HR 6270

ACCESS Act

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 12, 2008
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 17, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/6270

Sponsor

Name: Rep. Watson, Diane E. [D-CA-33]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burton, Dan [R-IN-5]	R · IN		Jun 12, 2008
Rep. Conyers, John, Jr. [D-MI-14]	D · MI		Jun 12, 2008
Rep. Cummings, Elijah E. [D-MD-7]	D · MD		Jun 12, 2008
Rep. Jackson-Lee, Sheila [D-TX-18]	D · TX		Jun 12, 2008
Rep. Johnson, Eddie Bernice [D-TX-30]	D · TX		Jun 12, 2008
Rep. Latham, Tom [R-IA-4]	R · IA		Jun 12, 2008
Rep. Solis, Hilda L. [D-CA-32]	D · CA		Jun 12, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Jun 12, 2008
Ways and Means Committee	House	Referred to	Jun 17, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 S 3046	Identical bill	**May 21, 2008:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 12, 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

- **Jun 17, 2008:** Referred to the Subcommittee on Health.
- **Jun 12, 2008:** Introduced in House
- **Jun 12, 2008:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.