

111TH CONGRESS
1ST SESSION

H. R. 1362

To amend the Public Health Service Act to provide for the establishment of permanent national surveillance systems for multiple sclerosis, Parkinson's disease, and other neurological diseases and disorders.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2009

Mr. VAN HOLLEN (for himself, Mr. BURGESS, Mrs. MALONEY, Mr. UPTON, Mr. CARNAHAN, and Mr. KING of New York) 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 permanent national surveillance systems for multiple sclerosis, Parkinson's disease, and other neurological diseases and disorders.

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 "National MS and Par-
5 kinson's Disease Registries Act".

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

1 (1) Multiple sclerosis (referred to in this section
2 as “MS”) is a progressive, disabling disease that af-
3 fects the brain and the spinal cord causing loss of
4 myelin, damage to axons, and cerebral atrophy.

5 (2) MS is a prime-of-life disease with an aver-
6 age age of onset at 30 to 35 years of age.

7 (3) More than 10,000 individuals in the United
8 States are diagnosed with MS annually, and it is
9 thought that more than 400,000 individuals in the
10 United States have MS.

11 (4) Parkinson’s disease is a chronic, progressive
12 neurological disease. The primary pathologic feature
13 of Parkinson’s disease is degeneration and pre-
14 mature death of dopamine-producing brain cells.

15 (5) Parkinson’s is the second-most common
16 neurodegenerative disease in the United States.

17 (6) It is estimated that more than 1,000,000
18 Americans are currently fighting Parkinson’s dis-
19 ease, and 60,000 Americans are newly diagnosed
20 every year.

21 (7) Although estimates exist, there is no con-
22 firmed data regarding prevalence or diagnosed cases
23 of Parkinson’s disease or MS.

24 (8) The causes of Parkinson’s disease and MS
25 are not well understood.

1 (9) There is no known cure for Parkinson’s dis-
2 ease or MS.

3 (10) Studies have found relationships between
4 both MS and Parkinson’s disease and environmental
5 and genetic factors, but those relationships are not
6 well understood.

7 (11) Better data are needed to understand the
8 economic impact of Parkinson’s disease, MS, and
9 other neurological diseases.

10 (12) There are several drugs currently approved
11 by the Food and Drug Administration for the treat-
12 ment of MS, which have shown modest success in re-
13 ducing relapses, slowing progression of disability,
14 and limiting the accumulation of brain lesions.

15 (13) Currently, state-of-the-art treatment for
16 Parkinson’s disease is based on a 40-year-old phar-
17 maceutical therapy, which only treats some of the
18 motor symptoms of Parkinson’s disease. Deep brain
19 stimulation surgery is available for certain patients
20 and treats some symptoms of Parkinson’s disease.

21 (14) No therapies exist that will slow or stop
22 progression of Parkinson’s disease. There is no ef-
23 fective, lasting therapy for all features of Parkin-
24 son’s disease.

1 (15) Central nervous system drugs, including
2 therapies for MS, Parkinson’s disease, and other
3 neurological diseases, are the slowest in the drug de-
4 velopment pipeline, taking an average of 15 years
5 post discovery for new therapies to reach the mar-
6 ket.

7 (16) Several small and uncoordinated MS and
8 Parkinson’s disease registries, surveillance systems,
9 and databases exist in the United States and
10 throughout the world.

11 (17) A single national system to collect and
12 store information on the incidence and prevalence of
13 MS, Parkinson’s disease, or other neurological dis-
14 eases in the United States does not exist.

15 (18) The Agency for Toxic Substances and Dis-
16 ease Registry (ATSDR) has established a series of
17 small pilot studies, beginning in fiscal year 2006, to
18 evaluate the feasibility of various methodologies to
19 create an MS surveillance system at the national
20 level.

21 (19) The national surveillance system method-
22 ology resulting from the MS pilot studies should be
23 expanded upon and developed into a national surveil-
24 lance system for Parkinson’s disease.

1 (20) The establishment of separate, coordinated
2 national surveillance systems for Parkinson’s disease
3 and MS will help—

4 (A) to identify the incidence and preva-
5 lence of these diseases in the United States;

6 (B) to collect demographic and other data
7 important to the study of MS and Parkinson’s
8 disease;

9 (C) to produce epidemiologically sound
10 data that can be used to compare with cluster
11 information, data sets of the Department of
12 Veterans Affairs, environmental exposure data,
13 and other information;

14 (D) to promote a better understanding of
15 causes, prevention, and treatment of disease;

16 (E) to better understand public and pri-
17 vate resource impact;

18 (F) to collect information that is important
19 for research into genetic and environmental risk
20 factors;

21 (G) to enhance biomedical and clinical re-
22 search by providing a basis for population com-
23 parisons;

1 (H) to enhance efforts to develop better di-
2 agnosis and progression biomarkers for MS and
3 Parkinson’s disease; and

4 (I) to enhance efforts to find treatments
5 and a cure for MS and Parkinson’s disease.

