

Calendar No. 461

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, Mr. COONS, Ms. COLLINS, Ms. KLOBUCHAR, Mr. PADILLA, Mrs. CAPITO, Mr. CURTIS, Mrs. GILLIBRAND, Ms. HASSAN, Mr. BANKS, Mr. MARKEY, and Mr. DAINES) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

JULY 16, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Accelerating Access
3 to Critical Therapies for ALS Reauthorization Act of
4 2026”.

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

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

10 (b) GRANTS FOR ALS RESEARCH.—Section 2(f) of
11 the Accelerating Access to Critical Therapies for ALS Act
12 (21 U.S.C. 360ee note) is amended by striking “2026”
13 and inserting “2031”.

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

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

20 “(4) CLINICAL TRIAL STATUS REVIEW.—

21 “(A) IN GENERAL.—In reviewing applica-
22 tions for renewals of a grant awarded under
23 this section with respect to an investigational
24 drug, the Secretary shall assess the status of a
25 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 “(e) 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 Section 6 of the Accelerating Access to Critical
 20 Therapies for ALS Act (Public Law 117–79) is amended,
 21 in the matter preceding paragraph (1)—

22 (1) by striking “4 years after the date of the
 23 enactment of this Act” and inserting “5 years after
 24 the date of enactment of the Accelerating Access to

1 Critical Therapies for ALS Reauthorization Act of
2 2026”; and

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

6 **SECTION 1. SHORT TITLE.**

7 *This Act may be cited as the “Accelerating Access to*
8 *Critical Therapies for ALS Reauthorization Act of 2026”.*

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

11 (a) *IN GENERAL.*—Section 7 of the Accelerating Access
12 to Critical Therapies for ALS Act (Public Law 117–79) is
13 amended by striking “2022 through 2026” and inserting
14 “2027 through 2031”.

15 (b) *GRANTS FOR ALS RESEARCH.*—Section 2(f) of the
16 Accelerating Access to Critical Therapies for ALS Act (21
17 U.S.C. 360ee note) is amended by striking “2026” and in-
18 serting “2031”.

19 **SEC. 3. IMPROVEMENTS TO PROGRAM FOR GRANTS FOR RE-**
20 **SEARCH ON THERAPIES FOR ALS.**

21 Section 2 of the Accelerating Access to Critical Thera-
22 pies for ALS Act (21 U.S.C. 360ee note) is amended—

23 (1) in subsection (a), by inserting “(referred to
24 in this section as ‘expanded access grants’)” before the
25 period at the end of the first sentence;

1 (2) in subsection (b)—

2 (A) by striking “(b) APPLICATION—” and
3 all that follows through “A participating” in
4 paragraph (1) and inserting the following:

5 “(b) APPLICATION.—A participating”;

6 (B) by redesignating paragraphs (2) and
7 (3) as paragraphs (1) and (2) respectively;

8 (C) in the matter preceding paragraph (1),
9 as so redesignated, by striking the period at the
10 end and inserting “including—”;

11 (D) by amending paragraph (1), as so re-
12 designated, to read as follows:

13 “(1) a description of how data generated through
14 the proposed expanded access grant will be used to
15 support research or development related to the preven-
16 tion, diagnosis, mitigation, treatment, or cure of
17 amyotrophic lateral sclerosis;”;

18 (E) in paragraph (2), as so redesignated—

19 (i) by striking “NONINTERFERENCE
20 WITH CLINICAL TRIALS—” and all that fol-
21 lows through “shall include”;

22 (ii) by striking “program” and insert-
23 ing “grant”; and

24 (iii) by striking the period at the end
25 and inserting “; and”; and

1 *(F) by adding at the end the following:*

2 *“(3) an assurance that such entity will promptly*
 3 *report to the Secretary available safety data from any*
 4 *ongoing clinical trial of the investigational drug as*
 5 *set forth in the terms and conditions of the grant.”;*

6 *(3) in subsection (c)—*

7 *(A) by redesignating subparagraphs (A)*
 8 *and (B) of paragraph (2) as clauses (i) and (ii),*
 9 *respectively, and adjusting the margins accord-*
 10 *ingly;*

11 *(B) by redesignating paragraphs (1)*
 12 *through (3) as subparagraphs (A) through (C),*
 13 *respectively, and adjusting the margins accord-*
 14 *ingly;*

15 *(C) in subparagraph (C), as so redesign-*
 16 *ated, by striking the period at the end and in-*
 17 *serting “; and”;*

