

# Union Calendar No. 148

117TH CONGRESS  
1ST SESSION

# H. R. 3537

[Report No. 117–207]

To direct the Secretary of Health and Human Services to support research on, and expanded access to, investigational drugs for amyotrophic lateral sclerosis, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 25, 2021

Mr. QUIGLEY (for himself, Mr. FORTENBERRY, Mr. BRENDAN F. BOYLE of Pennsylvania, Mr. MOULTON, Mr. GARCIA of California, Mr. CARBAJAL, Mr. LARSON of Connecticut, Ms. JACKSON LEE, Ms. DEAN, Mr. SUOZZI, Ms. VELÁZQUEZ, Mr. LEVIN of California, Mr. DEUTCH, Ms. NORTON, Mr. TIMMONS, Mr. BRADY, Mr. MCKINLEY, Mr. VAN DREW, Mr. CALVERT, Mr. KEATING, Mr. DIAZ-BALART, Mr. CARTER of Georgia, Mrs. MCBATH, Mr. SMITH of Missouri, Mr. TURNER, Mr. DUNCAN, Mr. HICE of Georgia, Mr. YOUNG, Mr. SMITH of Nebraska, Mr. GROTHMAN, Mr. RUPPERSBERGER, Mr. RUTHERFORD, Mr. SCHWEIKERT, Mr. RYAN, Mr. CROW, Mr. GUTHRIE, Mr. FITZPATRICK, Ms. MCCOLLUM, Mr. AUSTIN SCOTT of Georgia, Mr. BAIRD, Mr. RODNEY DAVIS of Illinois, Mr. VALADAO, Mr. MOOLENAAR, Mr. MALINOWSKI, Ms. ROYBAL-ALLARD, Mr. PAYNE, Mr. LYNCH, Ms. HERRERA BEUTLER, Mr. BUCK, Mr. MULLIN, Mr. GRIJALVA, Mr. COOPER, Mr. PANETTA, Mr. KIM of New Jersey, Mr. SIRES, Ms. LEE of California, Ms. MOORE of Wisconsin, Ms. SCHAKOWSKY, Mr. THOMPSON of California, Mr. GALLEG0, Mrs. AXNE, Mrs. NAPOLITANO, Mr. ESPAILLAT, Ms. PRESSLEY, Mr. FLEISCHMANN, Mr. RESCHENTHALER, Mr. CICILLINE, Ms. DEGETTE, Mr. BURCHETT, Mr. LAMALFA, Ms. MENG, Ms. BROWNLEY, Mr. TRONE, Ms. KUSTER, Mr. CONNOLLY, Mr. MEEKS, Mrs. KIRKPATRICK, Mrs. DEMINGS, Mr. O'HALLERAN, Mr. LIEU, Mr. DESAULNIER, Mr. GARAMENDI, Mr. KILMER, Mr. RUSH, Mr. MCCAUL, Mr. MCCLINTOCK, Mr. MFUME, Mr. LAMB, Mr. GREEN of Texas, Mr. SWALWELL, Mr. GOTTHEIMER, Ms. PINGREE, Ms. KAPTUR, Mr. FERGUSON, Ms. SCANLON, Mr. BACON, Mr. WITTMAN, Mr. MORELLE, Mr. AMODEI, and Mr. WALTZ) introduced the following bill; which was referred to the Committee on Energy and Commerce

