

NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE
SYSTEM ACT OF 2010

SEPTEMBER 28, 2010.—Committed to the Committee of the Whole House on the
State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1362]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Neurological Diseases Surveillance System Act of 2010”.

SEC. 2. NATIONAL NEUROLOGICAL DISEASES SURVEILLANCE SYSTEM.

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

“SEC. 399V-5 SURVEILLANCE OF NEUROLOGICAL DISEASES.

“(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

“(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson’s disease; and

“(2) incorporate information obtained through such activities into a statistically-sound, scientifically-credible, integrated surveillance system, to be known as the National Neurological Diseases Surveillance System.

“(b) RESEARCH.—The Secretary shall ensure that the National Neurological Diseases Surveillance System is designed in a manner that facilitates further research on neurological diseases.

“(c) CONTENT.—In carrying out subsection (a), the Secretary—

“(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

“(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

“(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

“(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

“(C) diagnosis and progression markers;

“(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

“(A) the epidemiology of the diseases;

“(B) the natural history of the diseases;

“(C) the prevention of the diseases;

“(D) the detection, management, and treatment approaches for the diseases; and

“(E) the development of outcomes measures; and

“(4) may address issues identified during the consultation process under subsection (d).

“(d) CONSULTATION.—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

“(1) epidemiologists with experience in disease surveillance or registries;

“(2) representatives of national voluntary health associations that—

“(A) focus on neurological diseases, including multiple sclerosis and Parkinson’s disease; and

“(B) have demonstrated experience in research, care, or patient services;

“(3) health information technology experts or other information management specialists;

“(4) clinicians with expertise in neurological diseases; and

“(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

“(e) GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

“(f) COORDINATION WITH OTHER FEDERAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense.

“(g) PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.

“(h) PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).

“(i) REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

“(1) the development and maintenance of the National Neurological Diseases Surveillance System;

“(2) the type of information collected and stored in the System;

“(3) the use and availability of such information, including guidelines for such use; and

“(4) the use and coordination of databases that collect or maintain information on neurological diseases.

“(j) DEFINITION.—In this section, the term ‘national voluntary health association’ means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.

“(k) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$5,000,000 for each of fiscal years 2012 through 2016.”.

PURPOSE AND SUMMARY

H.R. 1362, the “National Neurological Diseases Surveillance System Act of 2010”, was introduced on March 5, 2009, by Rep. Chris Van Hollen (D-MD), and referred to the Committee on Energy and Commerce.

The goal of H.R. 1362 is to improve our understanding of Multiple Sclerosis (MS), Parkinson’s disease, and other neurological diseases. The bill provides for systematic data collection, analysis, and interpretation (epidemiological surveillance) regarding these diseases.

BACKGROUND AND NEED FOR LEGISLATION

Multiple Sclerosis affects an estimated 400,000 people in the United States.¹ The exact cause of MS is unknown though it is thought to be an autoimmune disorder where the immune system incorrectly attacks healthy nerve fibers of the central nervous system (myelin).² Symptoms range from blurriness and difficulty with coordination and balance to partial or complete paralysis. There is currently no cure for MS, though use of certain Food and Drug Administration-approved therapies can reduce the duration and severity of attacks among some patients. Parkinson’s disease is diagnosed among an estimated 60,000 people each year; however, the exact prevalence of this disease is unknown.³ Parkinson’s disease results from the loss of dopamine-producing brain cells (or neurotransmitter cells).⁴ Parkinson’s is also a chronic and progressive disease though symptoms vary from patient-to-patient, and

¹National Multiple Sclerosis Society, FAQs about MS (online at <http://www.nationalmssociety.org/about-multiple-sclerosis/what-we-know-about-ms/faqs-about-ms/index.aspx>) (accessed Sept. 21, 2010).

²National Institute of Neurological Disorders and Stroke, NINDS Multiple Sclerosis Information Page (online at http://www.ninds.nih.gov/disorders/multiple_sclerosis/multiple_sclerosis.htm) (accessed Sept. 21, 2010).

