(Original Signature of Member)

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

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.
- 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             |
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| 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) |
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| 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 |
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| 2  | a drug intended to treat amyotrophic lateral scle-   |
| 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       |
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| 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                        |
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| 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.".