TAM26667 06F S.L.C.

Bill Cassidy, M.D.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

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.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 "2022 through 2026" and inserting "2027 through 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.

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

(1) in subsection (a), by inserting "(referred to in this section as 'expanded access grants')" before the period at the end of the first sentence;

(2) in subsection (b)—

(A) by striking "(b) APPLICATION—" and all that follows through "A participating" in paragraph (1) and inserting the following:

"(b) APPLICATION.—A participating";

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

(C) in the matter preceding paragraph (1), as so redesignated, by striking the period at the end and inserting "including—";

(D) by amending paragraph (1), as so redesignated, to read as follows:

"(1) a description of how data generated through the proposed expanded access grant will be used to support research or development related to the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis;";

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

(i) by striking "NONINTERFERENCE WITH CLINICAL TRIALS—" and all that follows through "shall include";

(ii) by striking "program" and inserting "grant"; and

(iii) by striking the period at the end and inserting "; and"; and

(F) by adding at the end the following:

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

(3) in subsection (e)—

(A) by redesignating subparagraphs (A) and (B) of paragraph (2) as clauses (i) and (ii),

respectively, and adjusting the margins accordingly;

(B) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively, and adjusting the margins accordingly;

(C) in subparagraph (C), as so redesignated, by striking the period at the end and inserting "; and";

(D) in the matter preceding subparagraph (A), as so redesignated, by striking "this section, confirm that—" and inserting the following: "this section—

"(1) confirm that—"; and

(E) by adding at the end the following:

"(2) in the case of a renewal of such a grant, request 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)—

(A) by inserting "and not later than 1 year after the date of enactment of the Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026 and every 5 years thereafter," after "this Act,"; and

(B) by inserting "develop, or update, as applicable, and" before "publish on";

(3) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking "initial";

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting "of relevant investigational new drug applications" after "sponsors";

(ii) in subparagraph (C) by inserting "for the prevention, diagnosis, mitigation, treatment, or cure of rare neurodegenerative diseases" before the semicolon; and

(iii) in subparagraph (D), by striking "; and" and inserting a semicolon;

(C) in paragraph (3), by striking the period at the end and inserting "; and"; and

(D) by adding at the end the following:

"(4) for each action plan published after the date of enactment of the Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026, include a description of—

"(A) previous actions taken by the Food and Drug Administration to implement the pre-

vious action plan published under subsection (a);

"(B) any other planned actions to implement such action plan; and

"(C) any barriers to implementing such action plan and related recommendations, which may include an estimate of resources necessary to address such barriers.".

SEC. 5. REPORTS.

Section 6 of the Accelerating Access to Critical Therapies for ALS Act (Public Law 117–79) is amended—

(1) in the heading, by striking "**GAO REPORT**" and inserting "**REPORTS**";

(2) by striking "Not later than" and inserting the following:

"(a) GAO REPORT.—Not later than";

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

(4) by adding at the end the following:

"(b) HHS REPORT.—Not later than 4 years after the date of enactment of the Accelerating Access to Critical

Therapies for ALS Reauthorization Act of 2026, the Secretary of Health and Human Services shall, in a manner that does not duplicate the information described in the action plan published pursuant to section 4, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report assessing the effectiveness of the activities carried out under sections 2, 3, and 5 and making recommendations to improve such activities.".

SEC. 6. TECHNICAL AMENDMENTS.

Section 3 of the Accelerating Access to Critical Therapies for ALS Act (42 U.S.C. 280g–7b) is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by striking "amytrophic" and inserting "amyotrophic"; and

(2) in subsection (b)(3)(A)(iii), by striking "rational".