HR 4732

Compassionate Access Act of 2010

Congress: 111 (2009–2011, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 2, 2010
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 8, 2010)
Official Text: https://www.congress.gov/bill/111th-congress/house-bill/4732

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		Mar 12, 2010
Rep. Latham, Tom [R-IA-4]	R · IA		Mar 16, 2010
Rep. Meeks, Gregory W. [D-NY-6]	D · NY		Mar 17, 2010
Rep. Farr, Sam [D-CA-17]	D · CA		Mar 25, 2010
Rep. Hall, John J. [D-NY-19]	D · NY		Apr 13, 2010
Rep. Rohrabacher, Dana [R-CA-46]	R · CA		May 19, 2010
Rep. Connolly, Gerald E. [D-VA-11]	D · VA		Sep 14, 2010

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Mar 2, 2010
Ways and Means Committee	House	Referred to	Mar 8, 2010

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 2, 2010)

Compassionate Access Act of 2010 - Amends the Federal Food, Drug, and Cosmetic Act to require the Secretary of Health and Human Services (HHS) 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.

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

- **Mar 8, 2010:** Referred to the Subcommittee on Health.
- **Mar 2, 2010:** Introduced in House
- **Mar 2, 2010:** Referred to House Energy and Commerce
- **Mar 2, 2010:** 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.
- **Mar 2, 2010:** Referred to House Ways and Means