

119TH CONGRESS
2D SESSION

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.

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

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
5 to Critical Therapies for ALS Reauthorization Act of
6 2026”.

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

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

6 (b) GRANTS FOR ALS RESEARCH.—Section 2(f) of
7 the Accelerating Access to Critical Therapies for ALS Act
8 (21 U.S.C. 360ee note) is amended by striking “2026”
9 and inserting “2031”.

10 (c) SENSE OF CONGRESS.—The Committee on En-
11 ergy and Commerce of the House of Representatives ex-
12 presses support for directly appropriating funds to carry
13 out each section of the Accelerating Access to Critical
14 Therapies for ALS Act (Public Law 117–79).

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

17 (a) CLINICAL TRIAL STATUS REVIEW.—Section 2(b)
18 of the Accelerating Access to Critical Therapies for ALS
19 Act (21 U.S.C. 360ee note) is amended by adding at the
20 end the following:

21 “(4) CLINICAL TRIAL STATUS REVIEW.—

22 “(A) IN GENERAL.—In reviewing applica-
23 tions for renewals of a grant awarded under
24 this section with respect to an investigational
25 drug, the Secretary shall assess the status of a
26 clinical trial carried out for such drug with re-

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

3 “(B) INTERIM CLINICAL TRIAL DATA.—To
 4 enable the Secretary to make the assessment
 5 under subparagraph (A) with respect to an in-
 6 vestigational drug, the Secretary shall request
 7 that the manufacturer of the investigational
 8 drug share interim clinical trial data with re-
 9 spect to such drug with the Secretary.”.

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

14 “(4) The term ‘phase 3’, with respect to a clin-
 15 ical trial, includes a phase 2/3 combined trial and a
 16 planned phase 3 clinical trial that is not yet enroll-
 17 ing participants.”.

18 **SEC. 4. REPORT ON ALS AND OTHER RARE**
 19 **NEURODEGENERATIVE DISEASE ACTION**
 20 **PLANS.**

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

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

1 later than one year after the date of enactment of the Ac-
2 celerating Access to Critical Therapies for ALS Reauthor-
3 ization Act of 2026, the Commissioner of Food and Drugs
4 shall publish on the website of the Food and Drug Admin-
5 istration a report that contains—

6 “(1) an updated action plan, including—

7 “(A) a description of the actions the Food
8 and Drug Administration intends to take dur-
9 ing the 5-year period following publication of
10 the plan with respect to the program enhance-
11 ments, policy development, regulatory science
12 initiatives, and other appropriate initiatives de-
13 scribed in subsection (a);

14 “(B) a description of the resources nec-
15 essary to implement each section of the plan
16 within such 5-year period; and

17 “(C) specific approaches the Commissioner
18 will take to improve coordination of implemen-
19 tation of the plan with rare neurodegenerative
20 disease communities that are not specifically
21 ALS communities; and

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

1 in this section as the ‘2022 Action Plan’), a descrip-
2 tion of—

3 “(A) the actions taken by the Food and
4 Drug Administration under the 2022 Action
5 Plan;

6 “(B) the effect of the implementation of
7 the 2022 Action Plan on the development of
8 therapies and regulatory consideration of thera-
9 pies for ALS and other rare neurodegenerative
10 diseases;

11 “(C) any programs and initiatives that es-
12 tablished or carried out as part of the imple-
13 mentation of the 2022 Action Plan; and

14 “(D) the extent to which the 2022 Action
15 Plan was implemented with respect to rare
16 neurodegenerative diseases that are not
17 amyotrophic lateral sclerosis.”.

18 **SEC. 5. GAO REPORT.**

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

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

