S 2236

Advancing Breakthrough Therapies for Patients Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 26, 2012
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 26, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/senate-bill/2236

Sponsor

Name: Sen. Bennet, Michael F. [D-CO]
Party: Democratic • **State:** CO • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Burr, Richard [R-NC]	R · NC		Mar 26, 2012
Sen. Hatch, Orrin G. [R-UT]	R · UT		Mar 26, 2012

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 26, 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 5334	Related bill	**May 11, 2012:** Referred to the Subcommittee on Health.
112 S 2516	Related bill	**May 7, 2012:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 389.

Summary (as of Mar 26, 2012)

Advancing Breakthrough Therapies for Patients Act of 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.

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

Requires the Secretary to contract with an independent entity to evaluate the manner by which the Food and Drug Administration (FDA) has applied the processes for the breakthrough therapy determination, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Requires an annual report from the Secretary to Congress on drugs for which breakthrough designations were requested and approved.

Actions Timeline

- **Mar 26, 2012:** Introduced in Senate
- **Mar 26, 2012:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.