

HR 5334

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to expedite the development and review of breakthrough therapies.

Congress: 112 (2011–2013, Ended)

Chamber: House

Policy Area: Health

Introduced: May 7, 2012

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (May 11, 2012)

Official Text: <https://www.congress.gov/bill/112th-congress/house-bill/5334>

Sponsor

Name: Rep. Bilbray, Brian P. [R-CA-50]

Party: Republican • **State:** CA • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeGette, Diana [D-CO-1]	D · CO		May 7, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 11, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
112 S 3187	Related bill	Jul 9, 2012: Became Public Law No: 112-144.
112 HR 5651	Related bill	Jun 4, 2012: Received in the Senate. Read twice. Placed on Senate Legislative Calendar under General Orders. Calendar No. 420.
112 S 2516	Related bill	May 7, 2012: Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.
112 S 2236	Related bill	Mar 26, 2012: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 7, 2012)

Amends the Federal Food, Drug, and Cosmetic Act to direct the Secretary of Health and Human Services (HHS), at the request of the sponsor of a drug, to expedite the drug's development and review if: (1) it is intended, either alone or in combination, to treat a serious life-threatening disease or condition; and (2) preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

Authorizes the drug's sponsor to request the Secretary to designate the drug as a breakthrough therapy. Requires the Secretary, within 60 days of such request, to determine whether the drug meets such criteria and, if so, make such designation, followed by appropriate actions to expedite its development and review for approval.

Requires an annual report from the Secretary to Congress on drugs for which breakthrough designations were requested and approved.

Directs the Secretary to issue guidance on implementing requirements with respect to breakthrough therapies and to amend promulgated regulations.

Requires the Comptroller General to assess the manner by which the Food and Drug Administration (FDA) has applied the processes established by this Act and their impact on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions.

Actions Timeline

- **May 11, 2012:** Referred to the Subcommittee on Health.
- **May 7, 2012:** Introduced in House
- **May 7, 2012:** Referred to the House Committee on Energy and Commerce.