

## HR 1548

Pathway for Biosimilars Act

**Congress:** 111 (2009–2011, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Mar 17, 2009

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (Mar 18, 2009)

**Official Text:** <https://www.congress.gov/bill/111th-congress/house-bill/1548>

### Sponsor

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

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

**Cosponsors** (149 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Baldwin, Tammy [D-WI-2]	D · WI		Mar 17, 2009
Rep. Barrow, John [D-GA-12]	D · GA		Mar 17, 2009
Rep. Barton, Joe [R-TX-6]	R · TX		Mar 17, 2009
Rep. Bean, Melissa L. [D-IL-8]	D · IL		Mar 17, 2009
Rep. Bilbray, Brian P. [R-CA-50]	R · CA		Mar 17, 2009
Rep. Bishop, Timothy H. [D-NY-1]	D · NY		Mar 17, 2009
Rep. Bono Mack, Mary [R-CA-45]	R · CA		Mar 17, 2009
Rep. Capuano, Michael E. [D-MA-8]	D · MA		Mar 17, 2009
Rep. Crowley, Joseph [D-NY-7]	D · NY		Mar 17, 2009
Rep. Davis, Susan A. [D-CA-53]	D · CA		Mar 17, 2009
Rep. Delahunt, Bill [D-MA-10]	D · MA		Mar 17, 2009
Rep. Dent, Charles W. [R-PA-15]	R · PA		Mar 17, 2009
Rep. Donnelly, Joe [D-IN-2]	D · IN		Mar 17, 2009
Rep. Dreier, David [R-CA-26]	R · CA		Mar 17, 2009
Rep. Ellsworth, Brad [D-IN-8]	D · IN		Mar 17, 2009
Rep. Gerlach, Jim [R-PA-6]	R · PA		Mar 17, 2009
Rep. Green, Gene [D-TX-29]	D · TX		Mar 17, 2009
Rep. Hall, Ralph M. [R-TX-4]	R · TX		Mar 17, 2009
Rep. Herger, Wally [R-CA-2]	R · CA		Mar 17, 2009
Rep. Hill, Baron P. [D-IN-9]	D · IN		Mar 17, 2009
Rep. Holt, Rush [D-NJ-12]	D · NJ		Mar 17, 2009
Rep. Honda, Michael M. [D-CA-15]	D · CA		Mar 17, 2009
Rep. Inslee, Jay [D-WA-1]	D · WA		Mar 17, 2009
Rep. Issa, Darrell E. [R-CA-49]	R · CA		Mar 17, 2009
Rep. Kind, Ron [D-WI-3]	D · WI		Mar 17, 2009
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Mar 17, 2009
Rep. Lofgren, Zoe [D-CA-16]	D · CA		Mar 17, 2009
Rep. Lynch, Stephen F. [D-MA-9]	D · MA		Mar 17, 2009
Rep. McCarthy, Kevin [R-CA-22]	R · CA		Mar 17, 2009
Rep. McGovern, James P. [D-MA-3]	D · MA		Mar 17, 2009
Rep. Murphy, Patrick J. [D-PA-8]	D · PA		Mar 17, 2009
Rep. Neal, Richard E. [D-MA-2]	D · MA		Mar 17, 2009
Rep. Nunes, Devin [R-CA-21]	R · CA		Mar 17, 2009
Rep. Pence, Mike [R-IN-6]	R · IN		Mar 17, 2009
Rep. Pitts, Joseph R. [R-PA-16]	R · PA		Mar 17, 2009
Rep. Rogers, Mike J. [R-MI-8]	R · MI		Mar 17, 2009
Rep. Scalise, Steve [R-LA-1]	R · LA		Mar 17, 2009
Rep. Smith, Adam [D-WA-9]	D · WA		Mar 17, 2009
Rep. Souder, Mark E. [R-IN-3]	R · IN		Mar 17, 2009
Rep. Tauscher, Ellen O. [D-CA-10]	D · CA		Mar 17, 2009
Rep. Thompson, Mike [D-CA-1]	D · CA		Mar 17, 2009

