

117TH CONGRESS
1ST SESSION

H. R. 5435

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence and a Neuroscience Translation Working Group, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 30, 2021

Mr. BLUMENAUER (for himself, Mr. PASCRELL, and Mr. BACON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services to establish a Neuroscience Center of Excellence and a Neuroscience Translation Working Group, 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 “Bringing Regulatory
5 Advances Into Neuroscience Act of 2021” or the “BRAIN
6 Act of 2021”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) The brain and central nervous system make
4 up the body's most complex organ system.

5 (2) Nearly one in five adults in the United
6 States (more than 50 million) live with a mental ill-
7 ness, disproportionately impacting women, people re-
8 porting two or more races, and individuals under age
9 fifty.

10 (3) Neuropsychiatric disorders are the leading
11 cause of disability in the Nation, making up 18.7
12 percent of years lost to disability and premature
13 death.

14 (4) Brain disorders, injuries, and diseases are
15 estimated to cost the United States more than \$1.5
16 trillion per year.

17 (5) Mental health and substance use disorder
18 treatment spending is expected to total \$280.5 bil-
19 lion in 2020.

20 (6) The SARS-CoV-2 virus can cause serious
21 psychiatric and neurologic effects and the COVID-
22 19 pandemic has exacerbated the burden of brain
23 and central nervous system conditions.

24 (7) Products targeting the brain and central
25 nervous system, including those conditions with few
26 or no approved treatments, take longer to develop

1 and are less likely to be approved than products for
2 other disease areas.

3 **SEC. 3. INSTITUTE AND ADVISORY COMMITTEE FOR DIS-**
4 **EASES AFFECTING THE BRAIN OR CENTRAL**
5 **NERVOUS SYSTEM.**

6 (a) ESTABLISHMENT OF NEUROSCIENCE CENTER OF
7 EXCELLENCE.—Section 1014 of the Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 399g) is amended by adding
9 at the end the following:

10 “(e) NEUROSCIENCE CENTER OF EXCELLENCE.—

11 “(1) IN GENERAL.—The Secretary shall estab-
12 lish an institute under subsection (a) to be known as
13 the Neuroscience Center of Excellence to carry out
14 activities under such subsection with respect to a
15 major disease area or areas affecting the brain or
16 central nervous system.

17 “(2) AUTHORIZATION OF APPROPRIATIONS.—

18 There are authorized to be appropriated to carry out
19 this subsection \$25,000,000 for each of fiscal years
20 2023 through 2027.”.

21 (b) NEUROSCIENCE TRANSLATION WORKING
22 GROUP.—Chapter X of the Federal Food, Drug, and Cos-
23 metic Act (21 U.S.C. 391 et seq.) is amended by adding
24 at the end the following:

1 **“SEC. 1015. NEUROSCIENCE TRANSLATION WORKING**
2 **GROUP.**

3 “(a) ESTABLISHMENT.—The Secretary shall estab-
4 lish and maintain an advisory board to be known as the
5 Neuroscience Translation Working Group to advise the
6 Director of the Neuroscience Center of Excellence under
7 section 1014(e) (or the Commissioner of Food and Drugs
8 in accordance with subsection (c)) on the following:

9 “(1) Issues with respect to translating neuro-
10 science discoveries to approved treatments for dis-
11 eases and conditions affecting the brain or central
12 nervous system.

13 “(2) Activities to increase the translation of
14 neuroscience discoveries to such approved treat-
15 ments.

16 “(3) The development of guidance with respect
17 to diseases and conditions affecting the brain or cen-
18 tral nervous system.

19 “(4) Funding, collaboration, and other opportu-
20 nities within the National Institute of Neurological
21 Disorders and Stroke, National Center for Advanc-
22 ing Translational Sciences, or other Government en-
23 tities to increase the translation of neuroscience dis-
24 coveries to such approved treatments.

1 “(5) The incorporation of patient preferences,
2 patient-reported outcomes, and real-world data in
3 the development of regulations.

4 “(b) MEMBERSHIP.—The Neuroscience Translation
5 Working Group shall consist of not more than eight mem-
6 bers, including—

7 “(1) the Director of the National Institute of
8 Neurological Disorders and Stroke (or designee);

9 “(2) the Director of the National Center for
10 Advancing Translational Sciences (or designee);

11 “(3) three representatives from patient advoca-
12 cacy or national organizations that focus on injuries,
13 diseases, or disorders affecting the brain or central
14 nervous system, including organizations that rep-
15 resent service delivery for patients;

16 “(4) two experts with experience conducting
17 clinical trials with respect to diseases and conditions
18 affecting the brain or central nervous system; and

19 “(5) one expert with expertise in the regulation
20 of drugs, devices, and biological products.

21 “(c) TERMINATION OF NEUROSCIENCE CENTER OF
22 EXCELLENCE.—If the Secretary, pursuant to section
23 1014(d), terminates the Neuroscience Center of Excel-
24 lence under section 1014(e), the Neuroscience Translation

1 Working Group shall advise the Commissioner of Food
2 and Drugs.”.

3 (c) APPLICABILITY.—Sections 1014(e) and 1015 of
4 the Federal Food, Drug, and Cosmetic Act, as added by
5 this section, shall apply on the date that is not later than
6 one year after the date of the enactment of this Act.

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