

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 8205  
OFFERED BY M . \_\_\_\_\_**

Strike all after the enacting clause and insert the following:

**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 Ac-  
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) RENEWAL OF GRANTS FOR RESEARCH ON  
17 THERAPIES FOR ALS REVIEW.—Section 2(b) of the Ac-  
18 celerating Access to Critical Therapies for ALS Act (21

1 U.S.C. 360ee note) is amended by adding at the end the  
2 following:

3           “(4) RENEWAL OF GRANTS FOR RESEARCH ON  
4 THERAPIES FOR ALS REVIEW.—In reviewing applica-  
5 tions for renewals of a grant awarded under this sec-  
6 tion with respect to an investigational drug, the Sec-  
7 retary shall request from the manufacturer or spon-  
8 sor, and assess, the enrollment, safety, and any  
9 available efficacy data relating to the investigational  
10 drug in the prevention, diagnosis, mitigation, treat-  
11 ment, or cure of amyotrophic lateral sclerosis.”.

12           (b) REPORTING SAFETY DATA.—Section 2(c) of the  
13 Accelerating Access to Critical Therapies for ALS Act (21  
14 U.S.C. 360ee note) is amended—

15           (1) in paragraph (2)(B), by striking “and” at  
16 the end;

17           (2) in paragraph (3), by striking the period at  
18 the end and inserting “; and”; and

19           (3) by adding at the end the following:

20           “(4) the entity seeking such grant will promptly  
21 report any new and serious adverse events and safe-  
22 ty information that is considered to be unexpected  
23 with respect to the phase 3 trial to the grant-making  
24 institution, in addition to complying with the safety  
25 reporting requirements under section 312.32 of title

1 21, Code of Federal Regulations (or any successor  
2 regulations).”.

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

7 “(4) The term ‘phase 3’, with respect to a clin-  
8 ical trial, includes a phase 2/3 combined trial that  
9 begins enrollment within a timeframe, determined by  
10 the Secretary through the terms and conditions of  
11 the grant awarded under this section.”.

12 **SEC. 4. FDA RARE NEURODEGENERATIVE DISEASE ACTION**  
13 **PLAN.**

14 Section 4 of the Accelerating Access to Critical  
15 Therapies for ALS Act (21 U.S.C. 360aa note) is amend-  
16 ed—

17 (1) in the section heading, by striking “**ALS**  
18 **AND OTHER RARE NEURODEGENERATIVE DIS-**  
19 **EASE ACTION PLAN**” and inserting “**FDA RARE**  
20 **NEURODEGENERATIVE DISEASE ACTION**  
21 **PLAN**”; and

22 (2) by adding at the end the following:

23 “(c) FDA RARE NEURODEGENERATIVE DISEASE AC-  
24 TION PLAN.—

1           “(1) IN GENERAL.—Not later than 18 months  
2 after the date of enactment of the Accelerating Ac-  
3 cess to Critical Therapies for ALS Reauthorization  
4 Act of 2026, the Commissioner of Food and Drugs  
5 shall publish on the website of the Food and Drug  
6 Administration an action plan that includes a de-  
7 scription of the actions that the Food and Drug Ad-  
8 ministration intends to take during the 5-year period  
9 following publication of the action plan with respect  
10 to the program enhancements, policy development,  
11 regulatory science initiatives, and other appropriate  
12 initiatives described in subsection (a).

13           “(2) REPORT.—Not later than 5 years after the  
14 date of enactment of the Accelerating Access to Crit-  
15 ical Therapies for ALS Reauthorization Act of 2026,  
16 the Commissioner of Food and Drugs shall publish  
17 on the website of the Food and Drug Administration  
18 a report that describes the actions taken by the  
19 Food and Drug Administration under the action  
20 plan published under paragraph (1) and the extent  
21 to which such action plan meets the requirements  
22 specified in paragraph (1).”.

