

## HR 5182

Promoting Life-Saving New Therapies for Neonates Act of 2016

**Congress:** 114 (2015–2017, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 10, 2016

**Current Status:** Referred to the Subcommittee on Health.

**Latest Action:** Referred to the Subcommittee on Health. (May 13, 2016)

**Official Text:** <https://www.congress.gov/bill/114th-congress/house-bill/5182>

### Sponsor

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**Name:** Rep. Long, Billy [R-MO-7]

**Party:** Republican • **State:** MO • **Chamber:** House

Cosponsors (33 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Lujan, Ben Ray [D-NM-3]	D · NM		May 10, 2016
Rep. Adams, Alma S. [D-NC-12]	D · NC		May 23, 2016
Rep. Connolly, Gerald E. [D-VA-11]	D · VA		Jun 8, 2016
Rep. Pascrell, Bill, Jr. [D-NJ-9]	D · NJ		Jun 10, 2016
Rep. Poliquin, Bruce [R-ME-2]	R · ME		Jun 10, 2016
Rep. Veasey, Marc A. [D-TX-33]	D · TX		Jun 10, 2016
Rep. Aguilar, Pete [D-CA-31]	D · CA		Jun 16, 2016
Rep. Gallego, Ruben [D-AZ-7]	D · AZ		Jun 16, 2016
Rep. Guthrie, Brett [R-KY-2]	R · KY		Jun 16, 2016
Rep. Norcross, Donald [D-NJ-1]	D · NJ		Jun 16, 2016
Rep. Duffy, Sean P. [R-WI-7]	R · WI		Jul 5, 2016
Rep. Murphy, Patrick [D-FL-18]	D · FL		Jul 5, 2016
Rep. Rice, Kathleen M. [D-NY-4]	D · NY		Jul 5, 2016
Rep. Sires, Albio [D-NJ-8]	D · NJ		Jul 5, 2016
Rep. Jenkins, Evan H. [R-WV-3]	R · WV		Jul 6, 2016
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Jul 6, 2016
Rep. Ashford, Brad [D-NE-2]	D · NE		Jul 12, 2016
Rep. Mooney, Alexander X. [R-WV-2]	R · WV		Jul 12, 2016
Rep. Moulton, Seth [D-MA-6]	D · MA		Jul 12, 2016
Rep. Napolitano, Grace F. [D-CA-32]	D · CA		Jul 12, 2016
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Jul 13, 2016
Rep. King, Peter T. [R-NY-2]	R · NY		Jul 13, 2016
Rep. Rush, Bobby L. [D-IL-1]	D · IL		Jul 13, 2016
Rep. Bishop, Mike [R-MI-8]	R · MI		Jul 14, 2016
Rep. Cárdenas, Tony [D-CA-29]	D · CA		Sep 6, 2016
Rep. Israel, Steve [D-NY-3]	D · NY		Sep 6, 2016
Rep. Kilmer, Derek [D-WA-6]	D · WA		Sep 6, 2016
Rep. Dold, Robert J. [R-IL-10]	R · IL		Sep 20, 2016
Rep. Kelly, Mike [R-PA-3]	R · PA		Sep 20, 2016
Rep. Peters, Scott H. [D-CA-52]	D · CA		Sep 22, 2016
Rep. Loebsack, David [D-IA-2]	D · IA		Sep 27, 2016
Rep. Paulsen, Erik [R-MN-3]	R · MN		Sep 28, 2016
Rep. Price, David E. [D-NC-4]	D · NC		Sep 28, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 13, 2016

Subjects & Policy Tags

Policy Area:

Health

## Related Bills

Bill	Relationship	Last Action
114 S 2041	Related bill	Sep 16, 2015: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## Summary (as of May 10, 2016)

### Promoting Life-Saving New Therapies for Neonates Act of 2016

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA) to award the sponsor of a new drug or biological product for the treatment of newborns a neonatal drug exclusivity voucher upon approval of the medication. A neonatal drug exclusivity voucher is a transferable voucher for a one-year extension of all existing patents and marketing exclusivities for a brand name medication. For a sponsor to be eligible for a voucher, the new medication must: (1) treat a condition identified in the Priority List of Critical Needs for Neonates required under this bill, and (2) have been studied in newborns.

A voucher may be revoked if the new medication is not marketed in the United States within one year of approval.

A voucher may not be used: (1) to extend the marketing exclusivity period for a drug for which the FDA requires an assessment of the safety and effectiveness in newborns, or (2) on the same product as a priority review voucher.

A sponsor intending to use a voucher must notify the FDA at least 15 months before the expiration of the patents or exclusivity to be extended.

The Government Accountability Office must study the effectiveness of this voucher program.

## Actions Timeline

- **May 13, 2016:** Referred to the Subcommittee on Health.
- **May 10, 2016:** Introduced in House
- **May 10, 2016:** Referred to the House Committee on Energy and Commerce.