S 1048

Enhanced Clinical Trial Design Act of 2017

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 4, 2017
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. (May 4, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/1048

Sponsor

Name: Sen. Hatch, Orrin G. [R-UT]
Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Bennet, Michael F. [D-CO]	D · CO		May 4, 2017
Sen. Burr, Richard [R-NC]	R · NC		May 4, 2017
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		May 4, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 4, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 HR 2430	Related bill	**Aug 18, 2017:** Became Public Law No: 115-52.
115 S 934	Related bill	**May 11, 2017:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 76.

Summary (as of May 4, 2017)

Enhanced Clinical Trial Design Act of 2017

This bill requires the Food and Drug Administration (FDA), in coordination with the National Institutes of Health, to convene a meeting to discuss clinical trial inclusion and exclusion criteria. The FDA must report on the meeting and issue guidance regarding eligibility criteria for clinical trials.

The Government Accountability Office must report on individual access to investigational drugs for serious conditions through the FDA's expanded access program (i.e., compassionate use).

The FDA must streamline review by institutional review boards of expanded access protocols for individual patients. The bill amends the Federal Food, Drug, and Cosmetic Act to require the manufacturer or distributor of an investigational drug for a serious condition that is designated a breakthrough therapy, fast track product, or regenerative advanced therapy to publish its expanded access policy not later than 15 days after the designation.

Actions Timeline

- **May 4, 2017:** Introduced in Senate
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