DECEMBER 8, 2021

Additional sponsors: Ms. SEWELL, Ms. SHERRILL, Mr. POSEY, Mr. COLE, Mr. CURTIS, Mr. CARSON, Mr. GONZALEZ of Ohio, Ms. CLARK of Massachusetts, Ms. HOULAHAN, Ms. NEWMAN, Mr. SMITH of New Jersey, Mr. LAHOOD, Mr. COSTA, Mr. SHERMAN, Mr. CHABOT, Mr. AGUILAR, Mrs. BEATTY, Ms. WASSERMAN SCHULTZ, Ms. DAVIDS of Kansas, Mr. HILL, Mrs. CAROLYN B. MALONEY of New York, Mr. VICENTE GONZALEZ of Texas, Ms. WEXTON, Mr. HUFFMAN, Mr. TONKO, Mrs. LURIA, Mr. BISHOP of Georgia, Mr. CORREA, Mr. KATKO, Mr. FOSTER, Ms. WILD, Mr. WOMACK, Ms. ROSS, Ms. LOIS FRANKEL of Florida, Mr. KELLER, Mr. STEWART, Mr. BROOKS, Mr. AUCHINCLOSS, Mr. WELCH, Mr. WILSON of South Carolina, Ms. SALAZAR, Mrs. TRAHAN, Ms. STEFANIK, Ms. MATSUI, Mr. CARTWRIGHT, Mr. YARMUTH, Mr. SCHNEIDER, Mr. DELGADO, Mr. WESTERMAN, Mr. GARCÍA of Illinois, Ms. MANNING, Ms. PORTER, Mr. CRAWFORD, Mr. DEFazio, Mr. LANGEVIN, Miss RICE of New York, Mr. GOLDEN, Mr. SESSIONS, Mr. HARDER of California, Mr. LOWENTHAL, Mr. SOTO, Mr. RASKIN, Mr. JOYCE of Ohio, Mr. LAMBORN, Mr. JOHNSON of Georgia, Ms. BARRAGÁN, Mr. DUNN, Mr. COURTNEY, Mr. CARTER of Louisiana, Mr. LUCAS, Mr. EMMER, Mr. GRAVES of Missouri, Ms. OMAR, Mr. PETERS, Ms. CRAIG, Mr. DANNY K. DAVIS of Illinois, Mr. BERA, Mr. BILIRAKIS, Ms. STRICKLAND, Mr. GIBBS, Mr. MEUSER, Mr. HIGGINS of New York, Mr. GALLAGHER, Mr. LAWSON of Florida, Mr. OWENS, Mrs. MILLER-MEEKS, Mr. CÁRDENAS, Mr. WENSTRUP, Ms. JACOBS of California, Mr. PERLMUTTER, Mrs. HARTZLER, Mr. STAUBER, Mr. KRISHNAMOORTHY, Mr. KILDEE, Ms. SLOTKIN, Mr. SARBANES, Mr. GRIFFITH, Ms. SPANBERGER, Mr. MCGOVERN, Mr. KHANNA, Mr. MANN, Mr. BIGGS, Mr. SEAN PATRICK MALONEY of New York, Mr. THOMPSON of Pennsylvania, Ms. DELBENE, Mr. NADLER, Ms. SÁNCHEZ, Mr. MCNERNEY, Mrs. WATSON COLEMAN, Mrs. FLETCHER, Mr. MAST, Mr. STANTON, Mr. SMITH of Washington, Mr. WEBER of Texas, Ms. KELLY of Illinois, Mr. JONES, Mr. NEGUSE, Mr. KAHELE, Mr. HIMES, Mr. HUIZENGA, Mr. HIGGINS of Louisiana, Mr. BERGMAN, Mr. BALDERSON, Mr. DAVID SCOTT of Georgia, Mr. ADERHOLT, Mr. ARMSTRONG, Mr. DESJARLAIS, Mr. MOORE of Alabama, Mr. SCHIFF, Mr. THOMPSON of Mississippi, Mrs. KIM of California, Mr. FEENSTRA, Ms. ADAMS, Mr. KELLY of Mississippi, Mr. ALLRED, Mr. COHEN, Mr. BROWN of Maryland, Mr. JOHNSON of Ohio, Mrs. MURPHY of Florida, Mr. LUETKEMEYER, Ms. WILLIAMS of Georgia, Mr. GOSAR, Mr. TIFFANY, Mr. CASTEN, Ms. CHENEY, Mrs. HAYES, Mr. JEFFRIES, Mr. SMUCKER, Ms. LOFGREN, Mr. HERN, Ms. TENNEY, Ms. BONAMICI, Mrs. STEEL, Mr. GARBARINO, Mr. NORCROSS, Ms. ESCOBAR, Mrs. CAMMACK, Mr. GOMEZ, Mr. TORRES of New York, Mr. BOWMAN, Ms. TLAIB, Ms. BASS, Ms. WILSON of Florida, Ms. CLARKE of New York, Mr. LEVIN of Michigan, Ms. STEVENS, Ms. LEGER FERNANDEZ, Ms. WATERS, Mr. KIND, Mr. CUELLAR, Mr. PHILLIPS, Mr. HAGEDORN, Mr. PALAZZO, Ms. BLUNT ROCHESTER, Mr. MOORE of Utah, Mr. BLUMENAUER, Ms. GRANGER, Ms. JAYAPAL, Mr. HORSFORD, Mr. CLINE, Ms. SPEIER, Mr. CARL, Mr. CAWTHORN, Mr. MURPHY of North Carolina, Mr. OBERNOLTE, Mr. KELLY of Pennsylvania, Mr. SCALISE, Ms. MALLIOTAKIS, Mr. EVANS, Mr. ZELDIN, Mr. SIMPSON, Mr. STEUBE, Mr.

