S. 4472, ACT for ALS Reauthorization Act

Section 1. Short Title

- Establishes the short title of the bill to be "Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026."

Section 2. Reauthorization of the ACT for ALS Act

- Subsection (a) – Extends Authorizations of Appropriations at current levels through 2031.
- Subsection (b) – Extends Grant making authority for Research on Therapies for ALS through 2031.

Section 3. Improvements to the Existing ALS Research Grant Program

This section strengthens how the federal government evaluates grant renewals and clarifies trial definitions.

- Subsection (a) - Adds new requirements for reviewing grant renewals
    - Before renewing a research grant for investigational drugs, the Secretary of HHS must now review the status of the clinical trial, focusing on patient enrollment data and request interim clinical trial data from the drug manufacturer.
- Subsection (b) Clarifies what qualifies as a "phase 3" clinical trial
    - The term "phase 3 clinical trial" is expanded to include combined phase 2/3 trials and planned phase 3 trials that have been designed but have not yet started enrolling participants.

Section 4. Report on ALS and Other Rare Neurodegenerative Disease Action Plans

This section requires FDA to publish a new, updated action plan and provide a detailed report on its work since 2022.

- Within one year of enactment, FDA must publish a new 5-year action plan for ALS and other rare neurodegenerative diseases. The action plan must describe FDA's planned initiatives, the resources needed and how FDA will collaborate not just with ALS communities, but with other rare neurodegenerative disease groups as well. The report must also evaluate FDA's implementation of the 2022 Action Plan, including actions FDA has taken since 2022, how those actions have impacted therapy development, new programs or initiatives created and how the plan has supported rare neurodegenerative diseases beyond ALS.

Section 5. GAO Report

This section updates an earlier requirement for a Government Accountability Office (GAO) review.

- Extends the due date from 4 years after enactment to 5 years.
- Requires GAO to review the entire 10-year period following enactment of the original 2021 law.