

Calendar No. 408

114TH CONGRESS
2D SESSION

S. 849

To amend the Public Health Service Act to provide for systematic data collection and analysis and epidemiological research regarding Multiple Sclerosis (MS), Parkinson's disease, and other neurological diseases.

IN THE SENATE OF THE UNITED STATES

MARCH 24, 2015

Mr. ISAKSON (for himself, Mr. MURPHY, Mr. VITTER, Mr. CASEY, Mr. WICKER, Ms. BALDWIN, Mr. COONS, Mrs. BOXER, Mr. CASSIDY, Ms. STABENOW, Mrs. FEINSTEIN, Mr. KIRK, Mr. MENENDEZ, Mr. CARPER, Mr. REED, Mr. MARKEY, Mr. PETERS, Mrs. GILLIBRAND, Ms. MURKOWSKI, Ms. KLOBUCHAR, Mr. BOOKER, Mr. ALEXANDER, Mr. NELSON, and Mr. BOOZMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 4, 2016

Reported by Mr. ALEXANDER, with an amendment

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

A BILL

To amend the Public Health Service Act to provide for systematic data collection and analysis and epidemiological research regarding Multiple Sclerosis (MS), Parkinson's disease, and other neurological diseases.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Advancing Research
3 for Neurological Diseases Act of 2015”.

4 **SEC. 2. NATIONAL NEUROLOGICAL DISEASES SURVEIL-**
5 **LANCE SYSTEM.**

6 Part P of title III of the Public Health Service Act
7 (42 U.S.C. 280g et seq.) is amended by adding at the end
8 the following:

9 **“SEC. 399V-6 SURVEILLANCE OF NEUROLOGICAL DISEASES.**

10 **“(a) IN GENERAL.—**The Secretary, acting through
11 the Director of the Centers for Disease Control and Pre-
12 vention, shall—

13 **“(1)** enhance and expand infrastructure and ac-
14 tivities to track the epidemiology of neurological dis-
15 eases, including multiple sclerosis and Parkinson’s
16 disease; and

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

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

1 “(e) CONTENT.—In carrying out subsection (a), the
2 Secretary—

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

6 “(2) to the extent practicable, shall provide for
7 the collection and storage of other available informa-
8 tion on neurological diseases, such as information
9 concerning—

10 “(A) demographics and other information
11 associated or possibly associated with neuro-
12 logical diseases, such as age, race, ethnicity,
13 sex, geographic location, and family history;

14 “(B) risk factors associated or possibly as-
15 sociated with neurological diseases, including
16 genetic and environmental risk factors; and

17 “(C) diagnosis and progression markers;

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

21 “(A) the epidemiology of the diseases;

22 “(B) the natural history of the diseases;

23 “(C) the prevention of the diseases;

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

1 “(E) the development of outcomes meas-
2 ures; and

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

5 “(d) CONSULTATION.—In carrying out this section,
6 the Secretary shall consult with individuals with appro-
7 priate expertise, including—

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

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

12 “(A) focus on neurological diseases, includ-
13 ing multiple sclerosis and Parkinson’s disease;
14 and

15 “(B) have demonstrated experience in re-
16 search, care, or patient services;

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

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

21 “(5) research scientists with experience con-
22 ducting translational research or utilizing surveil-
23 lance systems for scientific research purposes.

24 “(e) GRANTS.—The Secretary may award grants to,
25 or enter into contracts or cooperative agreements with,

1 public or private nonprofit entities to carry out activities
2 under this section.

3 “(f) ~~COORDINATION WITH OTHER FEDERAL AGEN-~~
4 ~~CIES.—~~Subject to subsection (h), the Secretary shall make
5 information and analysis in the National Neurological Dis-
6 eases Surveillance System available, as appropriate, to
7 Federal departments and agencies, such as the National
8 Institutes of Health, the Food and Drug Administration,
9 the Centers for Medicare & Medicaid Services, the Agency
10 for Healthcare Research and Quality, the Department of
11 Veterans Affairs, and the Department of Defense.

12 “(g) ~~PUBLIC ACCESS.—~~Subject to subsection (h), the
13 Secretary shall make information and analysis in the Na-
14 tional Neurological Diseases Surveillance System avail-
15 able, as appropriate, to the public, including researchers.

16 “(h) ~~PRIVACY.—~~The Secretary shall ensure that pri-
17 vacy and security protections applicable to the National
18 Neurological Diseases Surveillance System are at least as
19 stringent as the privacy and security protections under
20 HIPAA privacy and security law (as defined in section
21 3009(a)(2)).

22 “(i) ~~REPORT.—~~Not later than 4 years after the date
23 of the enactment of this section, the Secretary shall sub-
24 mit a report to the Congress concerning the implementa-

1 tion of this section. Such report shall include information
2 on—

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

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

7 “(3) the use and availability of such informa-
8 tion, including guidelines for such use; and

9 “(4) the use and coordination of databases that
10 collect or maintain information on neurological dis-
11 eases.

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

16 “(k) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there is authorized to be appro-
18 priated \$5,000,000 for each of fiscal years 2015 through
19 2019.”.