JOHNSON of Louisiana, Mr. LOUDERMILK, Mrs. HINSON, Mr. LATURNER, Ms. BOURDEAUX, Ms. JOHNSON of Texas, Mr. CASE, Mr. JACOBS of New York, Mrs. BICE of Oklahoma, Mrs. WAGNER, Mr. GOODEN of Texas, Mr. HARRIS, Mr. JACKSON, Mr. MOONEY, Mr. BURGESS, Ms. LETLOW, Mr. UPTON, Ms. SCHRIER, Mr. BUTTERFIELD, Mr. BENTZ, Mrs. FISCHBACH, Mr. GRAVES of Louisiana, Mr. WALBERG, Mr. GOOD of Virginia, Mrs. TORRES of California, Mr. PAPPAS, Mrs. McCLAIN, Mr. GUEST, Mr. C. SCOTT FRANKLIN of Florida, Mr. GOMERT, Mr. ROUZER, Mr. BOST, Mr. WILLIAMS of Texas, Mr. BANKS, Mrs. LAWRENCE, Mr. CRIST, Ms. CASTOR of Florida, Ms. ESHOO, Mr. CRENSHAW, and Mr. NEWHOUSE

DECEMBER 8, 2021

Reported with an amendment, committed to the Committee of the Whole  
House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italic*]

[For text of introduced bill, see copy of bill as introduced on May 25, 2021]

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## **A BILL**

To direct the Secretary of Health and Human Services to support research on, and expanded access to, investigational drugs for 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 to*  
5 *Critical Therapies for ALS Act”.*

6 **SEC. 2. GRANTS FOR RESEARCH ON THERAPIES FOR ALS.**

7 *(a) IN GENERAL.—The Secretary of Health and*  
8 *Human Services (referred to in this section as the “Sec-*  
9 *retary”)* shall award grants to participating entities for  
10 *purposes of scientific research utilizing data from expanded*  
11 *access to investigational drugs for individuals who are not*  
12 *otherwise eligible for clinical trials for the prevention, diag-*  
13 *nosis, mitigation, treatment, or cure of amyotrophic lateral*  
14 *sclerosis. In the case of a participating entity seeking such*  
15 *a grant, an expanded access request must be submitted, and*  
16 *allowed to proceed by the Secretary, under section 561 of*  
17 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
18 *360bbb) and part 312 of title 21, Code of Federal Regula-*  
19 *tions (or any successor regulations), before the application*  
20 *for such grant is submitted.*

21 *(b) APPLICATION.—*

22 *(1) IN GENERAL.—A participating entity seeking*  
23 *a grant under this section shall submit to the Sec-*  
24 *retary an application at such time, in such manner,*

1        *and containing such information as the Secretary*  
2        *shall specify.*

3            (2) *USE OF DATA.—An application submitted*  
4        *under paragraph (1) shall include a description of*  
5        *how data generated through an expanded access re-*  
6        *quest under section 561 of the Federal Food, Drug,*  
7        *and Cosmetic Act (21 U.S.C. 360bbb) with respect to*  
8        *the investigational drug involved will be used to sup-*  
9        *port research or development related to the preven-*  
10       *tion, diagnosis, mitigation, treatment, or cure of*  
11       *amyotrophic lateral sclerosis.*

12           (3) *NONINTERFERENCE WITH CLINICAL*  
13        *TRIALS.—An application submitted under paragraph*  
14        *(1) shall include a description of how the proposed ex-*  
15        *panded access program will be designed so as not to*  
16        *interfere with patient enrollment in ongoing clinical*  
17        *trials for investigational therapies for the prevention,*  
18        *diagnosis, mitigation, treatment, or cure of*  
19        *amyotrophic lateral sclerosis.*

20           (c) *SELECTION.—Consistent with sections 406 and 492*  
21        *of the Public Health Service Act (42 U.S.C. 284a, 289a),*  
22        *the Secretary shall, in determining whether to award a*  
23        *grant under this section, confirm that—*

24           (1) *such grant will be used to support a sci-*  
25        *entific research objective relating to the prevention,*

