HR 931

HEAL Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 12, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 13, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/931

Sponsor

Name: Rep. DeLauro, Rosa L. [D-CT-3]
Party: Democratic • **State:** CT • **Chamber:** House

Cosponsors (7 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Meng, Grace [D-NY-6]	D · NY		Feb 12, 2015
Rep. Slaughter, Louise McIntosh [D-NY-25]	D · NY		Feb 12, 2015
Rep. Ellison, Keith [D-MN-5]	D · MN		Feb 24, 2015
Rep. Grijalva, Raúl M. [D-AZ-3]	D · AZ		Feb 24, 2015
Rep. DeFazio, Peter A. [D-OR-4]	D · OR		Mar 16, 2015
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Apr 14, 2015
Rep. McCollum, Betty [D-MN-4]	D · MN		Jun 23, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 13, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 12, 2015)

Helping Effective Antibiotics Last Act of 2015 or the HEAL Act

This bill amends the Federal Food, Drug, and Cosmetic Act to allow the Food and Drug Administration (FDA) to approve an antibacterial drug or biological product that is intended to treat a serious or life-threatening condition only for treating a well-defined population of patients. To be approved, the antibacterial product must produce superior outcomes over available therapies in the well-defined patient population.

A product approved by this pathway must include in its prescribing information the population of patients expected to benefit from using the product and the method for identifying members of that population. The FDA must require each product to have a risk evaluation and mitigation strategy.

The Centers for Disease Control and Prevention must monitor changes to bacterial drug resistance and changes to patient outcomes caused by bacterial drug resistance.

Upon approval of antibacterial products, the FDA must identify susceptibility test interpretive criteria (the drug concentrations where a type of bacteria is categorized as susceptible, intermediate, or resistant) and update the criteria as needed based upon evidence of changes in patient outcomes.

To be eligible for an exclusivity period extension, a qualified infectious disease product must be demonstrated to produce superior outcomes over available therapies.
The FDA must issue guidance on the development of target product profiles for antibacterial drugs.

Actions Timeline

- **Feb 13, 2015:** Referred to the Subcommittee on Health.
- **Feb 12, 2015:** Introduced in House
- **Feb 12, 2015:** Referred to the House Committee on Energy and Commerce.

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