

109TH CONGRESS
1ST SESSION

S. 1353

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

JUNE 30, 2005

Mr. REID (for himself, Mr. WARNER, Ms. MURKOWSKI, Mr. COCHRAN, Mr. CORZINE, Ms. STABENOW, Mr. BINGAMAN, Mr. DURBIN, and Mr. VITTER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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
8 in this section as “ALS”) is a fatal, progressive

1 neurodegenerative disease that affects motor nerve
2 cells in the brain and the spinal cord.

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

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

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

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

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

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

18 (8) Scientists believe that there are significant
19 ties between ALS and any motor neuron diseases.

20 (9) Several ALS disease registries and data-
21 bases exist in the United States and throughout the
22 world, including the SOD1 database, the National
23 Institute of Neurological Disorders and Stroke re-
24 pository, and the Department of Veterans Affairs
25 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) The establishment of a national registry
5 will help—

6 (A) identify the incidence and prevalence
7 of ALS in the United States;

8 (B) collect data important to the study of
9 ALS;

10 (C) promote a better understanding of
11 ALS;

12 (D) promote research into the genetic and
13 environmental factors that cause ALS;

14 (E) provide a means for patients to contact
15 scientists researching the environmental and ge-
16 netic factors that cause ALS as well as those
17 engaged in clinical trials; and

18 (F) enhance efforts to find treatments and
19 a cure for ALS.

20 **SEC. 3. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
21 **ACT.**

22 Part P of title III of the Public Health Service Act
23 (42 U.S.C. 280g et seq.) is amended by adding at the end
24 the following:

1 **“SEC. 3990. AMYOTROPHIC LATERAL SCLEROSIS REG-**
2 **ISTRY.**

3 “(a) ESTABLISHMENT.—

4 “(1) IN GENERAL.—Not later than 6 months
5 after the receipt of the report described in sub-
6 section (b)(2)(A), the Secretary, acting through the
7 Director of the Centers for Disease Control and Pre-
8 vention and in consultation with a national voluntary
9 health organization with experience serving the pop-
10 ulation of individuals with amyotrophic lateral sele-
11 rosis (referred to in this section as ‘ALS’), shall—

12 “(A) develop a system to collect data on
13 ALS, including information with respect to the
14 incidence and prevalence of the disease in the
15 United States; and

16 “(B) establish a national registry for the
17 collection and storage of such data to include a
18 population-based registry of cases of ALS in
19 the United States.

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

22 “(A) gather data concerning—

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

1 “(ii) the environmental and occupa-
2 tional factors that may be associated with
3 the disease;

4 “(iii) the age, race or ethnicity, gen-
5 der, and family history of individuals who
6 are diagnosed with the disease; and

7 “(iv) other matters as recommended
8 by the Advisory Committee established
9 under subsection (b); and

10 “(B) establish a secure method to put pa-
11 tients in contact with scientists studying the en-
12 vironmental, and genetic causes of motor neu-
13 ron disease or conducting clinical trials on
14 therapies for motor neuron disease.

15 “(b) ADVISORY COMMITTEE.—

16 “(1) ESTABLISHMENT.—Not later than 60 days
17 after the date of the enactment of this section, the
18 Secretary, acting through the Director of the Cen-
19 ters for Disease Control and Prevention, shall estab-
20 lish a committee to be known as the Advisory Com-
21 mittee on the National ALS Registry (referred to in
22 this section as the ‘Advisory Committee’). The Advi-
23 sory Committee shall be composed of at least one
24 member, to be appointed by the Secretary, acting
25 through the Director of the Centers for Disease

1 Control and Prevention, representing each of the fol-
2 lowing:

3 “(A) National voluntary health associa-
4 tions that focus solely on ALS that have a dem-
5 onstrated experience in ALS research, care, and
6 patient services.

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

13 “(C) The Department of Veterans Affairs.

14 “(D) The Agency for Toxic Substances
15 and Disease Registry.

16 “(E) The Centers for Disease Control and
17 Prevention.

18 “(F) Patients with ALS or their family
19 members.

20 “(G) Clinicians who have worked with data
21 registries.

22 “(H) Epidemiologists with experience in
23 data registries.

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

4 “(J) Statisticians.

5 “(K) Ethicists.

6 “(L) Attorneys.

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

10 “(2) DUTIES.—The Advisory Committee shall
11 conduct a study and make recommendations to the
12 Secretary concerning—

13 “(A) the development and maintenance of
14 the National ALS Registry;

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

17 “(C) the manner in which such data is to
18 be collected;

19 “(D) the use and availability of such data
20 including guidelines for such use; and

21 “(E) the collection of information about
22 diseases and disorders that primarily affect
23 motor neurons that are considered essential to
24 furthering the study and cure of ALS.

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

7 “(c) GRANTS.—Notwithstanding the recommenda-
8 tions of the Advisory Committee under subsection (b), the
9 Secretary, acting through the Director of the Centers for
10 Disease Control and Prevention, may award grants to, and
11 enter into contracts and cooperative agreements with, pub-
12 lic or private nonprofit entities for the collection, analysis,
13 and reporting of data on ALS.

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

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

20 “(A) identify, build upon, expand, and co-
21 ordinate among existing data and surveillance
22 systems, surveys, registries, and other Federal
23 public health and environmental infrastructure
24 wherever possible, including—

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

3 “(ii) 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 “(iii) 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 “(iv) State-based ALS registries, in-
13 cluding the Massachusetts ALS Registry;

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

16 “(vi) 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 public access to an elec-
22 tronic national database that accepts data from
23 State-based registries, health care professionals,
24 and others as recommended by the Advisory
25 Committee established in subsection (b) in a

1 manner that protects personal privacy con-
2 sistent with medical privacy 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), the Secretary shall ensure
7 that epidemiological and other types of information
8 obtained under subsection (a) is made available to
9 the National Institutes of Health and the Depart-
10 ment of Veterans Affairs.

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

16 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
17 are authorized to be appropriated to carry out this section,
18 \$25,000,000 for fiscal year 2006, and such sums as may
19 be necessary for each of fiscal years 2007 through 2010.”.

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