1     *diagnosis, mitigation, treatment, or cure of*  
2     *amyotrophic lateral sclerosis (as described in sub-*  
3     *section (a));*

4             *(2) such grant shall not have the effect of dimin-*  
5     *ishing eligibility for, or impeding enrollment of, ongo-*  
6     *ing clinical trials for the prevention, diagnosis, miti-*  
7     *gation, treatment, or cure of amyotrophic lateral sle-*  
8     *rosis by determining that individuals who receive ex-*  
9     *panded access to investigational drugs through such a*  
10    *grant are not eligible for enrollment in—*

11            *(A) ongoing clinical trials that are reg-*  
12    *istered on ClinicalTrials.gov (or successor*  
13    *website), with respect to a drug for the preven-*  
14    *tion, diagnosis, mitigation, treatment, or cure of*  
15    *amyotrophic lateral sclerosis; or*

16            *(B) clinical trials for the prevention, diag-*  
17    *nosis, mitigation, treatment, or cure of*  
18    *amyotrophic lateral sclerosis for which an ex-*  
19    *emption under section 505(i) of the Federal*  
20    *Food, Drug, and Cosmetic Act (21 U.S.C. 355(i))*  
21    *has been granted by the Food and Drug Admin-*  
22    *istration and which are expected to begin enroll-*  
23    *ment within one year; and*

1           (3) *the resulting project funded by such grant*  
 2           *will allow for equitable access to investigational drugs*  
 3           *by minority and underserved populations.*

4           (d) *USE OF FUNDS.—A participating entity shall use*  
 5           *funds received through the grant—*

6           (1) *to pay the manufacturer or sponsor for the*  
 7           *direct costs of the investigational drug, as authorized*  
 8           *under section 312.8(d) of title 21, Code of Federal*  
 9           *Regulations (or successor regulations), to prevent, di-*  
 10          *agnose, mitigate, treat, or cure amyotrophic lateral*  
 11          *sclerosis that is the subject of an expanded access re-*  
 12          *quest described in subsection (a), if such costs are jus-*  
 13          *tified as part of peer review of the grant;*

14          (2) *for the entity’s direct costs incurred in pro-*  
 15          *viding such drug consistent with the research mission*  
 16          *of the grant; or*

17          (3) *for the direct and indirect costs of the entity*  
 18          *in conducting research with respect to such drug.*

19          (e) *DEFINITIONS.—In this section:*

20          (1) *The term “participating entity” means a*  
 21          *participating clinical trial site or sites sponsored by*  
 22          *a small business concern (as defined in section 3(a)*  
 23          *of the Small Business Act (15 U.S.C. 632(a))) that is*  
 24          *the sponsor of a drug that is the subject of an inves-*  
 25          *tigational new drug application under section 505(i)*

(3) *The term “participating clinical trial site” means a health care facility, or network of facilities, at which patients participating in a participating clinical trial receive an investigational drug through such trial.*

19 SEC. 3. *HHS PUBLIC-PRIVATE PARTNERSHIP FOR RARE*  
20 *NEURODEGENERATIVE DISEASES.*

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1 tional Institutes of Health, the Food and Drug Administra-  
2 tion, and one or more eligible entities (to be known and  
3 referred to in this section as the “Partnership”) through  
4 cooperative agreements, contracts, or other appropriate  
5 mechanisms with such eligible entities, for the purpose of  
6 advancing the understanding of neurodegenerative diseases  
7 and fostering the development of treatments for amyotrophic  
8 lateral sclerosis and other rare neurodegenerative diseases.  
9 The Partnership shall—

10 (1) establish partnerships and consortia with  
11 other public and private entities and individuals with  
12 expertise in amyotrophic lateral sclerosis and other  
13 rare neurodegenerative diseases for the purposes de-  
14 scribed in this subsection;

15 (2) focus on advancing regulatory science and  
16 scientific research that will support and accelerate the  
17 development and review of drugs for patients with  
18 amyotrophic lateral sclerosis and other rare  
19 neurodegenerative diseases; and

20 (3) foster the development of effective drugs that  
21 improve the lives of people that suffer from  
22 amyotrophic lateral sclerosis and other rare  
23 neurodegenerative diseases.

