

About The Bills:

1. Accelerating Access to Critical Therapies for ALS Act (HOUSE BILL)

- On June 1st, Congressman Jeff Fortenberry (R) and Congressman Mike Quigley (D) introduced the Accelerating Access to Critical Therapies for ALS Act (H.R.7071) in the House of Representatives.
- ACT for ALS will create the infrastructure to fund early access to promising therapies for patients diagnosed with fast-progressing terminal diseases like ALS.
- The bill authorizes \$75,000,000 in FY2021 and 2022 as part of a pilot to provide grants at the National Institutes of Health (NIH) to support expanded access programs.
- The bill will establish a Center of Excellence for Neurodegenerative Diseases at the FDA to accelerate the development and approval of therapies for the coming tide of neurodegenerative diseases that will cause a health and economic crisis.
- The Center will be modeled after FDA's Center of Excellence for Oncology that has driven forward many monumental discoveries in cancer research, including the creation of a corollary for Project Facilitate, which provides a single point of contact where FDA oncology staff will help physicians and their healthcare team through the process of submitting an Expanded Access request for an individual patient with cancer.

2. Promising Pathway Act (SENATE BILL)

- On June 4th, Senator Mike Braun, Senator Lisa Murkowski and Senator Martha McSally introduced the Promising Pathway Act (S.3872) in the Senate.
- The bill will speed up the regulatory process for getting drugs showing benefits to the patients who need them.
- It requires the FDA to establish a real-time, priority review pathway to evaluate provisional approval applications for drugs intended to treat, prevent, or diagnose serious or life-threatening diseases or conditions.
- Under this pathway, provisional approval would be granted by the FDA to treatments demonstrating substantial evidence of safety and relevant early evidence of positive therapeutic outcome(s).
- Moreover, the bill would require CMS to cover therapies provisionally approved through this pathway and prohibit private insurance from denying coverage to therapies that are made available under this pathway on the basis that they are investigational therapies.
- Finally, it would require the creation of registries for those using a provisionally approved drug and the sharing of data from these registries to help speed the overall fight.

Why We Need Your Support

- Today, ALS is 100% fatal, killing most within 2-5 years of diagnosis.
- We are at a pivotal point in history where treatments and cures are possible.
- What stands in our way is a system that does not work for many people living with ALS or other terminal diseases and does not provide functional pathways to access investigational therapies.
- These bills provide hope that a system that works for patients can and is being built.