

HR 1427

Promoting Innovation and Access to Life-Saving Medicine Act

Congress: 111 (2009–2011, Ended)

Chamber: House

Policy Area: Health

Introduced: Mar 11, 2009

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Mar 12, 2009)

Official Text: <https://www.congress.gov/bill/111th-congress/house-bill/1427>

Sponsor

Name: Rep. Waxman, Henry A. [D-CA-30]

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

Cosponsors (17 total)

| Cosponsor | Party / State | Role | Date Joined |
|-------------------------------------|---------------|------|--------------|
| Rep. Deal, Nathan [R-GA-9] | R · GA | | Mar 11, 2009 |
| Rep. Emerson, Jo Ann [R-MO-8] | R · MO | | Mar 11, 2009 |
| Rep. Pallone, Frank, Jr. [D-NJ-6] | D · NJ | | Mar 11, 2009 |
| Rep. Capps, Lois [D-CA-23] | D · CA | | Mar 18, 2009 |
| Rep. Himes, James A. [D-CT-4] | D · CT | | Mar 18, 2009 |
| Rep. Schakowsky, Janice D. [D-IL-9] | D · IL | | Mar 18, 2009 |
| Rep. Thornberry, Mac [R-TX-13] | R · TX | | Mar 18, 2009 |
| Rep. Kingston, Jack [R-GA-1] | R · GA | | Mar 25, 2009 |
| Rep. Sarbanes, John P. [D-MD-3] | D · MD | | Apr 1, 2009 |
| Rep. Grijalva, Raúl M. [D-AZ-7] | D · AZ | | Apr 21, 2009 |
| Rep. Wolf, Frank R. [R-VA-10] | R · VA | | Apr 27, 2009 |
| Rep. Linder, John [R-GA-7] | R · GA | | May 20, 2009 |
| Rep. Arcuri, Michael A. [D-NY-24] | D · NY | | Jun 15, 2009 |
| Rep. Conyers, John, Jr. [D-MI-14] | D · MI | | Jul 13, 2009 |
| Rep. Paul, Ron [R-TX-14] | R · TX | | Jul 20, 2009 |
| Rep. Kaptur, Marcy [D-OH-9] | D · OH | | Oct 7, 2009 |
| Rep. Young, Don [R-AK-At Large] | R · AK | | Oct 15, 2009 |

Committee Activity

| Committee | Chamber | Activity | Date |
|-------------------------------|---------|-------------|--------------|
| Energy and Commerce Committee | House | Referred to | Mar 12, 2009 |
| Judiciary Committee | House | Referred To | Mar 11, 2009 |

Subjects & Policy Tags

Policy Area:

Health

Related Bills

| Bill | Relationship | Last Action |
|-----------|----------------|--|
| 111 S 726 | Identical bill | Mar 26, 2009: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. |

Summary (as of Mar 11, 2009)

Promoting Innovation and Access to Life-Saving Medicine Act - Amends the Public Health Service Act to provide for the licensing of biosimilar and interchangeable biological products. Defines "biosimilar" and "interchangeability" for purposes of this Act.

Allows any person to file an abbreviated biological product application with the Secretary of Health and Human Services. Requires such applications to include information demonstrating a high degree of similarity or interchangeability between the biological product and the licensed biological product (reference product).

Requires the Secretary to: (1) approve an application and issue a license for a biosimilar product unless the Secretary finds and informs the applicant that the information in the application fails to demonstrate biosimilarity between the biological product and the reference product or the safety, purity, and potency of the biological product; and (2) establish requirements for the efficient review, approval, suspension, and revocation of abbreviated biological product applications.

Allows an applicant to request the Secretary to make a determination as to the interchangeability of a product and its reference product based on whether a product can be expected to produce the same clinical result as the reference product in any given patient. Grants market exclusivity to any biological product that is determined to be interchangeable for a specified period.

Sets forth provisions governing patent infringement claims involving comparable biological products and legal remedies to expedite the adjudication of patent infringement disputes.

Extends the period for approval of biological products to allow for studies of the use of new biological products in the pediatric population.

Actions Timeline

- **Mar 12, 2009:** Referred to the Subcommittee on Health.
- **Mar 11, 2009:** Introduced in House
- **Mar 11, 2009:** Referred to House Energy and Commerce
- **Mar 11, 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 11, 2009:** Referred to House Judiciary