

## HR 5629

Pathway for Biosimilars Act

**Congress:** 110 (2007–2009, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Mar 13, 2008

**Current Status:** Referred to the Subcommittee on Courts, the Internet, and Intellectual Property.

**Latest Action:** Referred to the Subcommittee on Courts, the Internet, and Intellectual Property. (Apr 14, 2008)

**Official Text:** <https://www.congress.gov/bill/110th-congress/house-bill/5629>

### Sponsor

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**Name:** Rep. Eshoo, Anna G. [D-CA-14]

**Party:** Democratic • **State:** CA • **Chamber:** House

**Cosponsors** (43 total)

<b>Cosponsor</b>	<b>Party / State</b>	<b>Role</b>	<b>Date Joined</b>
Rep. Barton, Joe [R-TX-6]	R · TX		Mar 13, 2008
Rep. Buyer, Steve [R-IN-4]	R · IN		Mar 13, 2008
Rep. Capuano, Michael E. [D-MA-8]	D · MA		Mar 13, 2008
Rep. Ferguson, Mike [R-NJ-7]	R · NJ		Mar 13, 2008
Rep. Hill, Baron P. [D-IN-9]	D · IN		Mar 13, 2008
Rep. Lofgren, Zoe [D-CA-16]	D · CA		Mar 13, 2008
Rep. Lynch, Stephen F. [D-MA-9]	D · MA		Mar 13, 2008
Rep. McGovern, James P. [D-MA-3]	D · MA		Mar 13, 2008
Rep. Murphy, Tim [R-PA-18]	R · PA		Mar 13, 2008
Rep. Pitts, Joseph R. [R-PA-16]	R · PA		Mar 13, 2008
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Mar 13, 2008
Rep. Upton, Fred [R-MI-6]	R · MI		Mar 13, 2008
Rep. Wynn, Albert Russell [D-MD-4]	D · MD		Mar 13, 2008
Rep. Boucher, Rick [D-VA-9]	D · VA		Apr 8, 2008
Rep. McCarthy, Kevin [R-CA-22]	R · CA		Apr 8, 2008
Rep. Delahunt, William D. [D-MA-10]	D · MA		Apr 15, 2008
Rep. Nunes, Devin [R-CA-21]	R · CA		Apr 15, 2008
Rep. Bilbray, Brian P. [R-CA-50]	R · CA		Apr 23, 2008
Rep. Thompson, Mike [D-CA-1]	D · CA		Apr 23, 2008
Rep. Honda, Michael M. [D-CA-15]	D · CA		Apr 29, 2008
Rep. Walsh, James T. [R-NY-25]	R · NY		Apr 30, 2008
Rep. Holden, Tim [D-PA-17]	D · PA		May 7, 2008
Rep. Sanchez, Loretta [D-CA-47]	D · CA		May 8, 2008
Rep. Shimkus, John [R-IL-19]	R · IL		May 14, 2008
Rep. Murphy, Patrick J. [D-PA-8]	D · PA		May 15, 2008
Rep. Carson, Andre [D-IN-7]	D · IN		May 20, 2008
Rep. Neal, Richard E. [D-MA-2]	D · MA		May 22, 2008
Rep. Price, David E. [D-NC-4]	D · NC		May 22, 2008
Rep. Pence, Mike [R-IN-6]	R · IN		Jun 12, 2008
Rep. Souder, Mark E. [R-IN-3]	R · IN		Jun 12, 2008
Rep. Davis, Susan A. [D-CA-53]	D · CA		Jun 17, 2008
Rep. Pascrell, Bill, Jr. [D-NJ-8]	D · NJ		Jun 26, 2008
Rep. Brady, Robert A. [D-PA-1]	D · PA		Jul 9, 2008
Rep. Herger, Wally [R-CA-2]	R · CA		Jul 10, 2008
Rep. Stearns, Cliff [R-FL-6]	R · FL		Jul 29, 2008
Rep. Petri, Thomas E. [R-WI-6]	R · WI		Jul 31, 2008
Rep. Ellsworth, Brad [D-IN-8]	D · IN		Aug 1, 2008
Rep. Donnelly, Joe [D-IN-2]	D · IN		Sep 17, 2008
Rep. Carney, Christopher P. [D-PA-10]	D · PA		Sep 23, 2008
Rep. Gerlach, Jim [R-PA-6]	R · PA		Sep 23, 2008
Rep. Fattah, Chaka [D-PA-2]	D · PA		Sep 26, 2008

Cosponsor	Party / State	Role	Date Joined
Rep. Dent, Charles W. [R-PA-15]	R · PA		Sep 29, 2008
Rep. Holt, Rush [D-NJ-12]	D · NJ		Sep 29, 2008

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 13, 2008
Judiciary Committee	House	Referred to	Apr 14, 2008

## Subjects & Policy Tags

### Policy Area:

Health

## Related Bills

*No related bills are listed.*

## Summary (as of Mar 13, 2008)

Pathway for Biosimilars Act - 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).

Requires the Secretary of Health and Human Services to approve the application if: (1) the biological product is biosimilar to the reference product with respect to each condition of use for which the reference product is approved; and (2) the applicant consents to the inspection of the facility that is the subject of the application.

Sets forth requirements for a determination by the Secretary that a biological product is interchangeable with a reference product.

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

Prohibits licensure under this Act of a biological product containing specified agents or toxins.

Prohibits the Secretary from making approval of an application under this Act effective until 12 years after the date on which the reference product was first licensed.

Provides for confidentiality of information received pursuant to this Act.

Sets forth provisions governing patent infringement actions related to this Act.

Deems as patent infringement the submission of a statement under this Act by the applicant setting forth reasons why the making, use, or sale of the biosimilar product would not infringe the patent, or why the patent is invalid or unenforceable, if the purpose of such submission is to obtain approval to engage in the commercial manufacture, use, or sale before the expiration of such patent.

## **Actions Timeline**

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- **Apr 14, 2008:** Referred to the Subcommittee on Courts, the Internet, and Intellectual Property.
- **Mar 13, 2008:** Introduced in House
- **Mar 13, 2008:** Sponsor introductory remarks on measure. (CR E401-402)
- **Mar 13, 2008:** Referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.
- **Mar 13, 2008:** Referred to the Subcommittee on Health.

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