

Union Calendar No. 637

119TH CONGRESS
2D SESSION

H. R. 8205

[Report No. 119-733]

To amend the Accelerating Access to Critical Therapies for ALS Act to reauthorize the provisions of such Act through fiscal year 2031, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 6, 2026

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

JULY 9, 2026

Additional sponsors: Mr. FITZPATRICK, Ms. SCHAKOWSKY, Mr. McCAUL, Mr. AUCHINCLOSS, Mr. DESJARLAIS, Ms. CRAIG, Mr. VALADAO, Mr. CROW, Mr. THOMPSON of Pennsylvania, Ms. MOORE of Wisconsin, Mr. HURD of Colorado, Mr. SCHNEIDER, Mr. JOYCE of Ohio, Mr. VEASEY, Ms. SALAZAR, Ms. BONAMICI, Mr. BILIRAKIS, Mr. SHERMAN, Mr. GARBARINO, Mr. LYNCH, Mr. BACON, Mr. COHEN, Mr. SESSIONS, Mr. SMITH of Washington, Mr. OBERNOLTE, Ms. DEAN of Pennsylvania, Mr. COLE, Mrs. FOUSHEE, Mr. RUTHERFORD, Ms. SEWELL, Mr. WILSON of South Carolina, Mr. DAVIS of Illinois, Mr. ADERHOLT, Mr. TORRES of New York, Mr. MANN, Ms. NORTON, Mr. VAN DREW, Mr. KRISHNAMOORTHY, Mr. ALFORD, Ms. UNDERWOOD, Mr. LALOTA, Ms. SCHRIER, Mrs. KIM, Ms. MATSUI, Mr. EDWARDS, Mrs. DINGELL, Mr. WALBERG, Ms. TLAIB, Mr. WEBER of Texas, Mr. THOMPSON of California, Mr. BOST, Mr. TONKO, Mrs. BICE, Ms. DELBENE, Mr. DIAZ-BALART, Mr. CORREA, Mr. LAHOOD, Mr. KENNEDY of New York, Mr. WOMACK, Mr. WHITESIDES, Mr. ROUZER, Mr. BISHOP, Ms. LETLOW, Ms. KELLY of Illinois, Mr. AMODEI of Nevada, Mr. GOTTHEIMER, Mr. MOORE of North Carolina, Mr. CLEAVER, Mr. CARTER of Texas, Mr. STANTON, Mr. WITTMAN, Mr. VINDMAN, Mr. GUEST, Ms. BYNUM, Mrs. MILLER of West Virginia, Mrs. HAYES, Mr. LATIMER, Mr. DAVIS of North Carolina, Ms. MCBRIDE, Mr. RILEY of New York, Mr. CONAWAY, Ms. STANSBURY, Ms. ROSS, Ms. PINGREE, Mr. HIMES, Mrs. WATSON COLEMAN, Mr. CASTEN, Mr. LANDSMAN, Mrs. GRIJALVA, Ms. MEJIA,

Mr. LARSON of Connecticut, Mr. SORENSEN, Mr. PETERS, Mr. JACKSON of Illinois, Ms. ADAMS, Ms. BUDZINSKI, Mrs. BEATTY, Mr. MAGAZINER, Ms. KAPTUR, Mr. CARTER of Louisiana, Mr. SUOZZI, and Ms. SCANLON

JULY 9, 2026

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 April 6, 2026]

A BILL

To amend the Accelerating Access to Critical Therapies for ALS Act to reauthorize the provisions of such Act through fiscal year 2031, 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 Reauthorization Act of 2026”.*

6 **SEC. 2. REAUTHORIZATION OF ACCELERATING ACCESS TO**
 7 **CRITICAL THERAPIES FOR ALS ACT.**

8 *(a) IN GENERAL.—Section 7 of the Accelerating Access*
 9 *to Critical Therapies for ALS Act (Public Law 117–79) is*
 10 *amended by striking “2026” and inserting “2031”.*

11 *(b) GRANTS FOR ALS RESEARCH.—Section 2(f) of the*
 12 *Accelerating Access to Critical Therapies for ALS Act (21*
 13 *U.S.C. 360ee note) is amended by striking “2026” and in-*
 14 *serting “2031”.*

