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ACCESS Act

Congress: 109 (2005–2007, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Nov 3, 2005
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S12355-12357) (Nov 3, 2005)
Official Text: https://www.congress.gov/bill/109th-congress/senate-bill/1956

Sponsor

Name: Sen. Brownback, Sam [R-KS]
Party: Republican • **State:** KS • **Chamber:** Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Inhofe, James M. [R-OK]	R · OK		Nov 3, 2005
Sen. Isakson, Johnny [R-GA]	R · GA		Dec 20, 2005
Sen. Allen, George [R-VA]	R · VA		Jan 25, 2006
Sen. Sessions, Jeff [R-AL]	R · AL		Feb 13, 2006

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Nov 3, 2005

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 HR 6303	Identical bill	**Oct 2, 2006:** Referred to the Subcommittee on Health.

Summary (as of Nov 3, 2005)

Access, Compassion, Care, and Ethics for Seriously Ill Patients Act or the ACCESS Act - Amends the Federal Food, Drug, and Cosmetic Act to replace the current fast track product approval process with a multi-tiered approval process for any investigational drug, biological product, or device. Provides for expedited approval for a drug, biological product, or device for a serious or life-threatening condition, with additional conditions such as additional studies, limits on advertising and promotional materials, and expedited withdrawal procedures.

Requires the Secretary of Health and Human Services to: (1) establish the Accelerated Approval Advisory Committee to issue recommendations to the Secretary on applications submitted by a sponsor of such a drug, product, or device; (2) prohibit placebo-only or no-treat-only concurrent controls in clinical investigations with respect to any life-threatening condition or disease where reasonably effective, approved, alternative therapies exist for the specific indication; (3) establish a program to encourage the development of surrogate endpoints and biomarkers that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for which there exist significant unmet medical needs; (4) request that the Institute of Medicine undertake a study to identify validated surrogate endpoints and biomarkers, and recommend research to validate surrogate endpoints and biomarkers, that may support approvals for products intended for the treatment of serious or life-threatening conditions or diseases; and (5) give equal weight to clinical judgment and statistical analysis in the evaluation of the safety and effectiveness of new products and not disapprove a product application solely on the basis of a statistical analysis or the rigid use of the 95 percent confidence level convention.

Requires the Food and Drug Administration (FDA) to establish a new program to expand access to investigation treatments for individuals with serious or life-threatening conditions and diseases.

Actions Timeline

- **Nov 3, 2005:** Introduced in Senate
- **Nov 3, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S12355-12357)