HR 3761

Promising Pathway Act

Congress: 117 (2021–2023, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 8, 2021
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 9, 2021)
Official Text: https://www.congress.gov/bill/117th-congress/house-bill/3761

Sponsor

Name: Rep. Gallagher, Mike [R-WI-8]
Party: Republican • **State:** WI • **Chamber:** House

Cosponsors (9 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Quigley, Mike [D-IL-5]	D · IL		Jun 8, 2021
Rep. Swalwell, Eric [D-CA-15]	D · CA		Jun 8, 2021
Rep. Westerman, Bruce [R-AR-4]	R · AR		Jun 8, 2021
Rep. Fitzpatrick, Brian K. [R-PA-1]	R · PA		Jun 22, 2021
Rep. Auchincloss, Jake [D-MA-4]	D · MA		Jul 28, 2021
Rep. Hartzler, Vicky [R-MO-4]	R · MO		Aug 17, 2021
Rep. McGovern, James P. [D-MA-2]	D · MA		Sep 10, 2021
Rep. Gonzalez, Anthony [R-OH-16]	R · OH		Oct 22, 2021
Rep. Trahan, Lori [D-MA-3]	D · MA		Nov 4, 2021

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 9, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 HR 8588	Related bill	**Nov 1, 2022:** Referred to the Subcommittee on Courts, Intellectual Property, and the Internet.
117 S 1644	Identical bill	**May 13, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 8, 2021)

Promising Pathway Act

This bill establishes a provisional approval pathway for medicines intended for serious or life-threatening diseases, including illnesses posing a threat of epidemic or pandemic. The period of the provisional approval is for two years and is potentially renewable.

The Food and Drug Administration (FDA) must establish a priority review system to evaluate completed provisional approval applications within 90 days of receipt. A provisional approval application may be approved if the FDA determines that (1) there is substantial evidence of safety for the drug; and (2) there is relevant early evidence of efficacy, based on adequate and well-controlled investigations.

During the COVID-19 (i.e., coronavirus disease 2019) pandemic, or another epidemic or pandemic, the FDA must accept and review various portions of a provisional approval application on a rolling basis.

The manufacturer of a provisionally approved drug must require patients to participate in an observational registry. A manufacturer that fails to comply with registry requirements is subject to civil penalties.

A provisionally approved drug must be labeled as such.

If a drug that receives provisional approval status is not brought to market within 180 days of the approval, the approval must be rescinded.

The bill also limits the liability of a manufacturer of a provisionally approved drug with respect to any claim under state law alleging that the drug is unsafe or ineffective.

Private health insurers and federal health care programs shall not deny coverage of a provisionally approved drug on the basis of it being experimental.

Actions Timeline

- **Jun 9, 2021:** Referred to the Subcommittee on Health.
- **Jun 8, 2021:** Introduced in House
- **Jun 8, 2021:** Referred to the House Committee on Energy and Commerce.