HR 6303

ACCESS Act

Congress: 109 (2005–2007, Ended)
Chamber: House
Policy Area: Health
Introduced: Sep 29, 2006
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 2, 2006)
Official Text: https://www.congress.gov/bill/109th-congress/house-bill/6303

Sponsor

Name: Rep. Shays, Christopher [R-CT-4]
Party: Republican • **State:** CT • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 2, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 S 1956	Identical bill	**Nov 3, 2005:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S12355-12357)

Summary (as of Sep 29, 2006)

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% 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

- **Oct 2, 2006:** Referred to the Subcommittee on Health.
- **Sep 29, 2006:** Introduced in House
- **Sep 29, 2006:** Introduced in House
- **Sep 29, 2006:** Referred to the House Committee on Energy and Commerce.