

112TH CONGRESS
2D SESSION

H. R. 4138

To amend the Public Health Service Act to create a National Neuromyelitis Optica Consortium to provide grants and coordinate research with respect to the causes of, and risk factors associated with, neuromyelitis optica, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 2012

Ms. LEE of California introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to create a National Neuromyelitis Optica Consortium to provide grants and coordinate research with respect to the causes of, and risk factors associated with, neuromyelitis optica, and for other purposes.

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 “Neuromyelitis Optica
5 Consortium Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Neuromyelitis optica (NMO) is a dev-
2 astating neurologic disease leading to blindness and
3 paralysis.

4 (2) There are an estimated 11,000 patients
5 with NMO in the United States.

6 (3) Women are affected 7 to 9 times more than
7 men, and a large proportion of NMO patients are
8 African-American.

9 (4) The average age at diagnosis is 41 years,
10 but the range is broad and includes children as
11 young as 2 years of age and adults as old as 89
12 years of age.

13 (5) NMO incurs substantial costs for affected
14 patients and their families.

15 (6) The cause of NMO is unknown, but it is hy-
16 pothesized to be autoimmune in nature.

17 (7) More than 90 percent of NMO patients will
18 suffer recurrent disease and accumulate neurologic
19 disability.

20 (8) Because of their relatively low overall inci-
21 dence, orphan diseases like NMO frequently do not
22 receive sufficient attention and research funding.

23 (9) No single institution has a sufficient num-
24 ber of patients to independently conduct research
25 that will adequately address the cause of NMO.

1 (10) There has been no comprehensive study
2 analyzing all relevant clinical, biological, and epide-
3 miological aspects of NMO to identify potential risk
4 factors and biomarkers for NMO.

5 (11) We can apply our understanding of NMO
6 to the study of other autoimmune diseases, including
7 multiple sclerosis and systemic lupus erythematosus.

8 **SEC. 3. SENSE OF CONGRESS.**

9 It is the sense of Congress that there is a need—

10 (1) to establish and coordinate a multicenter re-
11 search effort based on collaboration between regional
12 consortia and governmental and nongovernmental
13 entities in order to—

14 (A) comprehensively study the causes of
15 NMO; and

16 (B) identify potential biomarkers of disease
17 activity; and

18 (2) to encourage a collaborative effort among
19 academic medical centers with epidemiological study
20 groups to gather comprehensive and detailed infor-
21 mation for each patient enrolled in those groups, in
22 order to investigate environmental, nutritional, and
23 genetic factors with respect to, and the pathological
24 and epidemiological characteristics of, NMO.

1 **SEC. 4. ESTABLISHMENT OF THE NATIONAL**
 2 **NEUROMYELITIS OPTICA CONSORTIUM.**

3 Part B of title IV of the Public Health Service Act
 4 (42 U.S.C. 284 et seq.) is amended by adding after section
 5 409J the following new section:

6 **“SEC. 409K. NATIONAL NEUROMYELITIS OPTICA CONSOR-**
 7 **TIUM.**

8 **“(a) ESTABLISHMENT OF THE NATIONAL**
 9 **NEUROMYELITIS OPTICA CONSORTIUM.—**

10 **“(1) IN GENERAL.—**Not later than 1 year after
 11 the date of the enactment of this section, the Sec-
 12 retary, acting through the Director of NIH, and in
 13 coordination with the Director of the National Insti-
 14 tute on Minority Health and Health Disparities,
 15 shall establish, administer, and coordinate a Na-
 16 tional Neuromyelitis Optica Consortium (in this sec-
 17 tion referred to as the ‘NNO Consortium’) for the
 18 purposes described in paragraph (2).

19 **“(2) PURPOSES.—**The purposes of the NNO
 20 Consortium shall be the following:

21 **“(A) Providing grants of not fewer than 5**
 22 **years duration to eligible consortia for the pur-**
 23 **pose of conducting research with respect to the**
 24 **causes of, and the risk factors and biomarkers**
 25 **associated with, NMO.**

1 “(B) Assembling a panel of experts to pro-
2 vide, with respect to research funded by the
3 NNO Consortium, ongoing guidance and rec-
4 ommendations for the development of the fol-
5 lowing:

6 “(i) A common study design.

7 “(ii) Standard protocols, methods,
8 procedures, and assays for collecting from
9 individuals enrolled as study participants a
10 minimum dataset that includes the fol-
11 lowing:

12 “(I) Complete medical history.

13 “(II) Neurologic examination.

14 “(III) Biospecimens, including
15 blood, spinal fluid, DNA, and RNA.

16 “(IV) Radiological data including
17 magnetic resonance imaging (MRI).

18 “(iii) Specific analytical methods for
19 examining data.

20 “(iv) Provisions for consensus review
21 of enrolled cases.

22 “(v) An integrated data collection net-
23 work.

24 “(C) Designating a central laboratory to
25 collect, analyze, and aggregate data with re-

1 spect to research funded by the NNO Consor-
2 tium and to make such data and analysis avail-
3 able to researchers.

4 “(3) ELIGIBLE CONSORTIA.—To be eligible for
5 a grant under this section, a consortium shall dem-
6 onstrate the following:

7 “(A) The consortium has the capability to
8 enroll as research participants a minimum of 25
9 individuals with a diagnosis of NMO from the
10 consortium’s designated catchment area.

11 “(B) The designated catchment area of the
12 consortium does not overlap with the designated
13 catchment area of another consortium already
14 receiving a grant under this section.

15 “(4) REPORT.—Not later than 1 year after the
16 date of the enactment of this section and annually
17 thereafter, the Secretary, acting through the Direc-
18 tor of NIH, shall submit to Congress a report with
19 respect to the NNO Consortium, to be made publicly
20 available, including a summary of research funded
21 by the NNO Consortium and a list of consortia re-
22 ceiving grants through the NNO Consortium. At the
23 discretion of the Secretary, such report may be com-
24 bined with other similar or existing reports.

25 “(5) AUTHORIZATION OF APPROPRIATIONS.—

1 “(A) IN GENERAL.—There is authorized to
2 be appropriated \$25,000,000 for each of fiscal
3 years 2013 through 2017, to remain available
4 until expended, to carry out this section.

5 “(B) SENSE OF CONGRESS.—It is the
6 sense of Congress that funds appropriated to
7 carry out this section should be in addition to
8 funds otherwise available or appropriated to
9 carry out the activities described in this section.

10 “(b) DEFINITIONS.—For purposes of this section:

11 “(1) CATCHMENT AREA.—The term ‘catchment
12 area’ means a defined area for which population
13 data are available.

14 “(2) CONSORTIUM.—The term ‘consortium’
15 means a partnership of 2 or more universities,
16 health care organizations, or government agencies,
17 or any combination of such entities, serving a des-
18 ignated catchment area.”.

○