

117TH CONGRESS
1ST SESSION

S. 3427

To authorize the Secretary of Health and Human Services to establish a
Neuroscience Center of Excellence.

IN THE SENATE OF THE UNITED STATES

DECEMBER 16, 2021

Ms. COLLINS (for herself and Mr. LUJÁN) introduced the following bill; which
was read twice and referred to the Committee on Health, Education,
Labor, and Pensions

A BILL

To authorize the Secretary of Health and Human Services
to establish a Neuroscience Center of Excellence.

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 “Neuroscience Center
5 of Excellence Act of 2021”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Neuroscience at the Food and Drug Admin-
9 istration encompasses a broad range of neurological
10 and psychiatric diseases and disorders, including—

- 1 (A) addiction;
- 2 (B) Alzheimer's disease and other
- 3 neurodegenerative conditions that cause demen-
- 4 tia;
- 5 (C) amyotrophic lateral sclerosis;
- 6 (D) autism spectrum disorder, Down syn-
- 7 drome, and other neurodevelopmental disorders;
- 8 (E) bipolar disorder;
- 9 (F) brain aneurysms;
- 10 (G) brain tumors;
- 11 (H) cerebral palsy;
- 12 (I) anxiety and depression;
- 13 (J) dyspraxia;
- 14 (K) dystonia;
- 15 (L) epilepsy and other seizure disorders;
- 16 (M) hereditary brain and central nervous
- 17 system diseases;
- 18 (N) headaches and migraine disease;
- 19 (O) Huntington's disease;
- 20 (P) multiple sclerosis;
- 21 (Q) pain;
- 22 (R) Parkinson's disease and other move-
- 23 ment disorders, including parkinsonisms;
- 24 (S) personality disorders;
- 25 (T) psychotic disorders;

1 (U) traumatic brain injury and chronic
2 traumatic encephalopathy; and

3 (V) rare diseases that impact the brain
4 and central nervous system.

5 (2) Neurological and psychiatric diseases and
6 disorders are highly prevalent. According to the Na-
7 tional Institutes of Health, neurological disorders af-
8 fect an estimated 50,000,000 people in the United
9 States each year, and 51,500,000 adults in the
10 United States live with a mental illness.

11 (3) The prevalence of neuroscience diseases and
12 disorders continues to grow. The Centers for Disease
13 Control and Prevention forecasts that the burden of
14 dementias in the United States will double by 2060
15 to 13,900,000 people, which will be 3.3 percent of
16 the population.

17 (4) Neurological and psychiatric diseases and
18 disorders have a significant impact on health care
19 expenditures and the United States economy as a
20 whole. The impact of common neurological diseases,
21 including Alzheimer's disease and Parkinson's dis-
22 ease, on the United States economy is estimated by
23 the American Neurological Association at over
24 \$789,000,000,000.

1 (5) Factors associated with the COVID-19
2 pandemic, including job loss and social isolation,
3 have exacerbated the prevalence and impact of psy-
4 chiatric diseases and disorders. According to the
5 Centers for Disease Control and Prevention, during
6 the pandemic, more than one-third of adults in the
7 United States reported symptoms of anxiety or de-
8 pression.

9 (6) The National Institute of Neurological Dis-
10 orders and Stroke has recognized that the SARS-
11 CoV-2 virus can lead to serious neurological com-
12 plications, such as anosmia, headache, impaired con-
13 sciousness, and stroke, which may affect individuals'
14 ability to function or work after the pandemic ends.

15 (7) Despite the large societal need, medical
16 products for neurological and psychiatric diseases
17 and disorders are approved by the Food and Drug
18 Administration at a much lower rate than products
19 for other disease areas. According to a 2018 study
20 conducted by the Tufts Center for the Study of
21 Drug Development, central nervous system drugs
22 take 20 percent longer to develop and approve than
23 non-central nervous system drugs.

1 **SEC. 3. ESTABLISHMENT OF A NEUROSCIENCE CENTER OF**
2 **EXCELLENCE.**

3 (a) ESTABLISHMENT REQUIRED.—The first sentence
4 of section 1014(a) of the Federal Food, Drug, and Cos-
5 metic Act (21 U.S.C. 399g(a)) is amended by inserting
6 “, at least 1 of which shall be focused on neuroscience
7 diseases and disorders (as defined in section 1015)” before
8 the period at the end.