³Parkinson’s Action Network, About Parkinson’s Disease (online at <http://www.parkinsonsaction.org/parkinsons-disease/about-parkinsons-disease>) (accessed Sept. 21, 2010).

⁴National Institute of Neurological Disorders and Stroke, NINDS Parkinson’s Disease Information Page (online at http://www.ninds.nih.gov/disorders/parkinsons_disease/parkinsons_disease.htm) (accessed Sept. 21, 2010).

like MS, there is no cure for Parkinson's, but treatments can provide relief from symptoms.

The Centers for Disease Control and Prevention (CDC) does extensive monitoring of health and disease; however, with the exception of an amyotrophic lateral sclerosis (ALS) registry and tracking on causes of death, its surveillance efforts on MS, Parkinson's, and other neurological diseases to date have been limited. H.R. 1362 seeks to address the gaps in our understanding of MS, Parkinson's, and other neurological diseases through collection, analysis, and interpretation of data (epidemiological surveillance), including the incidence and prevalence of these diseases and the characteristics of people affected by them.

COMMITTEE CONSIDERATION

H.R. 1362, the "National Neurological Disease Surveillance System Act of 2010", was introduced by Mr. Van Hollen of Maryland on March 5, 2009, and referred to the Committee on Energy and Commerce. The bill was subsequently referred to the Subcommittee on Health on March 6, 2009. On September 15, 2010, the Subcommittee held a legislative hearing on the bill. The Subcommittee met in open markup session to consider H.R. 1362 on September 16, 2010. An amendment in the nature of a substitute by Mr. Burgess was adopted by a voice vote. Subsequently, H.R. 1362 was forwarded to the full Committee, amended, by a voice vote.

On September 23, 2010, the Committee on Energy and Commerce met in open markup session and considered H.R. 1362 as approved by the Subcommittee. There were no amendments offered in full Committee and subsequently the Committee ordered H.R. 1362 favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion to report legislation and amendments thereto. A motion by Mr. Pallone ordering H.R. 1362 reported to the House, as amended, was approved by a voice vote. There were no record votes taken during consideration of this bill.

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the oversight findings and recommendations of the Committee are reflected in the descriptive portions of this report, including the finding that CDC surveillance of MS, Parkinson's disease, and certain neurological diseases has been limited.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1362 would result in no new budget authority, entitlement authority, or tax expenditures or revenues.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report, including the goal of improving epidemiological surveillance regarding MS, Parkinson's, and other neurological diseases.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 1362 is provided under article I, section 8, clauses 3 and 18 of the Constitution of the United States.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 1362 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

FEDERAL ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., section 5(b) of the Federal Advisory Committee Act.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104-1 requires a description of the application of this bill to the legislative branch where the bill relates to terms and conditions of employment or access to public services and accommodations. H.R. 1362 contains no such provisions.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act of 1974 (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, Public Law 104-4) requires a statement on whether the provisions of the report include unfunded mandates. In compliance with this requirement the Committee adopts as its own the analysis of federal mandates prepared by the Director of the Congressional Budget Office regarding H.R. 1362.

COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the cost estimate of H.R. 1362 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

With respect to the requirements of clause (3)(c)(3) of rule XIII of the Rules of the House of Representatives and section 402 of the Congressional Budget Act of 1974, the Committee has received the

following cost estimate for H.R. 1362 from the Director of Congressional Budget Office:

SEPTEMBER 24, 2010.

Hon. HENRY A. WAXMAN,
*Chairman, Committee on Energy and Commerce,
 House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1362, the National Neurological Diseases Surveillance System Act of 2010.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard.

Sincerely,

DOUGLAS W. ELMENDORF.

Enclosure.

