

Union Calendar No. 236

110TH CONGRESS
1ST SESSION

H. R. 2295

[Report No. 110-379]

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

OCTOBER 15, 2007

Additional sponsors: Ms. ESHOO, Mr. CARNEY, Mr. BOOZMAN, Mr. HAYES, Ms. HOOLEY, Ms. SHEA-PORTER, Mr. WATT, Mr. SESSIONS, Mrs. SCHMIDT, Mr. WELLER of Illinois, Mr. RAMSTAD, Mr. KING of New York, Mr. HOEKSTRA, Mr. JINDAL, Mr. DEFazio, Mr. PETERSON of

Pennsylvania, Mr. TAYLOR, Mr. ALTMIRE, Mr. ISRAEL, Mr. FRELINGHUYSEN, Mr. OBERSTAR, Ms. WASSERMAN SCHULTZ, Mr. MICHAUD, Mr. SKELTON, Mr. BONNER, Ms. SLAUGHTER, Mr. FARR, Mr. KUCINICH, Mr. CHANDLER, Mr. NEAL of Massachusetts, Mrs. MALONEY of New York, Mr. CLAY, Mr. FRANK of Massachusetts, Mr. DOOLITTLE, Mr. PAYNE, Mrs. BIGGERT, Mr. MILLER of North Carolina, Mr. SCHIFF, Mr. KELLER of Florida, Mr. YOUNG of Florida, Mr. SMITH of Washington, Mr. DAVID DAVIS of Tennessee, Mr. SIMPSON, Mr. WOLF, Mr. CALVERT, Mr. MARSHALL, Mr. LOBIONDO, Mr. COBLE, Mr. PLATTS, Ms. LINDA T. SÁNCHEZ of California, Mr. RYAN of Ohio, Mr. WALZ of Minnesota, Mr. WALDEN of Oregon, Mr. STEARNS, Mr. PASTOR, Mr. LEWIS of Kentucky, Mr. LEWIS of Georgia, Mr. SENSENBRENNER, Mr. MCCOTTER, Mr. MCHENRY, Mr. ELLISON, Mr. ANDREWS, Mr. KLEIN of Florida, Mr. BRALEY of Iowa, Mr. FILNER, Mr. WILSON of South Carolina, Mr. MURPHY of Connecticut, Mr. SESTAK, Mr. EVERETT, Mr. COSTELLO, Mr. ACKERMAN, Mr. HINOJOSA, Mr. BLUMENAUER, Ms. MATSUI, Ms. PRYCE of Ohio, Mr. BERRY, Mr. DAVIS of Alabama, Mr. STUPAK, Mr. AL GREEN of Texas, Mr. SAXTON, Mr. SPACE, Mr. GRAVES, Mr. WU, Mr. KIRK, Mr. WELDON of Florida, Mr. CONAWAY, Mr. LAMPSON, Mr. WELCH of Vermont, Mr. PICKERING, Mr. GORDON of Tennessee, Ms. CASTOR, Mr. MCCAUL of Texas, Mr. LARSEN of Washington, Mr. CASTLE, Mr. BOREN, Mrs. CUBIN, Mr. LANGEVIN, Mr. ARCURI, Mr. JACKSON of Illinois, Mrs. GILLIBRAND, Mr. TIM MURPHY of Pennsylvania, Mr. WICKER, Mrs. DRAKE, Mrs. CAPITO, Mr. BAIRD, Mr. ORTIZ, Mr. CHABOT, Mr. DELAHUNT, Mr. YARMUTH, Mr. BUCHANAN, Ms. VELÁZQUEZ, Mr. RAHALL, Ms. BEAN, Mr. SOUDER, Mr. WEXLER, Mr. REICHERT, Ms. GINNY BROWN-WAITE of Florida, Mr. DENT, Mr. ENGLISH of Pennsylvania, Mr. PASCRELL, Ms. WATSON, Mr. ROGERS of Kentucky, Mr. PETERSON of Minnesota, Mr. SULLIVAN, Mr. TIBERI, Ms. WOOLSEY, Mrs. BLACKBURN, Mr. ALEXANDER, Mr. LUCAS, Mr. HOLT, Mr. CARNAHAN, Mr. THOMPSON of California, Mr. THOMPSON of Mississippi, Ms. SUTTON, Mr. KUHL of New York, Mr. SHULER, Mr. MELANCON, Mr. DOGGETT, Ms. HERSETH SANDLIN, Mr. JONES of North Carolina, Mr. MOORE of Kansas, Mr. BRADY of Pennsylvania, Mr. RUPPERSBERGER, Mrs. BOYDA of Kansas, Mr. DONNELLY, Mr. LEVIN, Mr. POMEROY, Mr. NUNES, Mr. DAVIS of Illinois, Mr. LAHOOD, Mr. SERRANO, Mr. RADANOVICH, Mr. BISHOP of Utah, Ms. DEGETTE, Ms. HARMAN, Mr. HILL, Ms. BERKLEY, Mr. BOUCHER, Mr. MCNERNEY, Mr. SARBANES, Mr. FORTENBERRY, Mr. CARTER, Mr. GARY G. MILLER of California, Mrs. EMERSON, Mr. HOLDEN, Mr. CANNON, Mr. CLEAVER, Mr. KILDEE, Mr. LATHAM, Mr. REYES, Mr. BAKER, Mr. FEENEY, Mr. ROGERS of Alabama, Mr. GEORGE MILLER of California, Mr. PUTNAM, Mr. MORAN of Virginia, Mr. RODRIGUEZ, Mr. CANTOR, Mrs. WILSON of New Mexico, Mr. HALL of New York, Mrs. DAVIS of California, Mr. MITCHELL, Mr. ELLSWORTH, Mr. BACHUS, Mr. MORAN of Kansas, Mr. LYNCH, Mr. JOHNSON of Illinois, Mrs. TAUSCHER, Ms. LEE, Mr. HELLER of Nevada, Mr. BURGESS, Ms. SCHWARTZ, and Mr. LARSON of Connecticut