9 (b) TIMING OF ESTABLISHMENT.—Subsection (c) of
10 section 1014 of the Federal Food, Drug, and Cosmetic
11 Act (21 U.S.C. 399g(c)) is amended to read as follows:

12 “(c) TIMING.—Not later than 1 year after the date
13 of enactment of the Neuroscience Center of Excellence Act
14 of 2021, the Secretary shall establish, in accordance with
15 this section and section 1015, an Institute under sub-
16 section (a) focused on neuroscience diseases and disorders,
17 to be known as the Neuroscience Center of Excellence.”.

18 (c) ACTIVITIES.—Chapter X of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
20 ed by adding at the end the following:

21 **“SEC. 1015. NEUROSCIENCE CENTER OF EXCELLENCE.**

22 “(a) ACTIVITIES.—The Neuroscience Center of Ex-
23 cellence established under section 1014(a), shall—

24 “(1) carry out the activities described in section
25 1014(a);

1 “(2) coordinate collaborations among the Cen-
 2 ters (within the meaning of section 1014(a)) and
 3 stakeholders to support the development of medical
 4 products for neuroscience diseases and disorders;

5 “(3) establish and carry out the programs de-
 6 scribed in subsection (c); and

7 “(4) issue reports to Congress on the activities
 8 of the Neuroscience Center of Excellence, as de-
 9 scribed in subsection (d).

10 “(b) DEFINITIONS.—In this section:

11 “(1) NEUROSCIENCE DISEASES AND DIS-
 12 ORDERS.—The term ‘neuroscience diseases and dis-
 13 orders’ means—

14 “(A) addiction;

15 “(B) Alzheimer’s disease and other
 16 neurodegenerative conditions that cause demen-
 17 tia;

18 “(C) amyotrophic lateral sclerosis;

19 “(D) autism spectrum disorder, Down syn-
 20 drome, and other neurodevelopmental disorders;

21 “(E) bipolar disorder;

22 “(F) brain aneurysms;

23 “(G) brain tumors;

24 “(H) cerebral palsy;

25 “(I) anxiety and depression;

- 1 “(J) dyspraxia;
- 2 “(K) dystonia;
- 3 “(L) epilepsy and other seizure disorders;
- 4 “(M) hereditary brain and central nervous
- 5 system diseases;
- 6 “(N) headaches and migraine disease;
- 7 “(O) Huntington’s disease;
- 8 “(P) multiple sclerosis;
- 9 “(Q) pain;
- 10 “(R) Parkinson’s disease and other move-
- 11 ment disorders, including parkinsonisms;
- 12 “(S) personality disorders;
- 13 “(T) psychotic disorders;
- 14 “(U) traumatic brain injury and chronic
- 15 traumatic encephalopathy; and
- 16 “(V) rare diseases that impact the brain
- 17 and central nervous system.
- 18 “(2) MEDICAL PRODUCT.—The term ‘medical
- 19 product’ means a drug, biological product, or device,
- 20 or a combination product described in section
- 21 503(g).
- 22 “(3) PATIENT EXPERIENCE DATA.—The term
- 23 ‘patient experience data’ has the meaning given such
- 24 term in section 569C(c).

1 “(c) PROGRAMS.—The Neuroscience Center of Excel-
 2 lence shall establish and implement the following pro-
 3 grams:

4 “(1) NEUROSCIENCE THERAPEUTICS PRO-
 5 GRAM.—

6 “(A) PUBLIC ENGAGEMENT.—

7 “(i) PUBLIC MEETING.—Not later
 8 than 2 years after the date of enactment
 9 of the Neuroscience Center of Excellence
 10 Act of 2021, and not less than once per
 11 year thereafter, the Secretary shall convene
 12 a public meeting of stakeholders (including
 13 scientists, researchers, patient advocacy or-
 14 ganizations, disease research foundations,
 15 and representatives of the drug and device
 16 industries) to identify and make rec-
 17 ommendations to address current and
 18 emerging regulatory science and public pol-
 19 icy challenges associated with developing
 20 medical products for neuroscience diseases
 21 and disorders. Issues addressed during
 22 such meetings shall include—

23 “(I) methods to support the ac-
 24 celerated qualification of appropriate
 25 biomarkers and endpoints, including

1 predictive biomarkers and endpoints,
2 for neuroscience diseases and dis-
3 orders; and

4 “(II) novel drug development
5 methodologies and study designs to
6 better support the rapid development
7 and approval of medical products for
8 neuroscience diseases and disorders.

9 “(ii) REPORT.—Not later than 3
10 months after the conclusion of each public
11 meeting under clause (i), the Secretary
12 shall publish a report identifying the chal-
13 lenges and opportunities for rapid improve-
14 ment discussed during such public meet-
15 ing, and as applicable, any recommenda-
16 tions to Congress regarding how to address
17 such challenges and ensure that patients
18 benefit from optimizing development of
19 medical products for neurosciences diseases
20 and disorders. The Secretary shall make
21 such report public on the website of the
22 Department of Health and Human Serv-
23 ices.

