

119TH CONGRESS
2D SESSION

S. 4472

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 SENATE OF THE UNITED STATES

APRIL 30, 2026

Ms. MURKOWSKI (for herself and Mr. COONS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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

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

16 “(4) CLINICAL TRIAL STATUS REVIEW.—

17 “(A) IN GENERAL.—In reviewing applica-
 18 tions for renewals of a grant awarded under
 19 this section with respect to an investigational
 20 drug, the Secretary shall assess the status of a
 21 clinical trial carried out for such drug with re-
 22 spect to data on enrollment of patients in such
 23 clinical trial.

24 “(B) INTERIM CLINICAL TRIAL DATA.—To
 25 enable the Secretary to make the assessment
 26 under subparagraph (A) with respect to an in-

1 vestigational drug, the Secretary shall request
 2 that the manufacturer of the investigational
 3 drug share interim clinical trial data with re-
 4 spect to such drug with the Secretary.”.

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

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

13 **SEC. 4. REPORT ON ALS AND OTHER RARE**
 14 **NEURODEGENERATIVE DISEASE ACTION**
 15 **PLANS.**

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

19 “(c) REPORT ON ALS AND OTHER RARE
 20 NEURODEGENERATIVE DISEASE ACTION PLANS.—Not
 21 later than one year after the date of enactment of the Ac-
 22 celerating Access to Critical Therapies for ALS Reauthor-
 23 ization Act of 2026, the Commissioner of Food and Drugs
 24 shall publish on the website of the Food and Drug Admin-
 25 istration a report that contains—

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

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

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

12 “(C) specific approaches the Commissioner
13 will take to improve coordination of implemen-
14 tation of the plan with rare neurodegenerative
15 disease communities that are not specifically
16 ALS communities; and

17 “(2) with respect to the Action Plan for Rare
18 Neurodegenerative Diseases including Amyotrophic
19 Lateral Sclerosis (ALS) published by the Food and
20 Drug Administration on June 23, 2022 (referred to
21 in this section as the ‘2022 Action Plan’), a descrip-
22 tion of—

23 “(A) the actions taken by the Food and
24 Drug Administration under the 2022 Action
25 Plan;

1 “(B) the effect of the implementation of
2 the 2022 Action Plan on the development of
3 therapies and regulatory consideration of thera-
4 pies for ALS and other rare neurodegenerative
5 diseases;

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

9 “(D) the extent to which the 2022 Action
10 Plan was implemented with respect to rare
11 neurodegenerative diseases that are not
12 amyotrophic lateral sclerosis.”.

13 **SEC. 5. GAO REPORT.**

14 Section 6 of the Accelerating Access to Critical
15 Therapies for ALS Act (Public Law 117–79) is amended,
16 in the matter preceding paragraph (1)—

17 (1) by striking “4 years after the date of the
18 enactment of this Act” and inserting “5 years after
19 the date of enactment of the Accelerating Access to
20 Critical Therapies for ALS Reauthorization Act of
21 2026”; and

22 (2) by inserting “, with respect to the 10-year
23 period starting on the date of enactment of this
24 Act” after “containing”.

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