

116TH CONGRESS
2D SESSION

H. R. 7071

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 1, 2020

Mr. FORTENBERRY (for himself and Mr. QUIGLEY) introduced the following bill; which was referred to the Committee on Energy and Commerce

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”.

6 **SEC. 2. GRANTS FOR RAPID DEVELOPMENT OF THERAPIES**
7 **FOR ALS AND OTHER RAPIDLY PROGRESSING**
8 **NEURODEGENERATIVE DISEASES.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services shall award grants to eligible entities for

1 the provision of investigational drugs through an expanded
2 access program pursuant to section 561 of the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for
4 individuals for the prevention, diagnosis, mitigation, treat-
5 ment, or cure of amyotrophic lateral sclerosis or another
6 rapidly progressing neurodegenerative disease.

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

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

17 (1) the Secretary, acting through the Director
18 of the National Institutes of Health, shall determine
19 whether to award the grant; and

20 (2) the Secretary acting through the Commis-
21 sioner of Food and Drugs (or by vesting authority
22 in the participating clinical trial site, as applicable)
23 shall make the determinations required of the Sec-
24 retary under subsection (b) or (c), as applicable, of
25 section 561 of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 360bbb) for the provision of
2 the investigational drug to occur.

3 (d) DEFINITIONS.—In this section:

4 (1) The term “Director” means the Director of
5 the National Institutes of Health.

6 (2) The term “eligible entity” means an entity
7 that is—

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

15 (B) a participating clinical trial site for
16 such an applicant.

17 (3) The term “participating clinical trial”
18 means a phase 2 or phase 3 clinical trial conducted
19 pursuant to an exemption under section 505(i) of
20 the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 355(i)) or section 351(a) of the Public
22 Health Service Act (42 U.S.C. 262(a)) to investigate
23 a drug intended to treat amyotrophic lateral sle-
24 rosis or another rapidly progressing
25 neurodegenerative disease.

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

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

7 (e) FUNDING.—

8 (1) AUTHORIZATION OF APPROPRIATIONS.—
9 There are authorized to be appropriated to carry out
10 this section—

11 (A) \$75,000,000 for each of fiscal years
12 2021 and 2022; and

13 (B) \$150,000,000 for each of fiscal years
14 2023 and 2024.

15 (2) GIFTS, GRANTS, AND OTHER DONATIONS TO
16 FOUNDATION.—

17 (A) ACCEPTANCE.—Pursuant to section
18 499(c) of the Public Health Service Act (42
19 U.S.C. 290b(c)), the Foundation for the Na-
20 tional Institutes of Health may solicit and ac-
21 cept gifts, grants, and other donations, estab-
22 lish accounts, and invest and expend funds in
23 support of carrying out this section.

24 (B) USE.—In addition to the amounts
25 made available pursuant to the authorizations

1 of appropriations in paragraph (1), the Director
2 may use, without further appropriation, any
3 funds derived from a gift, grant, or other dona-
4 tion accepted pursuant to subparagraph (A).

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

7 (1) the Secretary of Health and Human Serv-
8 ices shall convene an independent review panel that
9 includes representatives of patients, researchers,
10 drug sponsors, and government agencies; and

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

19 **SEC. 3. FDA CENTER OF EXCELLENCE FOR**
20 **NEURODEGENERATIVE DISEASES.**

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

1 **“SEC. 1015. CENTER OF EXCELLENCE FOR**
2 **NEURODEGENERATIVE DISEASES.**

3 “(a) ESTABLISHMENT.—Not later than September
4 2021, the Secretary shall establish within the Food and
5 Drug Administration a center of excellence, to be known
6 as the Center of Excellence for Neurodegenerative Dis-
7 eases (in this section referred to as the ‘Center of Excel-
8 lence’).

9 “(b) DUTIES AND AUTHORITIES.—The Center of Ex-
10 cellence shall have duties and authorities similar to those
11 of the Center of Excellence for Oncology established under
12 section 1014, including the duties and authorities of the
13 Center of Excellence for Oncology with respect to Project
14 Facilitate.”.

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