S 3046

ACCESS Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 21, 2008
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 21, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/3046

Sponsor

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

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Casey, Robert P., Jr. [D-PA]	D · PA		May 21, 2008
Sen. Coleman, Norm [R-MN]	R · MN		May 21, 2008
Sen. Inhofe, James M. [R-OK]	R · OK		May 21, 2008
Sen. Specter, Arlen [R-PA]	R · PA		May 21, 2008
Sen. Sessions, Jeff [R-AL]	R · AL		Sep 18, 2008

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 21, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HR 6270	Identical bill	**Jun 17, 2008:** Referred to the Subcommittee on Health.

Summary (as of May 21, 2008)

Access, Compassion, Care, and Ethics for Seriously Ill Patients Act or the ACCESS Act - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services to permit an investigational drug, biological product, or device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if specified Compassionate Investigational Access requirements are met.

Gives immunity to the manufacturer, distributor, administrator, sponsor, or physician from suit or liability relating to products approved under this Act.

Establishes a procedure for accelerated approval of an investigational drug, biological product, or device that is reasonably likely to predict clinical benefit to a patient suffering from a serious or life-threatening condition.

Requires the Secretary to establish: (1) the Accelerated Approval Advisory Committee; (2) a new program to expand access to investigational treatments for individuals with serious or life threatening conditions and diseases; and (3) a demonstration project under the Medicare program to pay for drugs, biological, products, and devices approved under this Act.

Amends title XVIII (Medicare) of the Social Security Act to revise the definition of "medically accepted indication" to provide for coverage of a covered Part D drug based on the sponsor's or organization's determination that the drug is for a medically accepted indication.

Requires the Secretary to consider the clinical judgment and risks to the patient from the disease or condition in evaluating the safety and effectiveness of drugs, biological products, and devices that treat serious or life-threatening diseases or conditions, including the evaluation of nonstatistical information.

Requires any committee evaluating investigational drugs, devices, or biological product applications to have at least two patient representatives as voting members.

Actions Timeline

- **May 21, 2008:** Introduced in Senate
- **May 21, 2008:** Sponsor introductory remarks on measure. (CR S4625)
- **May 21, 2008:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.