

1 “(B) examine appropriate factors, such as
2 environmental and occupational, that may be as-
3 sociated with the disease;

4 “(C) better outline key demographic factors
5 (such as age, race or ethnicity, gender, and fam-
6 ily history of individuals who are diagnosed
7 with the disease) associated with the disease;

8 “(D) better examine the connection between
9 ALS and other motor neuron disorders that can
10 be confused with ALS, misdiagnosed as ALS,
11 and in some cases progress to ALS; and

12 “(E) other matters as recommended by the
13 Advisory Committee established under subsection
14 (b).

15 “(b) *ADVISORY COMMITTEE.*—

16 “(1) *ESTABLISHMENT.*—Not later than 180 days
17 after the date of the enactment of this section, the Sec-
18 retary, acting through the Director of the Centers for
19 Disease Control and Prevention, shall establish a
20 committee to be known as the Advisory Committee on
21 the National ALS Registry (referred to in this section
22 as the ‘Advisory Committee’). The Advisory Com-
23 mittee shall be composed of not more than 27 mem-
24 bers to be appointed by the Secretary, acting through

1 *the Centers for Disease Control and Prevention, of*
2 *which—*

3 “(A) *two-thirds of such members shall rep-*
4 *resent governmental agencies—*

5 “(i) *including at least one member rep-*
6 *resenting—*

7 “(I) *the National Institutes of*
8 *Health, to include, upon the rec-*
9 *ommendation of the Director of the Na-*
10 *tional Institutes of Health, representa-*
11 *tives from the National Institute of*
12 *Neurological Disorders and Stroke and*
13 *the National Institute of Environ-*
14 *mental Health Sciences;*

15 “(II) *the Department of Veterans*
16 *Affairs;*

17 “(III) *the Agency for Toxic Sub-*
18 *stances and Disease Registry; and*

19 “(IV) *the Centers for Disease Con-*
20 *trol and Prevention; and*

21 “(ii) *of which at least one such member*
22 *shall be a clinician with expertise on ALS*
23 *and related diseases, an epidemiologist with*
24 *experience in data registries, a statistician,*
25 *an ethicist, and a privacy expert (relating*

1 to the privacy regulations under the *Health*
2 *Insurance Portability and Accountability*
3 *Act of 1996*); and

4 “(B) one-third of such members shall be
5 public members, including at least one member
6 representing—

7 “(i) national and voluntary health as-
8 sociations;

9 “(ii) patients with *ALS* or their fam-
10 ily members;

11 “(iii) clinicians with expertise on *ALS*
12 and related diseases;

13 “(iv) epidemiologists with experience
14 in data registries;

15 “(v) geneticists or experts in genetics
16 who have experience with the genetics of
17 *ALS* or other neurological diseases and

18 “(vi) other individuals with an interest
19 in developing and maintaining the Na-
20 tional *ALS* Registry.

21 “(2) *DUTIES*.—The Advisory Committee shall re-
22 view information and make recommendations to the
23 Secretary concerning—

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

1 “(B) the type of information to be collected
2 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 dis-
8 eases and disorders that primarily affect motor
9 neurons that are considered essential to fur-
10 thering the study and cure of ALS.

11 “(3) REPORT.—Not later than 270 days after the
12 date on which the Advisory Committee is established,
13 the Advisory Committee shall submit a report to the
14 Secretary concerning the review conducted under
15 paragraph (2) that contains the recommendations of
16 the Advisory Committee with respect to the results of
17 such review.

18 “(c) GRANTS.—The Secretary, acting through the Di-
19 rector of the Centers for Disease Control and Prevention,
20 may award grants to, and enter into contracts and coopera-
21 tive agreements with, public or private nonprofit entities
22 for the collection, analysis, and reporting of data on ALS
23 and other motor neuron disorders that can be confused with
24 ALS, misdiagnosed as ALS, and in some cases progress to
25 ALS after receiving the report under subsection (b)(3).

1 “(d) *COORDINATION WITH STATE, LOCAL, AND FED-*
2 *ERAL REGISTRIES.*—

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

7 “(A) *identify, build upon, expand, and co-*
8 *ordinate among existing data and surveillance*
9 *systems, surveys, registries, and other Federal*
10 *public health and environmental infrastructure*
11 *wherever possible, which may include—*

12 “(i) *any registry pilot projects pre-*
13 *viously supported by the Centers for Disease*
14 *Control and Prevention;*

15 “(ii) *the Department of Veterans Af-*
16 *airs ALS Registry;*

17 “(iii) *the DNA and Cell Line Reposi-*
18 *tory of the National Institute of Neuro-*
19 *logical Disorders and Stroke Human Genet-*
20 *ics Resource Center at the National Insti-*
21 *tutes of Health;*

22 “(iv) *Agency for Toxic Substances and*
23 *Disease Registry studies, including studies*
24 *conducted in Illinois, Missouri, El Paso and*
25 *San Antonio, Texas, and Massachusetts;*

1 “(v) *State-based ALS registries;*

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

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

9 “(B) *provide for research access to ALS*
10 *data as recommended by the Advisory Committee*
11 *established in subsection (b) to the extent per-*
12 *mitted by applicable statutes and regulations*
13 *and in a manner that protects personal privacy*
14 *consistent with applicable privacy statutes and*
15 *regulations.*

16 “(2) *COORDINATION WITH NIH AND DEPARTMENT*
17 *OF VETERANS AFFAIRS.—Consistent with applicable*
18 *privacy statutes and regulations, the Secretary shall*
19 *ensure that epidemiological and other types of infor-*
20 *mation obtained under subsection (a) is made avail-*
21 *able to the National Institutes of Health and the De-*
22 *partment of Veterans Affairs.*

23 “(e) *DEFINITION.—For the purposes of this section, the*
24 *term ‘national voluntary health association’ means a na-*
25 *tional non-profit organization with chapters or other affili-*

1 ated organizations in States throughout the United States
2 with experience serving the population of individuals with
3 ALS and have demonstrated experience in ALS research,
4 care, and patient services.

5 “(f) *AUTHORIZATION OF APPROPRIATIONS.*—There are
6 authorized to be appropriated to carry out this section,
7 \$2,000,000 for fiscal year 2008, \$25,000,000 for fiscal year
8 2009, and \$16,000,000 for each of fiscal years 2010 through
9 2012.”.

10 **SEC. 3. REPORT ON REGISTRIES.**

11 Not later than 18 months after the date of enactment
12 of this Act, the Secretary of Health and Human Services
13 shall submit to the appropriate committees of Congress a
14 report outlining—

- 15 (1) the registries currently under way;
- 16 (2) future planned registries;
- 17 (3) the criteria involved in determining what
18 registries to conduct, defer, or suspend; and
- 19 (4) the scope of those registries.

20 The report shall also include a description of the activities
21 the Secretary undertakes to establish partnerships with re-
22 search and patient advocacy communities to expand reg-
23 istries.

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