H.R. 1362—National Neurological Diseases Surveillance System Act of 2010

Summary: H.R. 1362 would amend the Public Health Service Act to require the Secretary of Health and Human Services to increase epidemiological tracking of neurological diseases. It also would authorize the Secretary to create a surveillance system for neurological disorders. CBO estimates that implementing H.R. 1362 would cost \$16 million over the 2011–2015 period, assuming appropriation of the authorized amounts. Enacting H.R. 1362 would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply.

H.R. 1362 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 1362 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

| | By fiscal year, in millions of dollars— | | | | | |
|--|---|------|------|------|------|-----------|
| | 2011 | 2012 | 2013 | 2014 | 2015 | 2011-2015 |
| CHANGES IN SPENDING SUBJECT TO APPROPRIATION | | | | | | |
| Authorization Level | 0 | 5 | 5 | 5 | 5 | 20 |
| Estimated Outlays | 0 | 2 | 4 | 5 | 5 | 16 |

Basis of estimate: H.R. 1362 would direct the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention (CDC), to expand tracking of the epidemiology of neurological diseases, such as multiple sclerosis and Parkinson's disease.

The Secretary would use this information to create a National Neurological Diseases Surveillance System, which would, in part, facilitate additional research into neurological diseases. Among the data collected and analyzed through the new tracking and surveillance systems would be information on demographic characteristics, risk factors, and diagnoses. The Secretary would ensure coordination with other federal agencies and compliance with existing privacy laws.

To implement the tracking and surveillance systems, the Secretary could award grants to, or enter into contracts or cooperative

agreements with, public or not-for-profit entities. The bill would authorize the appropriation of \$5 million a year for fiscal years 2012 through 2016 to implement those programs. Based on historical patterns of spending for grant programs administered by the CDC and assuming appropriation of the authorized amounts, CBO estimates that implementing the bill would cost \$16 million over the 2012–2015 period and an additional \$9 million after 2015.

Pay-As-You-Go considerations: None.

Intergovernmental and private-sector impact: H.R. 1362 contains no intergovernmental or private-sector mandates as defined in UMRA. State and local governments that collect and store information concerning neurological diseases would benefit from grant funds authorized in the bill.

Estimate prepared by: Federal costs: Lara Robillard; Impact on state, local, and tribal governments: Lisa Ramirez-Branum; Impact on the private sector: Jimmy Jin.

Estimate approved by: Holly Harvey, Deputy Assistant Director for Budget Analysis.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the “National Neurological Diseases Surveillance System Act of 2010”.

Section 2. National Neurological Diseases Surveillance System

Section 2 amends part P of title III of the Public Health Service Act to create a new section (399V–5) that requires the Secretary of Health and Human Services, acting through the Director of the CDC, to: (1) enhance and expand infrastructure and activities to track neurological diseases, including MS and Parkinson’s disease; and (2) incorporate information obtained through these efforts into a surveillance system.

In so doing, the Secretary is required to: (1) ensure the surveillance system is designed in a manner that facilitates further research; (2) collect and store certain information (incidence and prevalence and, to the extent practicable, other available information); (3) consult with individuals with specified expertise; (4) make information and analysis in the surveillance system available to federal departments and agencies and the public, including researchers (as appropriate); and (5) ensure that privacy and security provisions applicable to the surveillance system are at least as stringent as required under the Health Insurance Portability and Accountability Act (HIPAA).

Additionally, the Secretary is permitted to: (1) collect and store other information relevant to the analysis on neurological diseases; (2) address other issues identified through the required consultation process; and (3) award grants to, or enter into contracts with, public or private nonprofit entities to carry out the activities in the legislation.

Section 2 requires the Secretary to report to Congress no later than four years after enactment of the legislation on its implementation. This section also authorizes \$5 million for each of fiscal years 2012 through 2016 to carry out the activities in the legislation.

The bill provides the Secretary with discretion in collecting and storing data on neurological diseases to: (1) allow for maximum efficiency in data collection efforts, and (2) permit a more integrated approach that can include surveillance of other neurological diseases and incorporate new information as it becomes available.