24 “(B) GUIDANCE.—Not later than 2 years
25 after the date of enactment of the Neuroscience

Center of Excellence Act of 2021, the Secretary shall issue one or more final guidances that address—

“(i) recommendations to sponsors of medical products for neuroscience diseases and disorders regarding master protocols to simultaneously evaluate more than 1 investigational medical product or more than 1 type of disease or disorder within the same overall trial structure, as well as other novel or collaborative study designs and approaches; and

“(ii) approaches that may be used to incorporate clinical outcome assessments, including patient-reported outcomes, into endpoints for the development of medical products for neuroscience diseases and disorders.

“(2) NEUROSCIENCE PATIENT-FOCUSED DRUG DEVELOPMENT PROGRAM.—

“(A) IN GENERAL.—The Secretary shall establish, within the Neuroscience Center of Excellence, a program to facilitate the collection of patient experience data, and the systematic use of such data and related information, in the

1 development of medical products for neuro-
2 science diseases and disorders.

3 “(B) PUBLIC ENGAGEMENT.—Not later
4 than 2 years after the date of enactment of the
5 Neuroscience Center of Excellence Act of 2021,
6 and not less than once per year thereafter, the
7 Secretary shall convene stakeholders (including
8 patient advocacy groups and disease research
9 foundations) for a public workshop. Such work-
10 shop shall—

11 “(i) educate stakeholders on current
12 initiatives and activities at the Neuro-
13 science Center of Excellence;

14 “(ii) solicit feedback from stake-
15 holders on ongoing initiatives and activities
16 at the Neuroscience Center of Excellence;
17 and

18 “(iii) provide an opportunity for
19 stakeholders to discuss their personal expe-
20 riences, including with respect to symp-
21 toms, daily impact, and current approaches
22 to treatment for neuroscience diseases and
23 disorders.

24 “(C) STUDY.—Not later than 2 years after
25 the date of enactment of the Neuroscience Cen-

1 ter of Excellence Act of 2021, the Secretary
2 shall conduct a study on methods to assess the
3 patient experience in the development of med-
4 ical products for neuroscience diseases and dis-
5 orders. The Secretary shall make a report sum-
6 marizing the results of such study public on the
7 website of the Department of Health and
8 Human Services.

9 “(D) GUIDANCE.—Not later than 2 years
10 after the date of enactment of the Neuroscience
11 Center of Excellence Act of 2021, the Secretary
12 shall issue final guidance with recommendations
13 on the collection of patient experience data (as
14 defined in section 569C of the Federal Food,
15 Drug, and Cosmetic Act), and the use of such
16 data and related information, in the develop-
17 ment of medical products for neuroscience dis-
18 eases and disorders.

19 “(3) NEUROSCIENCE NATURAL HISTORY STUD-
20 IES PROGRAM.—

21 “(A) GUIDANCE.—Not later than 2 years
22 after the date of enactment of the Neuroscience
23 Center of Excellence Act of 2021, the Secretary
24 shall issue final guidance with recommendations
25 for sponsors on implementing natural history

1 studies that can be used to support the develop-
 2 ment of medical products for neuroscience dis-
 3 eases and disorders.

4 “(B) DEFINITION.—In this paragraph, the
 5 term ‘natural history study’ means a
 6 preplanned observational study intended to
 7 track the course of the disease.

8 “(4) DIGITAL HEALTH TECHNOLOGIES PRO-
 9 GRAM.—

10 “(A) GUIDANCE.—Not later than 2 years
 11 after the date of enactment of the Neuroscience
 12 Center of Excellence Act of 2021, the Secretary
 13 shall issue final guidance addressing approaches
 14 to—

15 “(i) using digital technologies and dig-
 16 ital endpoints in clinical trials evaluating
 17 medical products for neuroscience diseases
 18 and disorders; and

19 “(ii) using digital technologies for the
 20 treatment of such diseases and disorders.

21 “(5) COVID–19 IMPACTS PROGRAM.—

22 “(A) PUBLIC MEETING.—

23 “(i) IN GENERAL.—Not later than 2
 24 years after the date of enactment of the
 25 Neuroscience Center of Excellence Act of

1 2021, the Secretary shall convene not
2 fewer than 2 public meetings for stake-
3 holders (including scientists, researchers,
4 health care providers, academics, members
5 of the regulated industry, patient advocacy
6 organizations, and disease research foun-
7 dations) to discuss the impact of COVID-
8 19 on neuroscience diseases and disorders.

