

To the office of U.S. Representative Mike Quigley

Re: HR 8205 (119th Congress), Accelerating Access to Critical Therapies for ALS Reauthorization Act of 2026 • Latest action (2026-10-14): Message on Senate action sent to the House.

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Office of record (Congress.gov): 2083 Rayburn House Office Building, Washington, DC • (202) 225-4061

ALS Research Reauthorization with Transparent Safety Review

The measure, as described from the official record: Extend the federal ALS research and expanded-access research programs authorized by Public Law 117-79 through fiscal year 2031, strengthen review and safety reporting for research grants, and require an updated FDA plan and report for rare neurodegenerative diseases. The legislation supports research involving investigational drugs; it does not guarantee a patient access to a drug.

THE PROPOSAL

This VFA proposal would amend the Accelerating Access to Critical Therapies for ALS Act of 2021. It would extend the existing \$100 million annual authorization of appropriations through fiscal year 2031 and prohibit new awards of the Act's ALS expanded-access research grants on or after September 30, 2031, rather than September 30, 2026. The annual amount is the same as the authorization in current law; actual spending would still require Congress to appropriate funds. This proposal creates no entitlement to an investigational drug and does not change the Food and Drug Administration's expanded-access approval requirements.

For the ALS research grants, the Department of Health and Human Services would retain the existing eligibility and safeguards: an expanded-access request must be allowed to proceed before a grant application, the research must use data from patients who are not otherwise eligible for clinical trials, the grant must not impede clinical-trial enrollment, and the project must allow equitable access for minority and underserved populations. On an application to renew a grant, HHS would request from the manufacturer or sponsor and assess enrollment, safety, and any available efficacy data for the investigational drug. A combined phase 2/3 trial would qualify as a participating clinical trial only if enrollment begins within the period set by HHS in the grant terms. These renewal and trial-definition provisions follow H.R. 8205.

A grant applicant would have to commit to promptly reporting new and serious adverse events and unexpected safety information relating to the phase 3 trial to the grant-making institution, in addition to existing federal investigational-drug safety-reporting requirements. As an additional VFA safeguard, HHS would publish annual, aggregate information on grant awards, renewal decisions, and the timeliness of required safety reports. The public report would exclude patient-identifying information and protected trade secrets; it would not replace reports to FDA or the grant-making institution.

The existing FDA grant-and-contract program for ALS and other rare neurodegenerative diseases and the HHS public-private partnership would continue under their current statutory terms. FDA

would publish an updated rare-neurodegenerative-disease action plan within 18 months after enactment, describing work over the following five years, and publish a report on its actions within five years after enactment, as H.R. 8205 proposes. As an additional VFA measure, FDA would publish a plain-language explanation of the lawful expanded-access process and its limits for patients and families.

HHS would administer these duties through its existing grant and regulatory authorities, subject to annual appropriations and applicable privacy and research-safety law. The added public reporting duty would be reviewed by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions. The prohibition on new ALS expanded-access research grants would begin on September 30, 2031 unless Congress extends the date; the rest of the 2021 Act would not expire solely because that grant authority ends.

OPERATIVE PROVISIONS (VFA PROPOSAL)

Funding Source	Annual discretionary appropriations for HHS programs authorized by Public Law 117-79; no new tax or mandatory entitlement is proposed.
Funding Amount	\$100 million authorized to be appropriated for each fiscal year through FY2031, preserving the annual amount in Public Law 117-79 §7. Authorization is not an actual appropriation or a guarantee of spending.
Grant Award Cutoff	No new ALS section 2 grants on or after September 30, 2031; the broader Act has no blanket sunset.
Oversight Body	HHS, including NIH and FDA within their statutory roles; annual aggregate reporting added by VFA to the House Committee on Energy and Commerce and Senate Committee on Health, Education, Labor, and Pensions.
Enforcement Mechanism	HHS grant terms and existing FDA investigational-drug safety-reporting law; this proposal adds public aggregate reporting but no criminal penalty, state mandate, or automatic patient-access right.
Effective Date	Upon enactment; no new ALS section 2 grants on or after September 30, 2031; updated FDA action plan due within 18 months and FDA implementation report due within five years after enactment.

CONSTITUTIONAL BASIS

- Article I, Section 8, Clause 1 (Spending and General Welfare Clause)
- Article I, Section 8, Clause 18 (Necessary and Proper Clause)
- Article I, Section 9, Clause 7 (Appropriations Clause)

WHY BOTH SIDES CAN BACK IT (VFA'S ASSESSMENT)

The proposal retains the existing ALS research and patient-access research pathways, adds review of safety and available efficacy data, and makes program outcomes clearer to patients and Congress. It keeps the current \$100 million annual authorization instead of raising it, requires separate annual appropriations, and adds no state mandate or new patient entitlement. Those choices address patient and research priorities alongside cost control and oversight concerns without predicting support from any particular member.

CHECK BEFORE RELYING ON THIS

Basis: Public Law 117-79 §§2-5 and 7 establishes the ALS expanded-access research grants, partnership, FDA work, and \$100 million yearly authorization through FY2026 (<https://www.govinfo.gov/content/pkg/PLAW-117publ79/pdf/PLAW-117publ79.pdf>). The House-engrossed H.R. 8205 §§2-4 extends the authorization and section 2 grant-award date to 2031, adds renewal data review and serious/unexpected safety reporting, includes qualifying combined phase 2/3 trials, and requires an updated FDA action plan and report (<https://www.govinfo.gov/content/pkg/BILLS-119hr8205eh/html/BILLS-119hr8205eh.htm>).

The annual deidentified program report and plain-language patient guide are VFA additions, not existing law or provisions of H.R. 8205. The \$100 million figure is an authorization, not an appropriation or cost estimate; verify the final enrolled or enacted H.R. 8205 text and current appropriations before publication. Expanded access remains subject to existing FDA and grant eligibility rules and does not guarantee treatment to any patient.

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