S 623

Access to Life-Saving Medicine Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 15, 2007
Current Status: Star Print ordered on S. 623.
Latest Action: Star Print ordered on S. 623. (Feb 27, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/623

Sponsor

Name: Sen. Schumer, Charles E. [D-NY]
Party: Democratic • **State:** NY • **Chamber:** Senate

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Feb 15, 2007
Sen. Collins, Susan M. [R-ME]	R · ME		Feb 15, 2007
Sen. Leahy, Patrick J. [D-VT]	D · VT		Feb 15, 2007
Sen. Stabenow, Debbie [D-MI]	D · MI		Feb 15, 2007
Sen. Vitter, David [R-LA]	R · LA		Feb 15, 2007
Sen. Coleman, Norm [R-MN]	R · MN		Mar 6, 2007
Sen. Brown, Sherrod [D-OH]	D · OH		Mar 19, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 15, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
110 HR 1038	Identical bill	**Feb 15, 2007:** Referred to the Subcommittee on Health.

Summary (as of Feb 15, 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 27, 2007:** Star Print ordered on S. 623.
- **Feb 15, 2007:** Introduced in Senate
- **Feb 15, 2007:** Sponsor introductory remarks on measure. (CR S2053-2054)
- **Feb 15, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (text of measure as introduced: CR S2054-2058)