

## HR 4043

### Ensuring Patient Access to Critical Breakthrough Products Act of 2021

**Congress:** 117 (2021–2023, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Jun 22, 2021

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Jun 23, 2021)

**Official Text:** <https://www.congress.gov/bill/117th-congress/house-bill/4043>

## Sponsor

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**Name:** Rep. DelBene, Suzan K. [D-WA-1]

**Party:** Democratic • **State:** WA • **Chamber:** House

## Cosponsors (33 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Jun 22, 2021
Rep. Cárdenas, Tony [D-CA-29]	D · CA		Jun 22, 2021
Rep. Sewell, Terri A. [D-AL-7]	D · AL		Jun 22, 2021
Rep. Upton, Fred [R-MI-6]	R · MI		Jun 22, 2021
Rep. Walorski, Jackie [R-IN-2]	R · IN		Jun 22, 2021
Rep. Suozzi, Thomas R. [D-NY-3]	D · NY		Jul 30, 2021
Rep. Dunn, Neal P. [R-FL-2]	R · FL		Aug 31, 2021
Rep. Houlahan, Chrissy [D-PA-6]	D · PA		Aug 31, 2021
Rep. Bera, Ami [D-CA-7]	D · CA		Sep 21, 2021
Rep. Boyle, Brendan F. [D-PA-2]	D · PA		Sep 21, 2021
Rep. McGovern, James P. [D-MA-2]	D · MA		Sep 21, 2021
Rep. Correa, J. Luis [D-CA-46]	D · CA		Sep 30, 2021
Rep. Crenshaw, Dan [R-TX-2]	R · TX		Sep 30, 2021
Rep. Wenstrup, Brad R. [R-OH-2]	R · OH		Sep 30, 2021
Rep. Schrier, Kim [D-WA-8]	D · WA		Oct 15, 2021
Rep. Pappas, Chris [D-NH-1]	D · NH		Oct 22, 2021
Rep. Wild, Susan [D-PA-7]	D · PA		Oct 22, 2021
Rep. Peters, Scott H. [D-CA-52]	D · CA		Nov 5, 2021
Rep. Craig, Angie [D-MN-2]	D · MN		Nov 16, 2021
Rep. Kelly, Mike [R-PA-16]	R · PA		Nov 16, 2021
Rep. Lieu, Ted [D-CA-33]	D · CA		Nov 16, 2021
Rep. McKinley, David B. [R-WV-1]	R · WV		Nov 16, 2021
Rep. Aguilar, Pete [D-CA-31]	D · CA		Jan 21, 2022
Rep. Cheney, Liz [R-WY-At Large]	R · WY		Jan 21, 2022
Rep. Dean, Madeleine [D-PA-4]	D · PA		Jan 21, 2022
Rep. Emmer, Tom [R-MN-6]	R · MN		Jan 21, 2022
Rep. Miller, Carol D. [R-WV-3]	R · WV		Jan 21, 2022
Rep. Smucker, Lloyd [R-PA-11]	R · PA		Jan 21, 2022
Rep. Steel, Michelle [R-CA-48]	R · CA		Jan 21, 2022
Rep. Joyce, John [R-PA-13]	R · PA		Mar 15, 2022
Rep. Smith, Jason [R-MO-8]	R · MO		Mar 17, 2022
Rep. Lamb, Conor [D-PA-17]	D · PA		Apr 6, 2022
Rep. Auchincloss, Jake [D-MA-4]	D · MA		Oct 7, 2022

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 23, 2021
Ways and Means Committee	House	Referred to	Jun 22, 2021

## Subjects & Policy Tags

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### Policy Area:

Health

### Related Bills

Bill	Relationship	Last Action
117 HR 6000	Related bill	Jan 4, 2022: Referred to the Subcommittee on Biotechnology, Horticulture, and Research.

### Summary (as of Jun 22, 2021)

#### Ensuring Patient Access to Critical Breakthrough Products Act of 2021

This bill provides for Medicare coverage of medical devices that are approved under the Food and Drug Administration (FDA) Breakthrough Devices Program. (Under the program, manufacturers work with the FDA to expedite the review and approval of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions.)

The bill allows designated medical breakthrough devices to be temporarily covered under Medicare during a four-year transitional period. The Centers for Medicare & Medicaid Services (CMS) must assign payment codes for such devices within three months of FDA approval. The CMS must also establish a process to allow for continued coverage after the transitional period has expired, taking into account any additional evidence or data the CMS deems necessary.

The CMS must also provide for temporary and, where appropriate, permanent Medicare coverage of breakthrough devices for which there is no existing benefit category (i.e., classification).

### Actions Timeline

- **Jun 23, 2021:** Referred to the Subcommittee on Health.
- **Jun 22, 2021:** Introduced in House
- **Jun 22, 2021:** Referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
- **Jun 22, 2021:** Referred to the Subcommittee on Health.