24 (b) *ELIGIBLE ENTITY*.—In this section, the term “eli-  
25 gible entity” means an entity that—

1           (1) is—

2                   (A) *an institution of higher education (as*  
3                   *such term is defined in section 1001 of the High-*  
4                   *er Education Act of 1965 (20 U.S.C. 1001)) or*  
5                   *a consortium of such institutions; or*

6                   (B) *an organization described in section*  
7                   *501(c)(3) of the Internal Revenue Code of 1986*  
8                   *and exempt from tax under subsection (a) of*  
9                   *such section;*

10           (2) *has experienced personnel with clinical and*  
11           *other technical expertise in the field of biomedical*  
12           *sciences and demonstrated connection to the patient*  
13           *population;*

14           (3) *demonstrates to the Secretary's satisfaction*  
15           *that the entity is capable of identifying and estab-*  
16           *lishing collaborations between public and private en-*  
17           *tities and individuals with expertise in*  
18           *neurodegenerative diseases, including patients, in*  
19           *order to facilitate—*

20                   (A) *development and critical evaluation of*  
21                   *tools, methods, and processes—*

22                           (i) *to characterize neurodegenerative*  
23                           *diseases and their natural history;*

24                           (ii) *to identify molecular targets for*  
25                           *neurodegenerative diseases; and*

1                   (iii) to increase efficiency, predict-  
2                   ability, and productivity of clinical develop-  
3                   ment of therapies, including advancement of  
4                   rational therapeutic development and estab-  
5                   lishment of clinical trial networks; and

6                   (B) securing funding for the Partnership  
7                   from Federal and non-Federal governmental  
8                   sources, foundations, and private individuals;  
9                   and

10                  (4) provides an assurance that the entity will  
11                  not accept funding for a Partnership project from  
12                  any organization that manufactures or distributes  
13                  products regulated by the Food and Drug Adminis-  
14                  tration unless the entity provides assurances in its  
15                  agreement with the Secretary that the results of the  
16                  project will not be influenced by any source of fund-  
17                  ing.

18                  (c) GIFTS.—

19                  (1) IN GENERAL.—The Partnership may solicit  
20                  and accept gifts, grants, and other donations, estab-  
21                  lish accounts, and invest and expend funds in support  
22                  of basic research and research associated with phase  
23                  3 clinical trials conducted with respect to investiga-  
24                  tional drugs that are the subjects of expanded access

1        *requests under section 561 of the Federal Food, Drug,*  
 2        *and Cosmetic Act (21 U.S.C. 360bbb).*

3            (2) *USE.*—*In addition to any amounts appro-*  
 4        *priated for purposes of carrying out this section, the*  
 5        *Partnership may use, without further appropriation,*  
 6        *any funds derived from a gift, grant, or other dona-*  
 7        *tion accepted pursuant to paragraph (1).*

8        **SEC. 4. ALS AND OTHER RARE NEURODEGENERATIVE DIS-**  
 9            **EASE ACTION PLAN.**

10        (a) *IN GENERAL.*—*Not later than 6 months after the*  
 11        *date of enactment of this Act, the Commissioner of Food*  
 12        *and Drugs shall publish on the website of the Food and*  
 13        *Drug Administration an action plan describing actions the*  
 14        *Food and Drug Administration intends to take during the*  
 15        *5-year period following publication of the plan with respect*  
 16        *to program enhancements, policy development, regulatory*  
 17        *science initiatives, and other appropriate initiatives to—*

18            (1) *foster the development of safe and effective*  
 19        *drugs that improve or extend, or both, the lives of peo-*  
 20        *ple living with amyotrophic lateral sclerosis and other*  
 21        *rare neurodegenerative diseases; and*

22            (2) *facilitate access to investigational drugs for*  
 23        *amyotrophic lateral sclerosis and other rare*  
 24        *neurodegenerative diseases.*

1       (b) *CONTENTS.—The initial action plan published*  
2 *under subsection (a) shall—*

3           (1) *identify appropriate representation from*  
4 *within the Food and Drug Administration to be re-*  
5 *sponsible for implementation of such action plan;*

6           (2) *include elements to facilitate—*

7               (A) *interactions and collaboration between*  
8 *the Food and Drug Administration, including*  
9 *the review centers thereof, and stakeholders in-*  
10 *cluding patients, sponsors, and the external bio-*  
11 *medical research community;*

12               (B) *consideration of cross-cutting clinical*  
13 *and regulatory policy issues, including consist-*  
14 *ency of regulatory advice and decisionmaking;*

15               (C) *identification of key regulatory science*  
16 *and policy issues critical to advancing develop-*  
17 *ment of safe and effective drugs; and*

18               (D) *enhancement of collaboration and en-*  
19 *gagement of the relevant centers and offices of the*  
20 *Food and Drug Administration with other oper-*  
21 *ating divisions within the Department of Health*  
22 *and Human Services, the Partnership, and the*  
23 *broader neurodegenerative disease community;*  
24 *and*

1           (3) be subject to revision, as determined appro-  
2       priate by the Secretary of Health and Human Serv-  
3       ices.

