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(Original Signature of Member)

116TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

To provide for the acceleration of access to clinical therapies for the treatment of amyotrophic lateral sclerosis, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

Mr. FORTENBERRY introduced the following bill; which was referred to the Committee on \_\_\_\_\_

\_\_\_\_\_  
**A BILL**

To provide for the acceleration of access to clinical therapies for the treatment of amyotrophic lateral sclerosis, 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 “Accelerating Access  
5 to Critical Therapies for ALS Act”.

1 **SEC. 2. GRANTS FOR RAPID DEVELOPMENT OF THERAPIES**  
2 **FOR ALS AND OTHER RAPIDLY PROGRESSING**  
3 **NEURODEGENERATIVE DISEASES.**

4 (a) IN GENERAL.—The Secretary of Health and  
5 Human Services shall award grants to eligible entities for  
6 the provision of investigational drugs through an expanded  
7 access program pursuant to section 561 of the Federal  
8 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for  
9 individuals for the prevention, diagnosis, mitigation, treat-  
10 ment, or cure of amyotrophic lateral sclerosis or another  
11 rapidly progressing neurodegenerative disease.

12 (b) VESTED AUTHORITY.—For purposes of develop-  
13 ment of an investigational drug pursuant to subsection  
14 (a), the Secretary may vest authority in the participating  
15 clinical trial site or sites to make the determination under  
16 subsection (b)(2), (c)(6), or (c)(7), as applicable, of the  
17 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
18 360bbb).

19 (c) TIMING.—Not later than 60 days after the date  
20 of submission of an application for a grant under this sec-  
21 tion—

22 (1) the Secretary, acting through the Director  
23 of the National Institutes of Health, shall determine  
24 whether to award the grant; and

25 (2) the Secretary acting through the Commis-  
26 sioner of Food and Drugs (or by vesting authority

1 in the participating clinical trial site, as applicable)  
2 shall make the determinations required of the Sec-  
3 retary under subsection (b) or (c), as applicable, of  
4 section 561 of the Federal Food, Drug, and Cos-  
5 metic Act (21 U.S.C. 360bbb) for the provision of  
6 the investigational drug to occur.

7 (d) DEFINITIONS.—In this section:

8 (1) The term “Director” means the Director of  
9 the National Institutes of Health.

10 (2) The term “eligible entity” means an entity  
11 that is—

12 (A) a small business concern (as defined in  
13 section 3(a) of the Small Business Act (15  
14 U.S.C. 632(a)) that is the sponsor of a drug  
15 that is the subject of an investigational new  
16 drug application under section 505(i) of the  
17 Federal Food, Drug, and Cosmetic Act (21  
18 U.S.C. 355(i)); or

19 (B) a participating clinical trial site for  
20 such an applicant.

21 (3) The term “participating clinical trial”  
22 means a phase 2 or phase 3 clinical trial conducted  
23 pursuant to an exemption under section 505(i) of  
24 the Federal Food, Drug, and Cosmetic Act (21  
25 U.S.C. 355(i)) or section 351(a) of the Public

1 Health Service Act (42 U.S.C. 262(a)) to investigate  
2 a drug intended to treat amyotrophic lateral sclero-  
3 rosis or another rapidly progressing  
4 neurodegenerative disease.

5 (4) The term “participating clinical trial site”  
6 means a health care facility at which patients par-  
7 ticipating in a participating clinical trial receive  
8 treatment through such trial.

9 (5) The term “Secretary” means the Secretary  
10 of Health and Human Services.

11 (e) FUNDING.—

12 (1) AUTHORIZATION OF APPROPRIATIONS.—  
13 There are authorized to be appropriated to carry out  
14 this section—

15 (A) \$75,000,000 for each of fiscal years  
16 2021 and 2022; and

17 (B) \$150,000,000 for each of fiscal years  
18 2023 and 2024.

19 (2) GIFTS, GRANTS, AND OTHER DONATIONS TO  
20 FOUNDATION.—

21 (A) ACCEPTANCE.—Pursuant to section  
22 499(c) of the Public Health Service Act (42  
23 U.S.C. 290b(c)), the Foundation for the Na-  
24 tional Institutes of Health may solicit and ac-  
25 cept gifts, grants, and other donations, estab-

1           lish accounts, and invest and expend funds in  
2           support of carrying out this section.

3           (B) USE.—In addition to the amounts  
4           made available pursuant to the authorizations  
5           of appropriations in paragraph (1), the Director  
6           may use, without further appropriation, any  
7           funds derived from a gift, grant, or other dona-  
8           tion accepted pursuant to subparagraph (A).

9           (f) REVIEW AND EXPANSION.—Not later than 18  
10          months after the date of the enactment of this Act—

11           (1) the Secretary of Health and Human Serv-  
12          ices shall convene an independent review panel that  
13          includes representatives of patients, researchers,  
14          drug sponsors, and government agencies; and

15           (2) the independent review panel shall submit  
16          to the Committee on Energy and Commerce of the  
17          House of Representatives and the Committee on  
18          Health, Education, Labor and Pensions of the Sen-  
19          ate a report on the findings and conclusions of the  
20          panel with respect to the design and implementation  
21          of the program under this section for 2023 and  
22          2024.

1 **SEC. 3. FDA CENTER OF EXCELLENCE FOR**  
2 **NEURODEGENERATIVE DISEASES.**

3 Chapter X of the Federal Food, Drug, and Cosmetic  
4 Act (21 U.S.C. 391 et seq.) is amended by adding at the  
5 end the following:

6 **“SEC. 1015. CENTER OF EXCELLENCE FOR**  
7 **NEURODEGENERATIVE DISEASES.**

8 “(a) ESTABLISHMENT.—Not later than September  
9 2021, the Secretary shall establish within the Food and  
10 Drug Administration a center of excellence, to be known  
11 as the Center of Excellence for Neurodegenerative Dis-  
12 eases (in this section referred to as the ‘Center of Excel-  
13 lence’).

14 “(b) DUTIES AND AUTHORITIES.—The Center of Ex-  
15 cellence shall have duties and authorities similar to those  
16 of the Center of Excellence for Oncology established under  
17 section 1014, including the duties and authorities of the  
18 Center of Excellence for Oncology with respect to Project  
19 Facilitate.”.