6 **SEC. 3. SURVEILLANCE SYSTEMS.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.) is amended—

9 (1) by redesignating the second and third sec-
10 tions 399R (added by section 2 of Public Law 110–
11 373 and section 3 of Public Law 110–374) as sec-
12 tions 399S and 399T, respectively; and

13 (2) by adding at the end the following:

14 **“SEC. 399U. SURVEILLANCE OF NEUROLOGICAL DISEASES.**

15 **“(a) MULTIPLE SCLEROSIS NATIONAL SURVEIL-**
16 **LANCE SYSTEM.—**

17 **“(1) IN GENERAL.—**Not later than 1 year after
18 receipt of the report described in subsection (c)(3),
19 the Secretary, acting through the Director of the
20 Agency for Toxic Substances and Disease Registry
21 and in consultation with a national voluntary health
22 organization with experience serving the population
23 of individuals with multiple sclerosis (referred to in
24 this section as ‘MS’), shall—

1 “(A) develop a system to collect data on
2 MS including information with respect to the
3 incidence and prevalence of the disease in the
4 United States;

5 “(B) establish a national surveillance sys-
6 tem for the collection and storage of such data
7 to include a population-based registry of cases
8 of MS in the United States;

9 “(C) assist in application of MS national
10 surveillance system methodologies for the devel-
11 opment, piloting, and implementation of a na-
12 tional Parkinson’s disease national surveillance
13 system under subsection (b); and

14 “(D) provide analysis regarding expansion
15 of national disease surveillance systems for
16 other neurological diseases and disorders uti-
17 lizing the MS and Parkinson’s disease national
18 surveillance systems’ process and structure.

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

22 “(A) MS, including the incidence and prev-
23 alence of MS in the United States;

24 “(B) the age, race or ethnicity, gender,
25 military service if applicable, and family history

1 of individuals who are diagnosed with the dis-
2 ease; and

3 “(C) other matters as recommended by the
4 Advisory Committee established pursuant to
5 subsection (c).

6 “(b) PARKINSON’S DISEASE NATIONAL SURVEIL-
7 LANCE SYSTEM.—

8 “(1) IN GENERAL.—Not later than 1 year after
9 the receipt of the report described in subsection
10 (c)(3), the Secretary, acting through the Director of
11 the Agency for Toxic Substances and Disease Reg-
12 istry and in consultation with a national voluntary
13 health organization with experience serving the pop-
14 ulation of individuals with Parkinson’s disease,
15 shall—

16 “(A) develop a system to collect data on
17 Parkinson’s disease including information with
18 respect to the incidence and prevalence of the
19 disease in the United States;

20 “(B) establish a national surveillance sys-
21 tem for the collection and storage of such data
22 to include a population-based registry of cases
23 of Parkinson’s disease in the United States;
24 and

1 “(C) provide analysis regarding expansion
2 of national disease surveillance systems for
3 other neurological diseases utilizing the MS and
4 Parkinson’s disease national surveillance sys-
5 tems’ process and structure.

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

9 “(A) Parkinson’s disease, including the in-
10 cidence and prevalence of Parkinson’s disease in
11 the United States;

12 “(B) the age, race or ethnicity, gender,
13 military service if applicable, and family history
14 of individuals who are diagnosed with the dis-
15 ease; and

16 “(C) other matters as recommended by the
17 Advisory Committee established pursuant to
18 subsection (c).

19 “(c) ADVISORY COMMITTEE.—

20 “(1) ESTABLISHMENT.—Not later than 180
21 days after the date of the enactment of this section,
22 the Secretary, acting through the Director of the
23 Agency for Toxic Substances and Disease Registry,
24 shall establish a committee to be known as the Advi-
25 sory Committee on Neurological Disease Registries

1 (referred to in this section as the ‘Advisory Com-
2 mittee’). The Advisory Committee shall be composed
3 of at least one member, to be appointed by the Sec-
4 retary, acting through the Director of the Agency
5 for Toxic Substances and Disease Registry, rep-
6 resenting each of the following:

7 “(A) National voluntary health associa-
8 tions that focus solely on MS and have dem-
9 onstrated experience in MS research, care, or
10 patient services.

11 “(B) National voluntary health associa-
12 tions that focus solely on Parkinson’s disease
13 and have demonstrated experience in Parkin-
14 son’s disease public policy, research, care, or
15 patient services.

16 “(C) The National Institutes of Health, to
17 include, upon the recommendation of the Direc-
18 tor of the National Institutes of Health, rep-
19 resentatives from the Office of Portfolio Anal-
20 ysis and Strategic Initiatives, the National In-
21 stitute of Neurological Disorders and Stroke,
22 the National Institute of Environmental Health
23 Sciences, the National Institute on Aging, and
24 the National Institute of Allergy and Infectious
25 Diseases.

1 “(D) The Department of Veterans Affairs,
2 to include representatives from the Parkinson’s
3 Disease Research Education and Clinical Cen-
4 ters and the MS Centers of Excellence.

5 “(E) The Department of Defense, to in-
6 clude representatives from the Parkinson’s dis-
7 ease and MS research programs.

