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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

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

Mr. QUIGLEY introduced the following bill; which was referred to the Committee on _____

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''.

(c) SENSE OF CONGRESS.—The Committee on Energy and Commerce of the House of Representatives expresses support for directly appropriating funds to carry out each section of the Accelerating Access to Critical Therapies for ALS Act (Public Law 117–79).

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

(a) CLINICAL TRIAL STATUS 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) CLINICAL TRIAL STATUS REVIEW.—

''(A) IN GENERAL.—In reviewing applications for renewals of a grant awarded under this section with respect to an investigational drug, the Secretary shall assess the status of a clinical trial carried out for such drug with re-

spect to data on enrollment of patients in such clinical trial.

''(B) INTERIM CLINICAL TRIAL DATA.—To enable the Secretary to make the assessment under subparagraph (A) with respect to an investigational drug, the Secretary shall request that the manufacturer of the investigational drug share interim clinical trial data with respect to such drug with the Secretary.''.

(b) 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 and a planned phase 3 clinical trial that is not yet enrolling participants.''.

SEC. 4. REPORT ON ALS AND OTHER RARE NEURODEGENERATIVE DISEASE ACTION PLANS.

Section 4 of the Accelerating Access to Critical Therapies for ALS Act (21 U.S.C. 360aa note) is amended by adding at the end the following:

''(c) REPORT ON ALS AND OTHER RARE NEURODEGENERATIVE DISEASE ACTION PLANS.—Not

later than one year 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 contains—

''(1) an updated action plan, including—

''(A) a description of the actions the Food and Drug Administration intends to take during the 5-year period following publication of the plan with respect to the program enhancements, policy development, regulatory science initiatives, and other appropriate initiatives described in subsection (a);

''(B) a description of the resources necessary to implement each section of the plan within such 5-year period; and

''(C) specific approaches the Commissioner will take to improve coordination of implementation of the plan with rare neurodegenerative disease communities that are not specifically ALS communities; and

''(2) with respect to the Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis (ALS) published by the Food and Drug Administration on June 23, 2022 (referred to

in this section as the '2022 Action Plan'), a description of—

''(A) the actions taken by the Food and Drug Administration under the 2022 Action Plan;

''(B) the effect of the implementation of the 2022 Action Plan on the development of therapies and regulatory consideration of therapies for ALS and other rare neurodegenerative diseases;

''(C) any programs and initiatives that established or carried out as part of the implementation of the 2022 Action Plan; and

''(D) the extent to which the 2022 Action Plan was implemented with respect to rare neurodegenerative diseases that are not amyotrophic lateral sclerosis.''.

SEC. 5. GAO REPORT.

Not later than 4 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the analyses and data described in section 6 of the Accelerating Access to Critical Therapies for

ALS Act (Public Law 117–79) (as in effect on the date of enactment of this Act).