4   **SEC. 5. FDA RARE NEURODEGENERATIVE DISEASE GRANT**  
5                   **PROGRAM.**

6       The Secretary of Health and Human Services, acting  
7       through the Commissioner of Food and Drugs, shall award  
8       grants and contracts to public and private entities to cover  
9       the costs of research on, and development of interventions  
10      intended to prevent, diagnose, mitigate, treat, or cure,  
11      amyotrophic lateral sclerosis and other rare  
12      neurodegenerative diseases in adults and children, includ-  
13      ing costs incurred with respect to the development and crit-  
14      ical evaluation of tools, methods, and processes—

15           (1) to characterize such neurodegenerative dis-  
16      eases and their natural history;

17           (2) to identify molecular targets for such  
18      neurodegenerative diseases; and

19           (3) to increase efficiency and productivity of  
20      clinical development of therapies, including through—

21           (A) the use of master protocols and adaptive  
22      and add-on clinical trial designs; and

23           (B) efforts to establish new or leverage exist-  
24      ing clinical trial networks.

1 **SEC. 6. GAO REPORT.**

2       *Not later than 4 years after the date of the enactment*  
3 *of this Act, the Comptroller General of the United States*  
4 *shall submit to the Committee on Energy and Commerce*  
5 *of the House of Representatives and the Committee on*  
6 *Health, Education, Labor, and Pensions of the Senate a*  
7 *report containing—*

8               *(1) with respect to grants awarded under the*  
9       *program established under section 2—*

10                   *(A) an analysis of what is known about the*  
11       *impact of such grants on research or development*  
12       *related to the prevention, diagnosis, mitigation,*  
13       *treatment, or cure of amyotrophic lateral scler-*  
14       *osis; and*

15                   *(B) data concerning such grants, includ-*  
16       *ing—*

17                               *(i) the number of grants awarded;*

18                               *(ii) the participating entities to whom*  
19       *grants were awarded;*

20                               *(iii) the value of each such grant;*

21                               *(iv) a description of the research each*  
22       *such grant was used to further;*

23                               *(v) the number of patients who received*  
24       *expanded access to an investigational drug*  
25       *to prevent, diagnose, mitigate, treat, or cure*

1           *amyotrophic lateral sclerosis under each*  
2           *grant;*

3           *(vi) whether the investigational drug*  
4           *that was the subject of such a grant was ap-*  
5           *proved by the Food and Drug Administra-*  
6           *tion; and*

7           *(vii) the average number of days be-*  
8           *tween when a grant application is sub-*  
9           *mitted and when a grant is awarded; and*

10          *(2) with respect to grants awarded under the*  
11          *program established under section 5—*

12               *(A) an analysis of what is known about the*  
13               *impact of such grants on research or development*  
14               *related to the prevention, diagnosis, mitigation,*  
15               *treatment, or cure of amyotrophic lateral scler-*  
16               *osis;*

17               *(B) an analysis of what is known about*  
18               *how such grants increased efficiency and produc-*  
19               *tivity of the clinical development of therapies,*  
20               *including through the use of clinical trials that*  
21               *operated with common master protocols, or had*  
22               *adaptive or add-on clinical trial designs; and*

23               *(C) data concerning such grants, includ-*  
24               *ing—*

25               *(i) the number of grants awarded;*

- 1                   (ii) *the participating entities to whom*  
2                   *grants were awarded;*  
3                   (iii) *the value of each such grant;*  
4                   (iv) *a description of the research each*  
5                   *such grant was used to further; and*  
6                   (v) *whether the investigational drug*  
7                   *that was the subject of such a grant received*  
8                   *approval by the Food and Drug Adminis-*  
9                   *tration.*

10 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS.**

11           *For purposes of carrying out this Act, there are author-*  
12 *ized to be appropriated \$100,000,000 for each of fiscal years*  
13 *2022 through 2026.*



Union Calendar No. 148

117TH CONGRESS  
1ST Session

**H. R. 3537**

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