OCTOBER 15, 2007

Reported with an amendment, committed to the Committee of the Whole
House on the State of the Union, and ordered to be printed

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

[For text of introduced bill, see copy of bill as introduced on May 14, 2007]

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 with*
12 *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 by*
15 *the Food and Drug Administration for the treatment*

1 *of ALS, which has thus far shown only modest effects,*
2 *prolonging life by just a few months.*

3 *(5) There is no known cure for ALS.*

4 *(6) More than 5,000 individuals in the United*
5 *States are diagnosed with ALS annually and as*
6 *many as 30,000 individuals may be living with ALS*
7 *in the United States today.*

8 *(7) Studies have found relationships between*
9 *ALS and environmental and genetic factors, but those*
10 *relationships are not well understood.*

11 *(8) Scientists believe that there are significant*
12 *ties between ALS and other motor neuron diseases.*

13 *(9) Several ALS disease registries and databases*
14 *exist in the United States and throughout the world,*
15 *including the SOD1 database, the National Institute*
16 *of Neurological Disorders and Stroke repository, and*
17 *the Department of Veterans Affairs ALS Registry.*

18 *(10) A single national system to collect and store*
19 *information on the prevalence and incidence of ALS*
20 *in the United States does not exist.*

21 *(11) In each of fiscal years 2006 and 2007, Con-*
22 *gress directed \$887,000 to the Centers for Disease*
23 *Control and Prevention to begin a nationwide ALS*
24 *registry.*

1 (12) *The Centers for Disease Control and Preven-*
2 *tion and the Agency for Toxic Substances and Disease*
3 *Registry have established three pilot projects, begin-*
4 *ning in fiscal year 2006, to evaluate the science to*
5 *guide the creation of a national ALS registry.*

6 (13) *The establishment of a national registry*
7 *will help—*

8 (A) *to identify the incidence and prevalence*
9 *of ALS in the United States;*

10 (B) *to collect data important to the study of*
11 *ALS;*

12 (C) *to promote a better understanding of*
13 *ALS;*

14 (D) *to collect information that is important*
15 *for research into the genetic and environmental*
16 *factors that cause ALS;*

17 (E) *to strengthen the ability of a clearing-*
18 *house—*

19 (i) *to collect and disseminate research*
20 *findings on environmental, genetic, and*
21 *other causes of ALS and other motor neuron*
22 *disorders that can be confused with ALS,*
23 *misdiagnosed as ALS, and in some cases*
24 *progress to ALS;*

1 (ii) to make available information to
2 patients about research studies for which
3 they may be eligible; and

4 (iii) to maintain information about
5 clinical specialists and clinical trials on
6 therapies; and

7 (F) to enhance efforts to find treatments
8 and a cure for ALS.