9 “(ii) TOPICS.—The topics discussed at
10 the meeting under clause (i) shall in-
11 clude—

12 “(I) the impact of the SARS-
13 CoV-2 virus on patients diagnosed
14 with such diseases and disorders,
15 without regard to whether such diag-
16 noses occurred before or after such
17 patient contracted the SARS-CoV-2
18 virus;

19 “(II) the indirect impact of the
20 COVID-19 pandemic on such diseases
21 and disorders, including the effects of
22 social isolation and heightened levels
23 of stress and anxiety for those with
24 neuroscience disease and disorder di-
25 agnoses; and

1 “(III) strategies for the rapid de-
2 velopment of medical products to ad-
3 dress the direct and indirect impacts
4 of COVID–19 on such diseases and
5 disorders, including real-world data
6 collection and real-world evidence de-
7 velopment.

8 “(B) REPORT.—Not later than 1 year
9 after the date of enactment of the Neuroscience
10 Center of Excellence Act of 2021, the Secretary
11 shall publish a report on the direct and indirect
12 impacts of COVID–19 on neuroscience diseases
13 and disorders including, as applicable, any rec-
14 ommendations to Congress on the development
15 of medical products intended to address the im-
16 pact of COVID–19 for individuals with such
17 conditions. The Secretary shall make such re-
18 port public on the website of the Department of
19 Health and Human Services.

20 “(6) ENSURING EQUITY IN NEUROSCIENCE
21 PROGRAM.—

22 “(A) PUBLIC MEETING.—Not later than 2
23 years after the date of enactment of the Neuro-
24 science Center of Excellence Act of 2021, the
25 Secretary shall convene a public meeting of

1 stakeholders whose experience directly relates to
2 patients with neuroscience diseases and dis-
3 orders (including scientists, health care pro-
4 viders, academics, members of the regulated in-
5 dustry, patient advocacy organizations, and dis-
6 ease research foundations) to discuss how to
7 promote equity and inclusion of traditionally
8 underrepresented populations in the research
9 and development of medical products for neuro-
10 science diseases and disorders.

11 “(B) GUIDANCE.—Not later than 2 years
12 after the date of enactment of the Neuroscience
13 Center of Excellence Act of 2021, the Secretary
14 shall issue guidance for industry on how to en-
15 sure greater diversity in clinical trials for neu-
16 roscience diseases and disorders medical prod-
17 ucts. Such guidance shall consider the feedback
18 and recommendations from the public meeting
19 under subparagraph (A) the study under sec-
20 tion 3(d) of the Neuroscience Center of Excel-
21 lence Act of 2021.

22 “(d) REPORT.—Not later than 1 year after the date
23 of enactment of the Neuroscience Center of Excellence Act
24 of 2021, and annually thereafter, the Secretary shall sub-
25 mit a report to the Committee on Health, Education,

1 Labor, and Pensions of the Senate and the Committee on
2 Energy and Commerce of the House of Representatives
3 on the activities of the Neuroscience Center of Excellence.

4 Such report shall include—

5 “(1) the number of medical products for neuro-
6 science diseases and disorders that were approved by
7 the Food and Drug Administration in the previous
8 5 calendar years;

9 “(2) a summary of challenges to developing
10 medical products for neuroscience diseases and dis-
11 orders, and as applicable, recommendations to Con-
12 gress on how to address such challenges; and

13 “(3) the direct and indirect impacts of the
14 COVID–19 pandemic on neuroscience diseases and
15 disorders.

16 “(e) AUTHORIZATION OF APPROPRIATIONS.—To
17 carry out this section, there are authorized to be appro-
18 priated \$25,000,000 for the period of fiscal years 2023
19 through 2027.”.

20 (d) GAO STUDY.—Not later than 2 years after the
21 date of enactment of this Act, the Comptroller General
22 of the United States shall—

23 (1) complete a study that reviews the participa-
24 tion of traditionally underrepresented populations in
25 clinical trials for medical products (as defined in sec-

1 tion 1015 of the Federal Food, Drug, and Cosmetic
2 Act, as added by section 3) for the treatment or di-
3 agnosis of neuroscience diseases and disorders (as
4 defined in such section 1015); and

5 (2) submit a report to Congress on the results
6 of such study, including recommendations on poten-
7 tial changes in practices and policies to improve par-
8 ticipation by populations that have been traditionally
9 underrepresented in such trials.

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