15 **SEC. 3. IMPROVEMENTS TO PROGRAM FOR GRANTS FOR RE-**
 16 **SEARCH ON THERAPIES FOR ALS.**

17 *(a) RENEWAL OF GRANTS FOR RESEARCH ON THERA-*
 18 *PIES FOR ALS REVIEW.—Section 2(b) of the Accelerating*
 19 *Access to Critical Therapies for ALS Act (21 U.S.C. 360ee*
 20 *note) is amended by adding at the end the following:*

21 *“(4) RENEWAL OF GRANTS FOR RESEARCH ON*
 22 *THERAPIES FOR ALS REVIEW.—In reviewing applica-*
 23 *tions for renewals of a grant awarded under this sec-*
 24 *tion with respect to an investigational drug, the Sec-*
 25 *retary shall request from the manufacturer or spon-*

1 sor, and assess, the enrollment, safety, and any avail-
 2 able efficacy data relating to the investigational drug
 3 in the prevention, diagnosis, mitigation, treatment, or
 4 cure of amyotrophic lateral sclerosis.”.

5 (b) *REPORTING SAFETY DATA*.—Section 2(c) of the Ac-
 6 celerating Access to Critical Therapies for ALS Act (21
 7 U.S.C. 360ee note) is amended—

8 (1) in paragraph (2)(B), by striking “and” at
 9 the end;

10 (2) in paragraph (3), by striking the period at
 11 the end and inserting “; and”; and

12 (3) by adding at the end the following:

13 “(4) the entity seeking such grant will promptly
 14 report any new and serious adverse events and safety
 15 information that is considered to be unexpected with
 16 respect to the phase 3 trial to the grant-making insti-
 17 tution, in addition to complying with the safety re-
 18 porting requirements under section 312.32 of title 21,
 19 Code of Federal Regulations (or any successor regula-
 20 tions).”.

21 (c) *CLARIFYING PARTICIPATING CLINICAL TRIAL DEF-*
 22 inition.—Section 2(e) of the Accelerating Access to Critical
 23 Therapies for ALS Act (21 U.S.C. 360ee note) is amended
 24 by adding at the end the following:

1 “(4) The term ‘phase 3’, with respect to a clin-
 2 ical trial, includes a phase 2/3 combined trial that be-
 3 gins enrollment within a timeframe, determined by
 4 the Secretary through the terms and conditions of the
 5 grant awarded under this section.”.

6 **SEC. 4. FDA RARE NEURODEGENERATIVE DISEASE ACTION**
 7 **PLAN.**

8 Section 4 of the Accelerating Access to Critical Thera-
 9 pies for ALS Act (21 U.S.C. 360aa note) is amended—

10 (1) in the section heading, by striking “**ALS**
 11 **AND OTHER RARE NEURODEGENERATIVE DIS-**
 12 **EASE ACTION PLAN**” and inserting “**FDA RARE**
 13 **NEURODEGENERATIVE DISEASE ACTION PLAN**”;
 14 and

15 (2) by adding at the end the following:

16 “(c) **FDA RARE NEURODEGENERATIVE DISEASE AC-**
 17 **TION PLAN.**—

18 “(1) **IN GENERAL.**—Not later than 18 months
 19 after the date of enactment of the Accelerating Access
 20 to Critical Therapies for ALS Reauthorization Act of
 21 2026, the Commissioner of Food and Drugs shall pub-
 22 lish on the website of the Food and Drug Administra-
 23 tion an action plan that includes a description of the
 24 actions that the Food and Drug Administration in-
 25 tends to take during the 5-year period following pub-

1 *lication of the action plan with respect to the pro-*
2 *gram enhancements, policy development, regulatory*
3 *science initiatives, and other appropriate initiatives*
4 *described in subsection (a).*

5 *“(2) REPORT.—Not later than 5 years after the*
6 *date of enactment of the Accelerating Access to Crit-*
7 *ical Therapies for ALS Reauthorization Act of 2026,*
8 *the Commissioner of Food and Drugs shall publish on*
9 *the website of the Food and Drug Administration a*
10 *report that describes the actions taken by the Food*
11 *and Drug Administration under the action plan pub-*
12 *lished under paragraph (1) and the extent to which*
13 *such action plan meets the requirements specified in*
14 *paragraph (1).”.*

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