S 1421

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 21, 2015
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (May 21, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/1421

Sponsor

Name: Sen. Hatch, Orrin G. [R-UT]
Party: Republican • **State:** UT • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Klobuchar, Amy [D-MN]	D · MN		May 21, 2015
Sen. Scott, Tim [R-SC]	R · SC		Jun 9, 2015
Sen. Kirk, Mark Steven [R-IL]	R · IL		Feb 8, 2016
Sen. Menendez, Robert [D-NJ]	D · NJ		Apr 12, 2016
Sen. Tillis, Thomas [R-NC]	R · NC		Jun 9, 2016
Sen. Booker, Cory A. [D-NJ]	D · NJ		Jun 20, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 21, 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.
114 HR 971	Related bill	**Feb 20, 2015:** Referred to the Subcommittee on Health.

Summary (as of May 21, 2015)

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2015

Amends the Federal Food, Drug, and Cosmetic Act to require the Department of Health and Human Services (HHS) to extend by six months the exclusivity period for a drug or biological product approved by the Food and Drug Administration (FDA) when the product is additionally approved to prevent, diagnose, or treat a new indication that is a rare disease or condition (also known as an "orphan disease").

Allows HHS to revoke an extension if the application submitted to the FDA for the new indication contained an untrue material statement.

Requires the sponsor of a product receiving an extension to notify HHS one year prior to discontinuing production for commercial reasons.

Requires HHS to notify the public of products that receive this extension and patents related to those products.

Limits a product to one extension under this Act. Sets forth that extensions under this Act are in addition to other extensions.
Applies only to products approved after enactment of this Act for a new indication that is a rare disease or condition.

Actions Timeline

- **May 21, 2015:** Introduced in Senate
- **May 21, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.