January 26, 2026

The Honorable Chuck Grassley
Chairman
Senate Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Richard J. Durbin
Ranking Member
Senate Committee on the Judiciary
United States Senate
Washington, DC 20510

Re: Concerns with the Patent Eligibility Restoration Act of 2025 (S.1546)

Dear Chairman Grassley and Ranking Member Durbin:

On behalf of ALS United and the families we serve, we write to express our concerns with the Patent Eligibility Restoration Act of 2025 (PERA) (S. 1546).

ALS is a fatal, rapidly progressive neurodegenerative disease. Time matters for every person living with ALS, and so does access to the tools that can speed diagnosis, guide care, and move research into effective treatments. Increasingly, that progress depends on biomarkers, genetic insights, and diagnostic approaches that must be widely available across health systems and clinical laboratories to be validated, replicated, and used in real-world care.

We are concerned that PERA, as introduced, risks shifting leverage toward exclusive rights over foundational biological relationships that are central to diagnostics and biomarkers. In practice, that could mean fewer options for clinicians and patients, higher costs for testing, and slower multi-site validation. This is exactly the opposite of what the ALS community needs.

We recognize the goal of improving predictability in patent eligibility and supporting investment in innovation. But reforms should not come at the expense of patient access to clinically meaningful testing or the ability of researchers and clinicians to validate and deploy biomarkers at scale. The Senate Judiciary Subcommittee on Intellectual Property's October 8, 2025 hearing underscored that this is not an academic concern; it is a real-world access issue when patent policy moves closer to covering natural biological relationships and biomarker correlations.

If the Committee proceeds with PERA, any legislation must, at minimum, include clear guardrails that: (1) prevent patents from fencing off naturally occurring biomarker or gene–disease relationships; (2) preserve the ability of qualified clinical laboratories and clinicians to develop, validate, and offer testing without licensing barriers that restrict access or raise costs; and (3) avoid creating new patent-based roadblocks to research replication and multi-site clinical validation that are essential to progress in ALS.

Thank you for your consideration and for your leadership on the Judiciary Committee. ALS United would welcome the opportunity to be a resource as the Committee considers the patient-access implications of any patent eligibility reforms.

Sincerely,



Jerry Dawson
President and CEO
ALS United