

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

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

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.