S 1695

Biologics Price Competition and Innovation Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jun 26, 2007
Current Status: Placed on Senate Legislative Calendar under General Orders. Calendar No. 1127.
Latest Action: Placed on Senate Legislative Calendar under General Orders. Calendar No. 1127. (Nov 19, 2008)
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Sponsor

Name: Sen. Kennedy, Edward M. [D-MA]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Clinton, Hillary Rodham [D-NY]	D · NY		Jun 26, 2007
Sen. Enzi, Michael B. [R-WY]	R · WY		Jun 26, 2007
Sen. Hatch, Orrin G. [R-UT]	R · UT		Jun 26, 2007
Sen. Schumer, Charles E. [D-NY]	D · NY		Jun 27, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Reported By	Nov 19, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Nov 19, 2008)

Biologics Price Competition and Innovation Act of 2007 - Amends the Public Health Service Act to allow a person to submit an application for licensure of a biological product based on its similarity to a licensed biological product (the reference product). Sets forth application requirements, including that the application demonstrate that: (1) the biological is biosimilar to a reference product based upon data derived from studies; (2) the biological product and reference product utilize the same mechanism of action; and (3) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product. Allows an application to include information demonstrating that the biological product is interchangeable with the reference product.

Requires the Secretary of Health and Human Services to license the biological product if the information submitted in the application is sufficient to show that the biological product is biosimilar to or interchangeable with the reference product.

Allows products to be determined to be interchangeable if: (1) the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient; and (2) the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Prohibits a biological product from being evaluated against more than one reference product.

Prohibits the Secretary from determining that a second or subsequent biological product is interchangeable with a reference product for any condition of use for specified periods based on the marketing of, and the presence or status of litigation involving, the first biosimilar biological product deemed interchangeable with the same reference product.

Prohibits approval of an application under this Act from being made effective until 12 years after the reference product was first licensed.

Authorizes the Secretary to issue guidance with respect to the licensure of a biological product after public comment. Requires the Secretary to establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance. Sets forth requirements for any product class-specific guidance that may be issued by the Secretary, including that such guidance include a description of the criteria that the Secretary will use to determine whether a biological product is highly similar to or interchangeable with a reference product in such product class.

Allows the Secretary to indicate in a guidance document that the science and experience with respect to a product or product class does not allow approval of an application for a license under this Act.

Sets forth provisions governing the exchange of confidential information related to patents for biological products. Requires confidential information to be used for the sole and exclusive purpose of determining whether a claim of patent infringement could reasonably be brought against the biosimilar biological product. Deems a disclosure of any confidential information in violation of this Act to cause the applicant to suffer irreparable harm for which there is no adequate legal remedy.

Requires good faith negotiations between the reference product sponsor and an applicant under this Act.

Sets forth provisions regarding patent infringement lawsuits, including the time frame for a reference product sponsor to bring an action for patent infringement.

Requires the Secretary to: (1) develop recommendations with respect to the goals for the review process of biosimilar

biological product applications; (2) collect and evaluate data regarding the cost of reviewing such applications; and (3) determine whether to alter the user fee applicable to such applications.

Establishes the Biological Product Savings Fund in the Treasury to be funded with savings to the federal government as a result of the enactment of this Act and to be expended on activities authorized under the Public Health Service Act.

Directs the Comptroller General to study and report to Congress on: (1) the extent to which pediatric studies of biological products are required under the Federal Food, Drug, and Cosmetic Act; and (2) any pediatric needs not being met under existing authority.

Extends the time frame for a sponsor to have market exclusivity for a biological product designated for a rare disease or condition.

Actions Timeline

- **Nov 19, 2008:** Committee on Health, Education, Labor, and Pensions. Reported by Senator Kennedy with an amendment in the nature of a substitute. Without written report.
- **Nov 19, 2008:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 1127.
- **Jun 27, 2007:** Committee on Health, Education, Labor, and Pensions. Ordered to be reported with an amendment in the nature of a substitute favorably.
- **Jun 26, 2007:** Introduced in Senate
- **Jun 26, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.