U.S. Rep. Gallagher: Introduce bipartisan Promising Pathways Act

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WASHINGTON, D.C. — Rep. Mike Gallagher (R-WI) today joined Reps. Mike Quigley (D-IL), Bruce Westerman (R-AR), and Eric Swalwell (D-CA) in introducing the bipartisan, bicameral Promising Pathways Act. The bill would create a means for FDA to streamline provisional approval for drugs that may treat or prevent a serious or life-threatening disease or condition. Companion legislation was introduced in the U.S. Senate by Senator Mike Braun. Click HERE for bill text.

“By expediting the process in which critical medicines can hit the market, we support innovation and improve patients’ access to lifesaving treatments,” said Rep. Gallagher. “I’m proud to support this common-sense bill, and look forward to working with my colleagues to get this across the finish line.”
“I am proud to have introduced this legislation alongside my colleagues today,” said Rep. Quigley. “Every day, people across America are diagnosed with neurodegenerative diseases with few to no options for treatment or cures. As we continue to face a global pandemic, we have all had to sit with the fear that accompanies a fast-moving, devastating, fatal disease. This gives us just a small insight into the suffering patients with ALS—and other terminal illnesses—have been facing for years. This bill necessarily disrupts the status quo, prioritizes new strategies for treatment, and pushes the envelope for innovations in the effort to find cures.”
“Scientific research has made great progress with potential treatments and cures, but I frequently hear from patients suffering with terminal conditions and who can’t get access to necessary therapies,” said Rep. Westerman. “The lengthy approval process and high costs associated with clinical trials delay companies from getting potentially lifesaving medication into the hands of those who need it most. The Promising Pathways Act would create another avenue of access, allowing patients to receive safe, effective medicine, even if they don’t qualify for the strict clinical trial requirements. I’m pleased to join my colleagues in introducing this bill, and with Sen. Braun’s companion bill in the Senate, we can hopefully get this legislation passed and signed into law as quickly as possible.”
“The Promising Pathway Act would require the FDA to create a prioritized high-speed lane for evaluating drugs intended to treat, prevent, or diagnose serious or life-threatening diseases, including those that pose an epidemic or pandemic threat,” said Rep. Swalwell. “I’m committed to finding cures for those suffering from rare and potentially fatal diseases, and this bill helps us fight for those with conditions like ALS and cancer while also strengthening our response to future pandemics.”
As a member of the ALS caucus, this bill is a part of Rep. Gallagher’s work to improve access to lifesaving treatments for those with terminal illnesses like ALS.
“A tragic diagnosis of ALS automatically imparts a fatal and swift downward spiral. Urgency in finding a treatment and cure becomes the touchstone for each person living with ALS. By introducing the Promising Pathway Act Congressmen Gallagher, Quigley, Swalwell and Westerman are providing another arrow in the quiver for the FDA to quicken the release of potential life enhancing treatments. We encourage quick passage of this life saving legislation,” said Tom Kettler, Public Policy Chairman and Past President ALS Association Wisconsin Chapter.
“The ALS Association strongly supports the Promising Pathway Act to create a faster pathway for new therapies,” said Calaneet Balas, president and CEO of The ALS Association.“This bill advances efforts to bring effective treatments to everyone with ALS as soon as possible. We look forward to working together to ensure Congress passes this bill quickly.”
Background:
The Food and Drug Administration (FDA) refers to the clinical trial process for prescription drugs in phases, i.e. Phase I, II and III. Early clinical trials (Phases I and II) establish and confirm safety while providing a considerable amount of data, often enough to statistically predict successful confirmatory trials. Confirmatory trials (Phase III) further test effectiveness and are the last step to a drug entering the market for patients’ use under a New Drug Application or Biologics License Application approval. However, Phase III trials are extremely time-consuming and expensive, in some cases costing billions of dollars. If the FDA determines a drug doesn’t meet its standards of safety or effectiveness, small pharmaceuticals attempting to bring innovative drugs to market and compete with large drug companies can go bankrupt during Phase III trials.
The Promising Pathways Act would allow pharmaceutical companies to petition the FDA for provisional approval if the drug has cleared early stage clinical trials, already having proven safety and showing significant evidence of effectiveness. The company could then sell their drug at a market acceptable rate, give patients access to innovative treatments and compete with large, monopolistic pharmaceuticals to lower consumer cost.