HR 4408

Promising Pathway Act

Congress: 118 (2023–2025, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 30, 2023
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jul 7, 2023)
Official Text: https://www.congress.gov/bill/118th-congress/house-bill/4408

Sponsor

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

Cosponsors (10 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Fitzpatrick, Brian K. [R-PA-1]	R · PA		Jun 30, 2023
Rep. Quigley, Mike [D-IL-5]	D · IL		Jun 30, 2023
Rep. Swalwell, Eric [D-CA-14]	D · CA		Jun 30, 2023
Rep. Westerman, Bruce [R-AR-4]	R · AR		Jun 30, 2023
Rep. D'Esposito, Anthony [R-NY-4]	R · NY		Aug 8, 2023
Rep. Phillips, Dean [D-MN-3]	D · MN		Oct 26, 2023
Rep. Frankel, Lois [D-FL-22]	D · FL		Dec 7, 2023
Rep. Gottheimer, Josh [D-NJ-5]	D · NJ		Dec 7, 2023
Rep. Wilson, Joe [R-SC-2]	R · SC		Dec 7, 2023
Rep. Garcia, Mike [R-CA-27]	R · CA		Apr 5, 2024

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 7, 2023

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 S 1906	Identical bill	**Jun 8, 2023:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 30, 2023)

Promising Pathway Act

This bill provides for expedited, provisional approval of drugs for serious or life-threatening diseases or conditions.

Specifically, the bill allows for provisional approval of drugs that are used to treat, prevent, or diagnose a serious or life-threatening disease or condition for which premature death is likely without early medical intervention. The Food and Drug Administration (FDA) must evaluate applications within 90 days of receipt. The FDA may approve applications if there is early evidence, including real-world and real-time evidence, of the drug's efficacy, as well as substantial evidence of the drug's safety. Provisional approval is valid for two years and may be renewed for up to eight years. The FDA may withdraw provisional approval in the event of serious adverse health effects.

Drug sponsors that receive provisional approval must require all patients receiving the drug to participate in an observational registry, through which the drug sponsor may collect and submit data relating to the drug until it is fully approved. Registries may be operated by the drug sponsor or another entity. The FDA must annually review these registries; sponsors of registries that fail to meet the bill's requirements are subject to civil penalties.

Actions Timeline

- **Jul 7, 2023:** Referred to the Subcommittee on Health.
- **Jun 30, 2023:** Introduced in House
- **Jun 30, 2023:** Referred to the House Committee on Energy and Commerce.

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