H.R. 1362 requires the Secretary to collect and store other available information on neurological diseases (beyond incidence and prevalence) and provides two illustrative examples of this information—demographics and risk factors associated or possibly associated with these diseases. While currently-available information suggests a relationship or strong potential of a relationship between certain demographic variables and these diseases (e.g., age and MS), there may be other variables where a relationship may later be established (e.g., work history). With the proliferation of health information technology, and electronic health records in particular, the Committee expects additional information surrounding diagnosis and treatment of these diseases will become more readily available and facilitate opportunities for more in-depth surveillance of neurological and other diseases.

The Committee intends for the requirement that the Secretary share information and analysis from this surveillance effort with other federal departments and agencies to be a first step in facilitating collaboration and information-sharing to improve our understanding of these diseases, where appropriate and consistent with the privacy and security protections outlined in the legislation.

In carrying out H.R. 1362, the Committee expects the Secretary to first focus on the collection and storage of data on MS and Parkinson's. Contingent upon annual appropriations and the availability of information on other diseases, the Committee encourages the Secretary to broaden surveillance efforts to also capture additional neurological diseases.

EXPLANATION OF AMENDMENT

During the Subcommittee on Health markup of H.R. 1362, Mr. Burgess of Texas offered an amendment in the nature of a substitute, which was adopted by a voice vote. The substance of the substitute amendment is reflected in the section-by-section analysis contained in this report.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in *italic* and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

* * * * *

PART P—ADDITIONAL PROGRAMS

* * * * *

SEC. 399V-5. SURVEILLANCE OF NEUROLOGICAL DISEASES.

(a) *IN GENERAL.*—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, including multiple sclerosis and Parkinson's disease; and

(2) incorporate information obtained through such activities into a statistically-sound, scientifically-credible, integrated surveillance system, to be known as the National Neurological Diseases Surveillance System.

(b) *RESEARCH.*—The Secretary shall ensure that the National Neurological Diseases Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) *CONTENT.*—In carrying out subsection (a), the Secretary—

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, such as information concerning—

(A) demographics and other information associated or possibly associated with neurological diseases, such as age, race, ethnicity, sex, geographic location, and family history;

(B) risk factors associated or possibly associated with neurological diseases, including genetic and environmental risk factors; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the epidemiology of the diseases;

(B) the natural history of the diseases;

(C) the prevention of the diseases;

(D) the detection, management, and treatment approaches for the diseases; and

(E) the development of outcomes measures; and

(4) may address issues identified during the consultation process under subsection (d).

(d) *CONSULTATION.*—In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, including—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases, including multiple sclerosis and Parkinson's disease; and

(B) have demonstrated experience in research, care, or patient services;

(3) health information technology experts or other information management specialists;

(4) clinicians with expertise in neurological diseases; and

(5) *research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.*

(e) *GRANTS.—The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.*

(f) *COORDINATION WITH OTHER FEDERAL AGENCIES.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to Federal departments and agencies, such as the National Institutes of Health, the Food and Drug Administration, the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Department of Veterans Affairs, and the Department of Defense.*

(g) *PUBLIC ACCESS.—Subject to subsection (h), the Secretary shall make information and analysis in the National Neurological Diseases Surveillance System available, as appropriate, to the public, including researchers.*

(h) *PRIVACY.—The Secretary shall ensure that privacy and security protections applicable to the National Neurological Diseases Surveillance System are at least as stringent as the privacy and security protections under HIPAA privacy and security law (as defined in section 3009(a)(2)).*

(i) *REPORT.—Not later than 4 years after the date of the enactment of this section, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—*

- (1) *the development and maintenance of the National Neurological Diseases Surveillance System;*
- (2) *the type of information collected and stored in the System;*
- (3) *the use and availability of such information, including guidelines for such use; and*
- (4) *the use and coordination of databases that collect or maintain information on neurological diseases.*

(j) *DEFINITION.—In this section, the term “national voluntary health association” means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States.*

(k) *AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated \$5,000,000 for each of fiscal years 2012 through 2016.*

* * * * *