20 **SECTION 1. SHORT TITLE.**

21 *This Act may be cited as the “Advancing Research for*
22 *Neurological Diseases Act of 2016”.*

1 **SEC. 2. ADVANCING RESEARCH FOR NEUROLOGICAL DIS-**
2 **EASES.**

3 *Part P of title III of the Public Health Service Act*
4 *(42 U.S.C. 280g et seq.) is amended by inserting after sec-*
5 *tion 399S, the following:*

6 **“SEC. 399S-1. ADVANCING RESEARCH FOR NEUROLOGICAL**
7 **DISEASES.**

8 *“(a) IN GENERAL.—The Secretary may improve the*
9 *collection of epidemiological and surveillance data on neu-*
10 *rological diseases (including, for purposes of this section,*
11 *both neurological diseases and neurological conditions),*
12 *which may include the incorporation of such data into a*
13 *registry, to facilitate research and improve public health,*
14 *including, as appropriate, by leveraging existing surveil-*
15 *lance activities and registries established under this Act.*

16 *“(b) CONTENT.—In carrying out subsection (a), the*
17 *Secretary—*

18 *“(1) shall provide for the collection and storage*
19 *of information to better describe the incidence and*
20 *prevalence of neurological diseases in the United*
21 *States identified under paragraph (2);*

22 *“(2) shall initially identify and focus on up to*
23 *five neurological diseases that available data indicate*
24 *are the most prevalent or present a significant public*
25 *health burden;*

1 “(3) shall identify, build upon, leverage, and co-
2 ordinate among existing data and surveillance sys-
3 tems, surveys, registries, and other existing Federal
4 public health and infrastructure wherever possible;

5 “(4) shall ensure that any neurological disease
6 surveillance activities conducted pursuant to this sec-
7 tion, including any such registry, are designed in a
8 manner that facilitates research on neurological dis-
9 eases;

10 “(5) shall, to the extent practicable, provide for
11 the collection and storage of information relevant to
12 the identified neurological diseases, such as—

13 “(A) demographics, such as age, race, eth-
14 nicity, sex, geographic location, and family his-
15 tory, and other information, as appropriate;

16 “(B) risk factors that may be associated
17 with certain neurological diseases; and

18 “(C) diagnosis and progression markers;

19 “(6) may provide for the collection and storage
20 of additional information relevant to analysis on neu-
21 rological diseases, such as information regarding—

22 “(A) the natural history of the diseases;

23 “(B) the prevention, detection, management,
24 and treatments or treatment approaches for the
25 diseases; and

1 “(C) *the development of outcomes measures;*

2 *and*

3 “(7) *may address issues identified during the*
4 *consultation process described in subsection (c).*

5 “(c) *CONSULTATION.—In carrying out this section, the*
6 *Secretary shall consult with experts, who may include—*

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

9 “(2) *representatives of national and voluntary*
10 *health associations that focus on neurological diseases*
11 *and have demonstrated experience in research, care,*
12 *or patient services;*

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

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

17 “(5) *research scientists with experience con-*
18 *ducting translational research or utilizing surveil-*
19 *lance systems or registries for scientific research pur-*
20 *poses.*

21 “(d) *GRANTS.—The Secretary may award grants to,*
22 *or enter into contracts or cooperative agreements with, pub-*
23 *lic or private nonprofit entities to carry out activities under*
24 *this section.*

1 “(e) *COORDINATION WITH OTHER FEDERAL AGEN-*
2 *CIES.—Consistent with applicable privacy laws, the Sec-*
3 *retary shall make information and analysis pertaining to*
4 *information collected under this section available, as appro-*
5 *priate, to relevant Federal departments and agencies.*

6 “(f) *ACCESS FOR BIOMEDICAL RESEARCH.—The Sec-*
7 *retary shall make data collected under this section available*
8 *for purposes of biomedical research as determined appro-*
9 *priate by the Secretary, to the extent permitted by applica-*
10 *ble laws, and in a manner that protects personal privacy.*

11 “(g) *REPORTS.—*

12 “(1) *INTERIM REPORT.—Not later than 1 year*
13 *after the date on which any registry is established*
14 *and operational under this section, the Secretary shall*
15 *submit an interim report to the Committee on Health,*
16 *Education, Labor, and Pensions of the Senate and the*
17 *Committee on Energy and Commerce of the House of*
18 *Representatives regarding aggregate information col-*
19 *lected pursuant to this section and epidemiological*
20 *analyses, as appropriate. Such report shall be posted*
21 *on the Internet website of the Department of Health*
22 *and Human Services and shall be updated biennially*
23 *thereafter.*

24 “(2) *IMPLEMENTATION REPORT.—Not later than*
25 *4 years after the date of the enactment of this section,*

1 *the Secretary shall submit a report to the Committee*
2 *on Health, Education, Labor, and Pensions of the*
3 *Senate and the Committee on Energy and Commerce*
4 *of the House of Representatives regarding the imple-*
5 *mentation of this section. Such report shall include*
6 *information on—*

7 “(A) *the development and maintenance of*
8 *any means of collecting neurological disease sur-*
9 *veillance information gathered pursuant to this*
10 *section;*

11 “(B) *the type of information collected and*
12 *stored;*

13 “(C) *the use and availability of such infor-*
14 *mation, including guidelines for such use; and*

15 “(D) *the use and coordination of databases*
16 *that collect or maintain information on neuro-*
17 *logical diseases.”.*

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