8 “(F) The Food and Drug Administration.

9 “(G) The Centers for Disease Control and
10 Prevention, to include representatives from the
11 Agency for Toxic Substances and Disease Reg-
12 istry.

13 “(H) Patients with MS and Parkinson’s
14 disease or their family members.

15 “(I) Clinicians with expertise on MS and
16 Parkinson’s disease.

17 “(J) Research scientists with experience
18 conducting translational research or creating
19 systems that support translating basic discov-
20 eries into treatments.

21 “(K) Epidemiologists with experience in
22 data registries.

23 “(L) Geneticists or experts in genetics who
24 have experience with the genetics of MS and
25 Parkinson’s disease.

1 “(M) Statisticians.

2 “(N) Bioethicists.

3 “(O) Attorneys.

4 “(P) Other individuals, organizations, or
5 agencies with an interest in developing and
6 maintaining the MS and Parkinson’s disease
7 national surveillance systems.

8 “(Q) Experts in additional neurological
9 diseases, as appropriate, based on development
10 and implementation of national surveillance sys-
11 tems for other neurological diseases and dis-
12 orders.

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

16 “(A) the development and maintenance of
17 the MS and Parkinson’s disease national sur-
18 veillance systems;

19 “(B) the use and coordination of existing
20 databases that collect or maintain information
21 on neurological diseases and disorders;

22 “(C) the type of information to be collected
23 and stored in the systems;

24 “(D) the manner in which such data is to
25 be collected;

1 “(E) the use and availability of such data
2 including guidelines for such use; and

3 “(F) the application of MS and Parkin-
4 son’s disease registry methodologies to benefit
5 other neurological diseases and disorders, in-
6 cluding analysis of how other neurological dis-
7 ease surveillance systems or registries can be
8 developed, piloted, and implemented nationally
9 utilizing the MS and Parkinson’s disease na-
10 tional surveillance systems’ process and struc-
11 ture.

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

19 “(d) GRANTS.—Notwithstanding the recommenda-
20 tions of the Advisory Committee under subsection (c), the
21 Secretary, acting through the Director of the Agency for
22 Toxic Substances and Disease Registry, may award grants
23 to, and enter into contracts and cooperative agreements
24 with, public or private nonprofit entities for the collection,

1 analysis, and reporting of data on MS and Parkinson’s
2 disease.

3 “(e) COORDINATION WITH STATE, LOCAL, AND FED-
4 ERAL REGISTRIES.—

5 “(1) IN GENERAL.—In establishing the MS and
6 Parkinson’s disease national surveillance systems
7 under subsections (a) and (b), the Secretary, acting
8 through the Director of the Agency for Toxic Sub-
9 stances and Disease Registry, shall—

10 “(A) identify, build upon, expand, and co-
11 ordinate existing data and surveillance systems,
12 surveys, registries, and other Federal public
13 health and environmental infrastructure wher-
14 ever possible, including—

15 “(i) the 2 MS surveillance pilot stud-
16 ies initiated in fiscal year 2006 by the Cen-
17 ters for Disease Control and Prevention
18 and the Agency for Toxic Substances and
19 Disease Registry;

20 “(ii) the Parkinson’s disease and MS
21 databases of the Department of Veterans
22 Affairs;

23 “(iii) current Parkinson’s disease reg-
24 istries and surveillance systems, including

1 the Nebraska and California State reg-
2 istries;

3 “(iv) current MS registries, including
4 the New York State MS Registry and the
5 North American Research Committee on
6 MS (NARCOMS) Registry; and

7 “(v) any other existing or relevant
8 databases that collect or maintain informa-
9 tion on neurological diseases and disorders
10 identified by researchers or recommended
11 by the Advisory Committee pursuant to
12 subsection (c); and

13 “(B) provide for and conduct outreach in
14 support of research access to Parkinson’s dis-
15 ease and MS data as recommended by the Advi-
16 sory Committee established pursuant to sub-
17 section (c) to the extent permitted by applicable
18 statutes and regulations and in a manner that
19 protects personal privacy consistent with appli-
20 cable privacy statutes and regulations.

21 “(2) COORDINATION WITH OTHER FEDERAL
22 AGENCIES.—Notwithstanding the recommendations
23 of the Advisory Committee established pursuant to
24 subsection (c), and consistent with applicable privacy
25 statutes and regulations, the Secretary shall ensure

1 that epidemiological and other types of information
2 obtained under subsections (a) and (b) are made
3 available to agencies such as the National Institutes
4 of Health, the Food and Drug Administration, the
5 Department of Veterans Affairs, and the Depart-
6 ment of Defense.

7 “(f) DEFINITION.—For the purposes of this section,
8 the term ‘national voluntary health association’ means a
9 national nonprofit organization with chapters, other affili-
10 ated organizations, or networks in States throughout the
11 United States.

12 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
13 is authorized to be appropriated to carry out this section
14 \$5,000,000 for each of fiscal years 2010 through 2014.”.

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