HR 1956

Patient Protection and Innovative Biologic Medicines Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 19, 2007
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 20, 2007)
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Sponsor

Name: Rep. Inslee, Jay [D-WA-1]
Party: Democratic • **State:** WA • **Chamber:** House

Cosponsors (25 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Baldwin, Tammy [D-WI-2]	D · WI		Apr 19, 2007
Rep. Green, Gene [D-TX-29]	D · TX		Apr 19, 2007
Rep. Towns, Edolphus [D-NY-10]	D · NY		May 1, 2007
Rep. Butterfield, G. K. [D-NC-1]	D · NC		May 9, 2007
Rep. Davis, Artur [D-AL-7]	D · AL		May 17, 2007
Rep. Kind, Ron [D-WI-3]	D · WI		May 17, 2007
Rep. Smith, Adam [D-WA-9]	D · WA		May 17, 2007
Rep. Crowley, Joseph [D-NY-7]	D · NY		May 21, 2007
Rep. Tauscher, Ellen O. [D-CA-10]	D · CA		May 21, 2007
Rep. Meeks, Gregory W. [D-NY-6]	D · NY		May 24, 2007
Rep. Melancon, Charlie [D-LA-3]	D · LA		Jun 25, 2007
Rep. Bishop, Timothy H. [D-NY-1]	D · NY		Jun 28, 2007
Rep. Moran, James P. [D-VA-8]	D · VA		Jul 17, 2007
Rep. Hooley, Darlene [D-OR-5]	D · OR		Jul 31, 2007
Rep. Hill, Baron P. [D-IN-9]	D · IN		Sep 25, 2007
Rep. Richardson, Laura [D-CA-37]	D · CA		Jan 29, 2008
Rep. Carson, Andre [D-IN-7]	D · IN		Apr 29, 2008
Rep. Murphy, Patrick J. [D-PA-8]	D · PA		May 15, 2008
Rep. Paul, Ron [R-TX-14]	R · TX		Jun 3, 2008
Rep. Sestak, Joe [D-PA-7]	D · PA		Jun 3, 2008
Rep. Kagen, Steve [D-WI-8]	D · WI		Jul 31, 2008
Rep. Baca, Joe [D-CA-43]	D · CA		Sep 9, 2008
Rep. Barrow, John [D-GA-12]	D · GA		Sep 23, 2008
Rep. Carney, Christopher P. [D-PA-10]	D · PA		Sep 23, 2008
Rep. Hinojosa, Ruben [D-TX-15]	D · TX		Sep 23, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 20, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 19, 2007)

Patient Protection and Innovative Biologic Medicines Act of 2007 - Amends the Public Health Service Act to allow any person to submit an application for approval of a biologics license for a biological product that is claimed to be similar to a qualified biological product (reference product) after 12 years have elapsed since the reference product was approved or licensed.

Allows the Secretary of Health and Human Services to approve such a similar biological product: (1) only if the applicant demonstrates that the product conforms to the applicable final product-class specific guidance and the Secretary concludes the product is safe, pure, and potent; (2) only for indications for which the reference product is approved; and (3) to be effective only after at least 14 years have elapsed since the reference product was approved or licensed.

Prohibits the Secretary from designating a similar biological product as therapeutically equivalent to the reference product.

Prohibits the Secretary from approving a product that is claimed to be similar to or the same as a reference product under any other provision of law.

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

Requires the Secretary to establish a Similar Biological Products Advisory Committee.

Sets forth provisions governing the naming of biotechnology-derived therapeutic protein and other biological products. Amends the Federal Food, Drug, and Cosmetic Act to deem a biotechnology-derived therapeutic protein to be misbranded if its labeling fails to meet the requirements of this Act.

Actions Timeline

- **Apr 20, 2007:** Referred to the Subcommittee on Health.
- **Apr 19, 2007:** Introduced in House
- **Apr 19, 2007:** Referred to the House Committee on Energy and Commerce.