

HR 6257

Access to Life-Saving Medicine 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/6257>

Sponsor

Name: Rep. Waxman, Henry A. [D-CA-30]

Party: Democratic • State: CA • Chamber: House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Brown, Sherrod [D-OH-13]	D · OH		Sep 29, 2006

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 2, 2006
Judiciary Committee	House	Referred To	Sep 29, 2006
Ways and Means Committee	House	Referred To	Sep 29, 2006

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
109 S 4016	Related bill	Sep 29, 2006: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Access to Life-Saving Medicine Act - Amends the Public Health Service Act to establish a process for the approval of a comparable biological product based on its similarity to a previously licensed biological product (the reference product). Allows a person to file an abbreviated comparable product application with the Secretary of Health and Human Services that includes: (1) data demonstrating that the product is comparable to the reference product; (2) information to show that the conditions or conditions of use prescribed, recommended, or suggested in the labeling proposed for the comparable product have been previously approved for the reference product; and (3) information to show that the route of administration, the dosage form, and the strength of the comparable product are the same as those of the reference product.

Sets forth conditions for approval of such an application by the Secretary.

Allows an applicant to request that the Secretary make a determination as to the interchangeability of a comparable product and the reference product. Provides market exclusivity to such an interchangeable product.

Requires the Secretary to establish requirements for the efficient review, approval, suspension, and revocation of comparable product applications.

Sets forth provisions governing patent infringement claims against the license holder of a comparable product.

Amends the Internal Review Code to allow a tax credit for qualified clinical testing expenses.

Actions Timeline

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