Cosponsor	Party / State	Role	Date Joined
Rep. Towns, Edolphus [D-NY-10]	D · NY		Mar 17, 2009
Rep. Upton, Fred [R-MI-6]	R · MI		Mar 17, 2009
Rep. Carney, Christopher P. [D-PA-10]	D · PA		Mar 18, 2009
Rep. Fattah, Chaka [D-PA-2]	D · PA		Mar 18, 2009
Rep. Holden, Tim [D-PA-17]	D · PA		Mar 18, 2009
Rep. Larson, John B. [D-CT-1]	D · CT		Mar 18, 2009
Rep. Pascrell, Bill, Jr. [D-NJ-8]	D · NJ		Mar 18, 2009
Rep. Sullivan, John [R-OK-1]	R · OK		Mar 18, 2009
Rep. Sanchez, Loretta [D-CA-47]	D · CA		Mar 19, 2009
Rep. Brady, Robert A. [D-PA-1]	D · PA		Mar 24, 2009
Rep. Petri, Thomas E. [R-WI-6]	R · WI		Mar 24, 2009
Rep. Wilson, Joe [R-SC-2]	R · SC		Mar 24, 2009
Rep. Carson, Andre [D-IN-7]	D · IN		Mar 25, 2009
Rep. Kagen, Steve [D-WI-8]	D · WI		Apr 1, 2009
Rep. Meeks, Gregory W. [D-NY-6]	D · NY		Apr 1, 2009
Rep. Ros-Lehtinen, Ileana [R-FL-18]	R · FL		Apr 1, 2009
Rep. Sessions, Pete [R-TX-32]	R · TX		Apr 1, 2009
Rep. Price, David E. [D-NC-4]	D · NC		Apr 2, 2009
Rep. Biggert, Judy [R-IL-13]	R · IL		Apr 22, 2009
Rep. McCotter, Thaddeus G. [R-MI-11]	R · MI		Apr 22, 2009
Rep. Shuler, Heath [D-NC-11]	D · NC		Apr 22, 2009
Rep. Courtney, Joe [D-CT-2]	D · CT		Apr 23, 2009
Rep. McMahon, Michael E. [D-NY-13]	D · NY		Apr 23, 2009
Rep. Schwartz, Allyson Y. [D-PA-13]	D · PA		Apr 23, 2009
Rep. Whitfield, Ed [R-KY-1]	R · KY		Apr 27, 2009
Rep. Melancon, Charlie [D-LA-3]	D · LA		May 4, 2009
Rep. Hodes, Paul W. [D-NH-2]	D · NH		May 5, 2009
Rep. Kosmas, Suzanne M. [D-FL-24]	D · FL		May 5, 2009
Rep. Walden, Greg [R-OR-2]	R · OR		May 11, 2009
Rep. Adler, John H. [D-NJ-3]	D · NJ		May 12, 2009
Rep. Altmire, Jason [D-PA-4]	D · PA		May 12, 2009
Rep. Neugebauer, Randy [R-TX-19]	R · TX		May 12, 2009
Rep. Edwards, Chet [D-TX-17]	D · TX		May 13, 2009
Rep. Johnson, Sam [R-TX-3]	R · TX		May 18, 2009
Rep. Cao, Anh "Joseph" [R-LA-2]	R · LA		May 20, 2009
Rep. Kratovil, Frank, Jr. [D-MD-1]	D · MD		May 20, 2009
Rep. Murtha, John P. [D-PA-12]	D · PA		May 20, 2009
Rep. Cassidy, Bill [R-LA-6]	R · LA		Jun 2, 2009
Rep. Gonzalez, Charles A. [D-TX-20]	D · TX		Jun 2, 2009
Rep. Graves, Sam [R-MO-6]	R · MO		Jun 2, 2009
Rep. Halvorson, Deborah L. [D-IL-11]	D · IL		Jun 2, 2009
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Jun 2, 2009

Cosponsor	Party / State	Role	Date Joined
Rep. Roe, David P. [R-TN-1]	R · TN		Jun 2, 2009
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Jun 4, 2009
Rep. Latham, Tom [R-IA-4]	R · IA		Jun 4, 2009
Rep. Matheson, Jim [D-UT-2]	D · UT		Jun 4, 2009
Resident Commissioner Pierluisi, Pedro R. [D-PR-At Large]	D · PR		Jun 9, 2009
Rep. Alexander, Rodney [R-LA-5]	R · LA		Jun 10, 2009
Rep. Lee, Christopher J. [R-NY-26]	R · NY		Jun 10, 2009
Rep. Lungren, Daniel E. [R-CA-3]	R · CA		Jun 10, 2009
Rep. Speier, Jackie [D-CA-12]	D · CA		Jun 10, 2009
Rep. Boyd, Allen [D-FL-2]	D · FL		Jun 12, 2009
Rep. Grayson, Alan [D-FL-8]	D · FL		Jun 12, 2009
Rep. Markey, Betsy [D-CO-4]	D · CO		Jun 12, 2009
Rep. Michaud, Michael H. [D-ME-2]	D · ME		Jun 12, 2009
Rep. Tiberi, Patrick J. [R-OH-12]	R · OH		Jun 12, 2009
Rep. Farr, Sam [D-CA-17]	D · CA		Jun 15, 2009
Rep. Garrett, Scott [R-NJ-5]	R · NJ		Jun 15, 2009
Rep. Davis, Danny K. [D-IL-7]	D · IL		Jun 16, 2009
Rep. Moran, Jerry [R-KS-1]	R · KS		Jun 16, 2009
Rep. Kissell, Larry [D-NC-8]	D · NC		Jun 18, 2009
Rep. Latta, Robert E. [R-OH-5]	R · OH		Jun 18, 2009
Rep. Massa, Eric J. J. [D-NY-29]	D · NY		Jun 19, 2009
Rep. Coble, Howard [R-NC-6]	R · NC		Jun 23, 2009
Rep. Schock, Aaron [R-IL-18]	R · IL		Jun 23, 2009
Rep. Smith, Adrian [R-NE-3]	R · NE		Jun 24, 2009
Rep. Buyer, Steve [R-IN-4]	R · IN		Jun 26, 2009
Rep. Baca, Joe [D-CA-43]	D · CA		Jul 7, 2009
Rep. Griffith, Parker [D-AL-5]	D · AL		Jul 7, 2009
Rep. Richardson, Laura [D-CA-37]	D · CA		Jul 7, 2009
Rep. Roskam, Peter J. [R-IL-6]	R · IL		Jul 7, 2009
Rep. Bartlett, Roscoe G. [R-MD-6]	R · MD		Jul 8, 2009
Rep. Austria, Steve [R-OH-7]	R · OH		Jul 9, 2009
Rep. Boustany, Charles W., Jr. [R-LA-7]	R · LA		Jul 9, 2009
Rep. Connolly, Gerald E. [D-VA-11]	D · VA		Jul 9, 2009
Rep. Conyers, John, Jr. [D-MI-14]	D · MI		Jul 9, 2009
Rep. Hastings, Alcee L. [D-FL-23]	D · FL		Jul 9, 2009
Rep. Kennedy, Patrick J. [D-RI-1]	D · RI		Jul 9, 2009
Rep. McHenry, Patrick T. [R-NC-10]	R · NC		Jul 9, 2009
Rep. Miller, Brad [D-NC-13]	D · NC		Jul 9, 2009
Rep. Reichert, David G. [R-WA-8]	R · WA		Jul 9, 2009
Rep. Waters, Maxine [D-CA-35]	D · CA		Jul 9, 2009
Rep. Woolsey, Lynn C. [D-CA-6]	D · CA		Jul 9, 2009
Rep. Wu, David [D-OR-1]	D · OR		Jul 9, 2009