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

10 Part P of title III of the Public Health Service Act
11 (42 U.S.C. 280g et seq.) is amended by adding at the end
12 the following:

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

14 “(a) ESTABLISHMENT.—

15 “(1) IN GENERAL.—Not later than 1 year after
16 the receipt of the report described in subsection (b)(3),
17 the Secretary, acting through the Director of the Cen-
18 ters for Disease Control and Prevention and in con-
19 sultation with a national voluntary health organiza-
20 tion with experience serving the population of indi-
21 viduals with amyotrophic lateral sclerosis (referred to
22 in this section as ‘ALS’), shall—

23 “(A) develop a system to collect data on
24 ALS and other motor neuron disorders that can
25 be confused with ALS, misdiagnosed as ALS,

1 *and in some cases progress to ALS, including in-*
2 *formation with respect to the incidence and prev-*
3 *alence of the disease in the United States; and*

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

10 *“(2) PURPOSE.—It is the purpose of the registry*
11 *established under paragraph (1)(B) to gather avail-*
12 *able data concerning—*

13 *“(A) ALS, including the incidence and*
14 *prevalence of ALS in the United States;*

15 *“(B) the environmental and occupational*
16 *factors that may be associated with the disease;*

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

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

23 *“(E) other matters as recommended by the*
24 *Advisory Committee established under subsection*
25 *(b).*

1 “(b) *ADVISORY COMMITTEE.*—

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

13 “(A) National voluntary health associations
14 that focus solely on ALS and have demonstrated
15 experience in ALS research, care, and patient
16 services, as well as other voluntary associations
17 focusing on neurodegenerative diseases that rep-
18 resent and advocate on behalf of patients with
19 ALS and patients with other motor neuron dis-
20 orders that can be confused with ALS,
21 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 and*
6 *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 other*
17 *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 re-*
2 *view information and make recommendations to the*
3 *Secretary concerning—*

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

6 “(B) *the type of information to be collected*
7 *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 dis-*
13 *eases and disorders that primarily affect motor*
14 *neurons that are considered essential to fur-*
15 *thering the study and cure of ALS.*

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

22 “(c) *GRANTS.*—*Notwithstanding the recommendations*
23 *of the Advisory Committee under subsection (b), the Sec-*
24 *retary, acting through the Director of the Centers for Dis-*
25 *ease Control and Prevention, may award grants to, and*

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

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

8 “(1) *IN GENERAL.*—*In establishing the National*
9 *ALS Registry under subsection (a), the Secretary,*
10 *acting through the Director of the Centers for Disease*
11 *Control and Prevention, shall—*

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

17 “(i) *the 3 ALS registry pilot projects*
18 *initiated in fiscal year 2006 by the Centers*
19 *for Disease Control and Prevention and the*
20 *Agency for Toxic Substances and Disease*
21 *Registry at the South Carolina Office of Re-*
22 *search & Statistics; the Mayo Clinic in*
23 *Rochester, Minnesota; and Emory Univer-*
24 *sity 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 Genet-
6 ics Resource Center;

7 “(iv) the 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 Committee
23 established in subsection (b) to the extent per-
24 mitted by applicable statutes and regulations
25 and in a manner that protects personal privacy

1 *consistent with applicable privacy statutes and*
2 *regulations.*

3 “(2) *COORDINATION WITH NIH AND DEPARTMENT*
4 *OF VETERANS AFFAIRS.—Notwithstanding the rec-*
5 *ommendations of the Advisory Committee established*
6 *in subsection (b), and consistent with applicable pri-*
7 *vacy statutes and regulations, the Secretary shall en-*
8 *sure that epidemiological and other types of informa-*
9 *tion obtained under subsection (a) is made available*
10 *to the National Institutes of Health and the Depart-*
11 *ment of Veterans Affairs.*

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

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

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