S 1505

Affordable Biologics for Consumers Act

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 24, 2007
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. (May 24, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/1505

Sponsor

Name: Sen. Gregg, Judd [R-NH]
Party: Republican • **State:** NH • **Chamber:** Senate

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Burr, Richard [R-NC]	R · NC		May 24, 2007
Sen. Coburn, Tom [R-OK]	R · OK		May 24, 2007

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 24, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 24, 2007)

Affordable Biologics for Consumers Act - Amends the Public Health Service Act to allow any person to submit an application for approval of a biologics license for a biosimilar, which is defined as a biological product that is claimed to be similar to a qualified biological product (the reference product). Defines a "qualified biological product" as a biotechnology-derived therapeutic biological or protein product licensed or approved under the Federal Food, Drug, and Cosmetic Act.

Allows the Secretary of Health and Human Services to approve an application for a biosimilar only: (1) for indications for which the reference product is approved; and (2) if the application conforms to the applicable final product class-specific rule and the Secretary concludes that the product is safe, pure, and potent.

Authorizes a person to request the issuance of a product class-specific rule applicable to a qualified biological product and its class.

Requires the Secretary to establish a Biosimilars Advisory Committee.

Prohibits the approval of a biosimilar until at least 14 years have elapsed from approval of the reference product.

Prohibits the Secretary from: (1) approving a product that is claimed to be similar to or the same as a reference product under any other provision of law; (2) approving another biosimilar for one year after approving the first biosimilar that relies on the same reference product; and (3) designating a biosimilar as interchangeable with (or therapeutically equivalent to) the applicable reference product.

Sets forth provisions related to patents for a reference product. Allows approval of an application for a biosimilar to be effective even if patent litigation has not concluded.

Amends the Federal Food, Drug, and Cosmetic Act to deem as misbranded a biotechnology-derived therapeutic protein if its labeling fails to meet specified requirements.

Actions Timeline

- **May 24, 2007:** Introduced in Senate
- **May 24, 2007:** Sponsor introductory remarks on measure. (CR S6867)
- **May 24, 2007:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.