Cosponsor	Party / State	Role	Date Joined
Rep. Himes, James A. [D-CT-4]	D · CT		Jul 10, 2009
Rep. Rehberg, Denny [R-MT-At Large]	R · MT		Jul 10, 2009
Rep. Murphy, Scott [D-NY-20]	D · NY		Jul 13, 2009
Rep. Olson, Pete [R-TX-22]	R · TX		Jul 13, 2009
Rep. Rodriguez, Ciro D. [D-TX-23]	D · TX		Jul 13, 2009
Rep. Tanner, John S. [D-TN-8]	D · TN		Jul 13, 2009
Rep. Murphy, Christopher [D-CT-5]	D · CT		Jul 15, 2009
Rep. Stearns, Cliff [R-FL-6]	R · FL		Jul 15, 2009
Rep. Campbell, John [R-CA-48]	R · CA		Jul 16, 2009
Rep. Carter, John R. [R-TX-31]	R · TX		Jul 16, 2009
Rep. Space, Zachary T. [D-OH-18]	D · OH		Jul 16, 2009
Rep. Ruppersberger, C. A. Dutch [D-MD-2]	D · MD		Jul 20, 2009
Rep. Burton, Dan [R-IN-5]	R · IN		Jul 22, 2009
Rep. Conaway, K. Michael [R-TX-11]	R · TX		Jul 22, 2009
Rep. Heinrich, Martin [D-NM-1]	D · NM		Jul 28, 2009
Rep. Kanjorski, Paul E. [D-PA-11]	D · PA		Jul 28, 2009
Rep. Teague, Harry [D-NM-2]	D · NM		Jul 29, 2009
Rep. Peters, Gary C. [D-MI-9]	D · MI		Sep 22, 2009
Rep. Luetkemeyer, Blaine [R-MO-9]	R · MO		Sep 29, 2009
Rep. Moran, James P. [D-VA-8]	D · VA		Oct 7, 2009
Rep. Terry, Lee [R-NE-2]	R · NE		Oct 27, 2009
Rep. Clarke, Yvette D. [D-NY-11]	D · NY		Oct 29, 2009
Rep. Foster, Bill [D-IL-14]	D · IL		Oct 29, 2009
Rep. Castle, Michael N. [R-DE-At Large]	R · DE		Nov 3, 2009

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 18, 2009
Judiciary Committee	House	Referred To	Mar 17, 2009

### Subjects & Policy Tags

#### Policy Area:

Health

#### Related Bills

No related bills are listed.

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 or a schedule I or II controlled substance unless the Secretary determines there would be no increased risk to the security or health of the public from licensing such a biological product.

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.

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## **Actions Timeline**

- **Mar 18, 2009:** Referred to the Subcommittee on Health.
- **Mar 17, 2009:** Introduced in House
- **Mar 17, 2009:** Sponsor introductory remarks on measure. (CR E687-688)
- **Mar 17, 2009:** Referred to House Energy and Commerce
- **Mar 17, 2009:** 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 17, 2009:** Referred to House Judiciary