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Public Law 119–138
119th Congress

An Act

Nov. 3, 2026
[H.R. 8205]

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026.
21 USC 301 note.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026".

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

135 Stat. 1538.

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

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

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

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

Assessment.
Data.

"(4) RENEWAL OF GRANTS FOR RESEARCH ON THERAPIES FOR ALS REVIEW.—In reviewing applications for renewals of a grant awarded under this section with respect to an investigational drug, the Secretary shall request from the manufacturer or sponsor, and assess, the enrollment, safety, and any available efficacy data relating to the investigational drug in the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.".

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

(1) in paragraph (2)(B), by striking "and" at the end;

(2) in paragraph (3), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

Compliance.

"(4) the entity seeking such grant will promptly report any new and serious adverse events and safety information that is considered to be unexpected with respect to the phase 3 trial to the grant-making institution, in addition to complying with the safety reporting requirements under section 312.32

of title 21, Code of Federal Regulations (or any successor regulations).".

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

"(4) The term 'phase 3', with respect to a clinical trial, includes a phase 2/3 combined trial that begins enrollment within a timeframe, determined by the Secretary through the terms and conditions of the grant awarded under this section.". Determination.

SEC. 4. FDA RARE NEURODEGENERATIVE DISEASE ACTION PLAN.

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

(1) in the section heading, by striking "**ALS AND OTHER RARE NEURODEGENERATIVE DISEASE ACTION PLAN**" and inserting "**FDA RARE NEURODEGENERATIVE DISEASE ACTION PLAN**"; and

(2) by adding at the end the following:

"(c) FDA RARE NEURODEGENERATIVE DISEASE ACTION PLAN.— Web postings.

"(1) IN GENERAL.—Not later than 18 months after the date of enactment of the Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026, the Commissioner of Food and Drugs shall publish on the website of the Food and Drug Administration an action plan that includes a description of the actions that the Food and Drug Administration intends to take during the 5-year period following publication of the action plan with respect to the program enhancements, policy development, regulatory science initiatives, and other appropriate initiatives described in subsection (a). Deadline. Time period.

"(2) REPORT.—Not later than 5 years after the date of enactment of the Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026, the Commissioner of Food and Drugs shall publish on the website of the Food and Drug Administration a report that describes the actions taken by the Food and Drug Administration under the action plan published under paragraph (1) and the extent to which such action plan meets the requirements specified in paragraph (1).".

Approved November 3, 2026.

LEGISLATIVE HISTORY—H.R. 8205 (S. 4472):

HOUSE REPORTS: No. 119–733 (Comm. on Energy and Commerce).
CONGRESSIONAL RECORD, Vol. 172 (2026):
July 20, 22, considered and passed House.
Sept. 28, considered and passed Senate.

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