Union Calendar No.

119TH CONGRESS
2D SESSION

H. R. 8205

[Report No. 119–]

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

JUNE --, 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.

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

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.

(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:

"(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 spon-

sor, 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:

"(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.".

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.—

"(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 pub-

lication of the action plan with respect to the program enhancements, policy development, regulatory science initiatives, and other appropriate initiatives described in subsection (a).

"(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).".