18 *(D) in the matter preceding subparagraph*
 19 *(A), as so redesignated, by striking “this section,*
 20 *confirm that—” and inserting the following:*
 21 *“this section—*

22 *“(1) confirm that—”; and*

23 *(E) by adding at the end the following:*

24 *“(2) in the case of a renewal of such a grant, re-*
 25 *quest from the sponsor of the investigational new drug*

application involved, and assess, the enrollment, safety, and any available efficacy data of the drug related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis.”;

(4) in subsection (d)(1), by striking “request described in subsection (a)” and inserting “grant”; and

(5) in subsection (e)—

(A) in paragraph (2), by inserting “, and that begins enrollment within a timeframe as determined by the Secretary through the terms and conditions of the grant” before the period at the end; and

(B) by adding at the end the following:

“(4) The term ‘phase 3 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—

(1) in the section heading, by striking “**ALS AND OTHER**” and inserting “**FDA**”;

(2) in subsection (a), in the matter preceding paragraph (1)—

1 (A) by inserting “and not later than 1 year
 2 after the date of enactment of the Accelerating
 3 Access to Critical Therapies for ALS Reauthor-
 4 ization Act of 2026 and every 5 years there-
 5 after,” after “this Act,”; and

6 (B) by inserting “develop, or update, as ap-
 7 plicable, and” before “publish on”;

8 (3) in subsection (b)—

9 (A) in the matter preceding paragraph (1),
 10 by striking “initial”;

11 (B) in paragraph (2)—

12 (i) in subparagraph (A), by inserting
 13 “of relevant investigational new drug appli-
 14 cations” after “sponsors”;

15 (ii) in subparagraph (C) by inserting
 16 “for the prevention, diagnosis, mitigation,
 17 treatment, or cure of rare neurodegenerative
 18 diseases” before the semicolon; and

19 (iii) in subparagraph (D), by striking
 20 “; and” and inserting a semicolon;

21 (C) in paragraph (3), by striking the period
 22 at the end and inserting “; and”; and

23 (D) by adding at the end the following:

24 “(4) for each action plan published after the date
 25 of enactment of the Accelerating Access to Critical

1 *Therapies for ALS Reauthorization Act of 2026, in-*
 2 *clude a description of—*

3 “(A) previous actions taken by the Food
 4 and Drug Administration to implement the pre-
 5 vious action plan published under subsection (a);

6 “(B) any other planned actions to imple-
 7 ment such action plan; and

8 “(C) any barriers to implementing such ac-
 9 tion plan and related recommendations, which
 10 may include an estimate of resources necessary
 11 to address such barriers.”.

12 **SEC. 5. REPORTS.**

13 Section 6 of the *Accelerating Access to Critical Thera-*
 14 *pies for ALS Act (Public Law 117–79)* is amended—

15 (1) in the heading, by striking “**GAO REPORT**”
 16 and inserting “**REPORTS**”;

17 (2) by striking “Not later than” and inserting
 18 the following:

19 “(a) *GAO REPORT.—Not later than*”;

20 (3) in the matter preceding paragraph (1) of
 21 subsection (a), as so designated, by striking “this Act”
 22 and inserting “the *Accelerating Access to Critical*
 23 *Therapies for ALS Reauthorization Act of 2026*”; and

24 (4) by adding at the end the following:

1 “(b) *HHS REPORT*.—Not later than 4 years after the
 2 date of enactment of the *Accelerating Access to Critical*
 3 *Therapies for ALS Reauthorization Act of 2026*, the Sec-
 4 retary of Health and Human Services shall, in a manner
 5 that does not duplicate the information described in the ac-
 6 tion plan published pursuant to section 4, submit to the
 7 Committee on Health, Education, Labor, and Pensions of
 8 the Senate and the Committee on Energy and Commerce
 9 of the House of Representatives a report assessing the effec-
 10 tiveness of the activities carried out under sections 2, 3, and
 11 5 and making recommendations to improve such activi-
 12 ties.”.

13 **SEC. 6. TECHNICAL AMENDMENTS.**

14 Section 3 of the *Accelerating Access to Critical Thera-*
 15 pies for ALS Act (42 U.S.C. 280g–7b) is amended—

16 (1) in subsection (a), in the matter preceding
 17 paragraph (1), by striking “amytrophic” and insert-
 18 ing “amyotrophic”; and

19 (2) in subsection (b)(3)(A)(iii), by striking “ra-
 20 tional”.

Calendar No. 461

119TH CONGRESS
2D Session
S. 4472

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.

JULY 16, 2026

Reported with an amendment