

119TH CONGRESS
2D SESSION

H. R. 8205

AN ACT

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Accelerating Access
3 to Critical Therapies for ALS Reauthorization Act of
4 2026”.

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

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

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

14 **SEC. 3. IMPROVEMENTS TO PROGRAM FOR GRANTS FOR**
15 **RESEARCH ON THERAPIES FOR ALS.**

16 (a) RENEWAL OF GRANTS FOR RESEARCH ON
17 THERAPIES FOR ALS REVIEW.—Section 2(b) of the Ac-
18 celerating Access to Critical Therapies for ALS Act (21
19 U.S.C. 360ee note) is amended by adding at the end the
20 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-
26 sor, and assess, the enrollment, safety, and any

1 available efficacy data relating to the investigational
2 drug in the prevention, diagnosis, mitigation, treat-
3 ment, or cure of amyotrophic lateral sclerosis.”.

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

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

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

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

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

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

24 “(4) The term ‘phase 3’, with respect to a clin-
25 ical trial, includes a phase 2/3 combined trial that

1 begins enrollment within a timeframe, determined by
 2 the Secretary through the terms and conditions of
 3 the grant awarded under this section.”.

4 **SEC. 4. FDA RARE NEURODEGENERATIVE DISEASE ACTION**
 5 **PLAN.**

6 Section 4 of the Accelerating Access to Critical
 7 Therapies for ALS Act (21 U.S.C. 360aa note) is amend-
 8 ed—

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

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

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

17 “(1) IN GENERAL.—Not later than 18 months
 18 after the date of enactment of the Accelerating Ac-
 19 cess to Critical Therapies for ALS Reauthorization
 20 Act of 2026, the Commissioner of Food and Drugs
 21 shall publish on the website of the Food and Drug
 22 Administration an action plan that includes a de-
 23 scription of the actions that the Food and Drug Ad-
 24 ministration intends to take during the 5-year period
 25 following publication of the action plan with respect

1 to the program enhancements, policy development,
2 regulatory science initiatives, and other appropriate
3 initiatives described in subsection (a).

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

Passed the House of Representatives July 22, 2026.

Attest:

Clerk.

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