

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.

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## 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

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## 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.”.

○