

HR 1038

Access to Life-Saving Medicine Act

Congress: 110 (2007–2009, Ended)

Chamber: House

Policy Area: Health

Introduced: Feb 14, 2007

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Feb 15, 2007)

Official Text: <https://www.congress.gov/bill/110th-congress/house-bill/1038>

Sponsor

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

Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (35 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Emanuel, Rahm [D-IL-5]	D · IL		Feb 14, 2007
Rep. Emerson, Jo Ann [R-MO-8]	R · MO		Feb 14, 2007
Rep. Hirono, Mazie K. [D-HI-2]	D · HI		Feb 14, 2007
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Feb 14, 2007
Rep. Kilpatrick, Carolyn C. [D-MI-13]	D · MI		Feb 16, 2007
Rep. Stark, Fortney Pete [D-CA-13]	D · CA		Feb 16, 2007
Rep. Abercrombie, Neil [D-HI-1]	D · HI		Feb 27, 2007
Rep. Conyers, John, Jr. [D-MI-14]	D · MI		Feb 27, 2007
Rep. Wamp, Zach [R-TN-3]	R · TN		Mar 6, 2007
Rep. Grijalva, Raúl M. [D-AZ-7]	D · AZ		Mar 9, 2007
Rep. Pastor, Ed [D-AZ-4]	D · AZ		Mar 20, 2007
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Mar 26, 2007
Rep. Cohen, Steve [D-TN-9]	D · TN		Mar 26, 2007
Rep. Holden, Tim [D-PA-17]	D · PA		Mar 26, 2007
Rep. Thornberry, Mac [R-TX-13]	R · TX		Mar 26, 2007
Rep. Hoekstra, Peter [R-MI-2]	R · MI		Mar 28, 2007
Rep. Woolsey, Lynn C. [D-CA-6]	D · CA		Mar 29, 2007
Rep. McCollum, Betty [D-MN-4]	D · MN		Apr 23, 2007
Rep. Loebsack, David [D-IA-2]	D · IA		Apr 25, 2007
Rep. McCarthy, Carolyn [D-NY-4]	D · NY		Apr 25, 2007
Rep. Slaughter, Louise McIntosh [D-NY-28]	D · NY		Apr 25, 2007
Rep. Platts, Todd Russell [R-PA-19]	R · PA		May 7, 2007
Rep. Wolf, Frank R. [R-VA-10]	R · VA		May 17, 2007
Rep. Allen, Thomas H. [D-ME-1]	D · ME		Jun 5, 2007
Rep. Cooper, Jim [D-TN-5]	D · TN		Jun 11, 2007
Rep. Ellison, Keith [D-MN-5]	D · MN		Jun 26, 2007
Rep. Clay, Wm. Lacy [D-MO-1]	D · MO		Jul 16, 2007
Rep. Kildee, Dale E. [D-MI-5]	D · MI		Jul 31, 2007
Rep. Speier, Jackie [D-CA-12]	D · CA		Apr 22, 2008
Del. Bordallo, Madeleine Z. [D-GU-At Large]	D · GU		Jun 12, 2008
Rep. Boozman, John [R-AR-3]	R · AR		Jun 18, 2008
Rep. Paul, Ron [R-TX-14]	R · TX		Jun 18, 2008
Rep. Bishop, Timothy H. [D-NY-1]	D · NY		Jul 30, 2008
Rep. Rothman, Steven R. [D-NJ-9]	D · NJ		Sep 9, 2008
Rep. Fattah, Chaka [D-PA-2]	D · PA		Sep 29, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 15, 2007
Judiciary Committee	House	Referred To	Feb 14, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 S 623	Identical bill	Feb 27, 2007: Star Print ordered on S. 623.

Summary (as of Feb 14, 2007)

Access to Life-Saving Medicine Act - Amends the Public Health Service Act to establish a process for the approval of an abbreviated biological product application for products that contain the same or similar active ingredients as a previously licensed biological product (the reference product). Allows a person to file an abbreviated biological product application with the Secretary of Health and Human Services that includes: (1) data demonstrating that the product is comparable to or interchangeable with the reference product; (2) information to show that the conditions or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological 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 biological 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 based on whether a product can be expected to produce the same clinical result as the reference product in any given patient. Provides market exclusivity to such an interchangeable product. Requires the Secretary to defer issuing a determination of interchangeability for a subsequent comparable biological product during the period of market exclusivity for a prior interchangeable comparable biological product.

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

Sets forth provisions governing patent infringement claims against an applicant or prospective applicant for a comparable biological product license.

Actions Timeline

- **Feb 15, 2007:** Referred to the Subcommittee on Health.
- **Feb 14, 2007:** Introduced in House
- **Feb 14, 2007:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, 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.