HR 971

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 13, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 20, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/971

Sponsor

Name: Rep. Bilirakis, Gus M. [R-FL-12]
Party: Republican • **State:** FL • **Chamber:** House

Cosponsors (21 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Feb 13, 2015
Rep. McCaul, Michael T. [R-TX-10]	R · TX		Feb 13, 2015
Rep. Graves, Sam [R-MO-6]	R · MO		Mar 3, 2015
Rep. Grothman, Glenn [R-WI-6]	R · WI		Mar 3, 2015
Rep. Poliquin, Bruce [R-ME-2]	R · ME		Mar 3, 2015
Rep. Fortenberry, Jeff [R-NE-1]	R · NE		Mar 17, 2015
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Mar 17, 2015
Rep. Davis, Rodney [R-IL-13]	R · IL		Apr 13, 2015
Rep. Hastings, Alcee L. [D-FL-20]	D · FL		Apr 13, 2015
Rep. Quigley, Mike [D-IL-5]	D · IL		Apr 15, 2015
Rep. Gibson, Christopher P. [R-NY-19]	R · NY		Apr 21, 2015
Rep. Nugent, Richard B. [R-FL-11]	R · FL		Apr 21, 2015
Rep. Paulsen, Erik [R-MN-3]	R · MN		Apr 28, 2015
Rep. Scalise, Steve [R-LA-1]	R · LA		May 13, 2015
Rep. Huffman, Jared [D-CA-2]	D · CA		Jun 2, 2015
Rep. Ashford, Brad [D-NE-2]	D · NE		Mar 7, 2016
Rep. Rohrabacher, Dana [R-CA-48]	R · CA		Mar 7, 2016
Rep. Frelinghuysen, Rodney P. [R-NJ-11]	R · NJ		Mar 17, 2016
Rep. Smith, Christopher H. [R-NJ-4]	R · NJ		May 13, 2016
Rep. Fitzpatrick, Michael G. [R-PA-8]	R · PA		Sep 7, 2016
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Sep 8, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 20, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 S 1421	Related bill	**May 21, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Feb 13, 2015)

Orphan Product Extensions Now Accelerating Cures and Treatments Act of 2015

Amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to extend by six months the exclusivity period for an approved drug or biological product 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 the FDA to revoke an extension if the application for the new indication contained an untrue material statement.

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

Requires the FDA 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

- **Feb 20, 2015:** Referred to the Subcommittee on Health.
- **Feb 13, 2015:** Introduced in House
- **Feb 13, 2015:** Referred to the House Committee on Energy and Commerce.

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