HR 2629

Antibiotic Development to Advance Patient Treatment Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Jun 3, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Jun 5, 2015)
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Sponsor

Name: Rep. Shimkus, John [R-IL-15]
Party: Republican • **State:** IL • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Green, Gene [D-TX-29]	D · TX		Jun 3, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 5, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jun 3, 2015)

Antibiotic Development to Advance Patient Treatment Act

This bill amends the Federal Food, Drug, and Cosmetic Act to allow the Food and Drug Administration (FDA) to agree with the sponsor of an applicable medication on a process for approving the medication for use in a limited population of patients. Applicable medications are antibacterial or antifungal drugs or biological products for the treatment of a serious infection. The FDA may rely on alternate study endpoints, limited data sets, and additional data, including preclinical evidence, in approving such a medication.

A medication approved for use in a limited population must be labeled accordingly.

The Public Health Service Act is amended to require the Department of Health and Human Services to monitor the use of antibacterial and antifungal medications and monitor antibacterial and antifungal resistance. (An individual infected by a strain of bacteria or fungi that is resistant to a medication cannot be treated with that medication. Resistance can develop naturally with the use of a medication.)

The FDA must identify and publish susceptibility test interpretive criteria for antimicrobial medications. (These criteria are used to characterize the resistance of microbes to antimicrobial medications. "Microbes" or "microorganisms" include bacteria, some fungi, and other organisms.)

Every six months, the FDA must evaluate any new or updated susceptibility test interpretive criteria established by a standard development organization and recognize new criteria or withdraw recognition of criteria, as appropriate. The FDA may allow marketing of medical devices that use these criteria without premarket approval.

Actions Timeline

- **Jun 5, 2015:** Referred to the Subcommittee on Health.
- **Jun 3, 2015:** Introduced in House
- **Jun 3, 2015:** Referred to the House Committee on Energy and Commerce.