S 726

Promoting Innovation and Access to Life-Saving Medicine Act

Congress: 111 (2009–2011, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Mar 26, 2009
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Mar 26, 2009)
Official Text: https://www.congress.gov/bill/111th-congress/senate-bill/726

Sponsor

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

Cosponsors (9 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Brown, Sherrod [D-OH]	D · OH		Mar 26, 2009
Sen. Collins, Susan M. [R-ME]	R · ME		Mar 26, 2009
Sen. Martinez, Mel [R-FL]	R · FL		Mar 26, 2009
Sen. Shaheen, Jeanne [D-NH]	D · NH		Mar 26, 2009
Sen. Stabenow, Debbie [D-MI]	D · MI		Mar 26, 2009
Sen. Vitter, David [R-LA]	R · LA		Mar 26, 2009
Sen. Bingaman, Jeff [D-NM]	D · NM		May 18, 2009
Sen. Lincoln, Blanche L. [D-AR]	D · AR		Jul 22, 2009
Sen. Nelson, Bill [D-FL]	D · FL		Aug 6, 2009

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Mar 26, 2009

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
111 HR 1427	Identical bill	**Mar 12, 2009:** Referred to the Subcommittee on Health.

Summary (as of Mar 26, 2009)

Promoting Innovation and Access to Life-Saving Medicine Act - Amends the Public Health Service Act to provide for the licensing of biosimilar and interchangeable biological products. Defines "biosimilar" and "interchangeability" for purposes of this Act.

Allows any person to file an abbreviated biological product application with the Secretary of Health and Human Services. Requires such applications to include information demonstrating a high degree of similarity or interchangeability between the biological product and the licensed biological product (reference product).

Requires the Secretary to: (1) approve an application and issue a license for a biosimilar product unless the Secretary finds and informs the applicant that the information in the application fails to demonstrate biosimilarity between the biological product and the reference product or the safety, purity, and potency of the biological product; and (2) establish requirements for the efficient review, approval, suspension, and revocation of abbreviated biological product applications.

Allows an applicant to request the Secretary to make a determination as to the interchangeability of a product and its reference product based on whether a product can be expected to produce the same clinical result as the reference product in any given patient. Grants market exclusivity to any biological product that is determined to be interchangeable for a specified period.

Sets forth provisions governing patent infringement claims involving comparable biological products and legal remedies to expedite the adjudication of patent infringement disputes.

Extends the period for approval of biological products to allow for studies of the use of new biological products in the pediatric population.

Actions Timeline

- **Mar 26, 2009:** Introduced in Senate
- **Mar 26, 2009:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.