

116TH CONGRESS  
1ST SESSION

# H. R. 321

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.

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## IN THE HOUSE OF REPRESENTATIVES

JANUARY 8, 2019

Ms. LEE of California 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 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 16,000 to 17,000  
5           people with NMO in the United States and a quar-  
6           ter-million worldwide.

7           (3) Women are affected 4 to 5 times more than  
8           men, and Afro-Caribbeans are about 2.5 times more  
9           predisposed to NMO than Caucasians. The reasons  
10          why Blacks are disproportionately affected cannot be  
11          fully understood without further studies.

12          (4) The average age at diagnosis is between 40  
13          and 50 years, but the range is broad and includes  
14          children as young as 3 years of age and adults as  
15          old as 90 years of age.

16          (5) NMO incurs substantial costs for affected  
17          patients and their families.

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

20          (7) More than 90 percent of NMO patients will  
21          suffer recurrent disease and accumulate neurologic  
22          disability.

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

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

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

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

11 **SEC. 3. SENSE OF CONGRESS.**

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

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

17                   (A) comprehensively study the causes of  
18 NMO; and

19                   (B) identify potential biomarkers of disease  
20 activity; and

21           (2) to encourage a collaborative effort among  
22 academic medical centers with epidemiological study  
23 groups to gather comprehensive and detailed infor-  
24 mation for each patient enrolled in those groups, in  
25 order to investigate environmental, nutritional, and

1 genetic factors with respect to, and the pathological  
2 and epidemiological characteristics of, NMO.

3 **SEC. 4. ESTABLISHMENT OF THE NATIONAL NEUROMYELI-**  
4 **TIS OPTICA CONSORTIUM.**

5 Part B of title IV of the Public Health Service Act  
6 (42 U.S.C. 284 et seq.) is amended by adding after section  
7 409J the following new section:

8 **“SEC. 409K. NATIONAL NEUROMYELITIS OPTICA CONSOR-**  
9 **TIUM.**

10 “(a) ESTABLISHMENT OF THE NATIONAL  
11 NEUROMYELITIS OPTICA CONSORTIUM.—

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

21 “(2) PURPOSES.—The purposes of the NNO  
22 Consortium shall be the following:

23 “(A) Providing grants of not fewer than 5-  
24 years’ duration to eligible consortia for the pur-  
25 pose of conducting research with respect to the

1 causes of, and the risk factors and biomarkers  
2 associated with, NMO.

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

8 “(i) A common study design.

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

14 “(I) Complete medical history.

15 “(II) Neurologic examination.

16 “(III) Biospecimens, including  
17 blood, spinal fluid, DNA, and RNA.

18 “(IV) Radiological data, includ-  
19 ing magnetic resonance imaging  
20 (MRI).

21 “(iii) Specific analytical methods for  
22 examining data.

23 “(iv) Provisions for consensus review  
24 of enrolled cases.

1                   “(v) An integrated data collection net-  
2                   work.

3                   “(C) Designating a central laboratory to  
4                   collect, analyze, and aggregate data with re-  
5                   spect to research funded by the NNO Consor-  
6                   tium and to make such data and analysis avail-  
7                   able to researchers.

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

11                  “(A) The consortium has the capability to  
12                  enroll as research participants a minimum of 25  
13                  individuals with a diagnosis of NMO from the  
14                  consortium’s designated catchment area.

15                  “(B) The designated catchment area of the  
16                  consortium does not overlap with the designated  
17                  catchment area of another consortium already  
18                  receiving a grant under this section.

19                  “(4) REPORT.—Not later than 1 year after the  
20                  date of the enactment of this section, and annually  
21                  thereafter, the Secretary, acting through the Direc-  
22                  tor of NIH, shall submit to Congress a report with  
23                  respect to the NNO Consortium, to be made publicly  
24                  available, including a summary of research funded  
25                  by the NNO Consortium and a list of consortia re-

1 ceiving grants through the NNO Consortium. At the  
2 discretion of the Secretary, such report may be com-  
3 bined with other similar or existing reports.

4 “(5) AUTHORIZATION OF APPROPRIATIONS.—

5 “(A) IN GENERAL.—There is authorized to  
6 be appropriated \$25,000,000 for each of fiscal  
7 years 2019 through 2022, to remain available  
8 until expended, to carry out this section.

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

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

15 “(1) CATCHMENT AREA.—The term ‘catchment  
16 area’ means a defined area for which population  
17 data are available.

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

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