

## HR 2641

### Promoting Life-Saving New Therapies for Neonates Act of 2017

**Congress:** 115 (2017–2019, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** May 24, 2017

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

**Latest Action:** Referred to the Subcommittee on Health. (May 26, 2017)

**Official Text:** <https://www.congress.gov/bill/115th-congress/house-bill/2641>

## Sponsor

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

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

## Cosponsors (37 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Lujan, Ben Ray [D-NM-3]	D · NM		May 24, 2017
Rep. Garamendi, John [D-CA-3]	D · CA		Jun 7, 2017
Rep. Napolitano, Grace F. [D-CA-32]	D · CA		Jun 7, 2017
Rep. Pascrell, Bill, Jr. [D-NJ-9]	D · NJ		Jun 7, 2017
Rep. Blunt Rochester, Lisa [D-DE-At Large]	D · DE		Jun 13, 2017
Rep. Cárdenas, Tony [D-CA-29]	D · CA		Jun 13, 2017
Rep. Connolly, Gerald E. [D-VA-11]	D · VA		Jun 13, 2017
Rep. DeSaulnier, Mark [D-CA-11]	D · CA		Jun 13, 2017
Rep. Kilmer, Derek [D-WA-6]	D · WA		Jun 13, 2017
Rep. Moulton, Seth [D-MA-6]	D · MA		Jun 13, 2017
Rep. Peters, Scott H. [D-CA-52]	D · CA		Jun 13, 2017
Rep. Rice, Kathleen M. [D-NY-4]	D · NY		Jun 13, 2017
Rep. Aguilar, Pete [D-CA-31]	D · CA		Jun 21, 2017
Rep. Guthrie, Brett [R-KY-2]	R · KY		Jun 21, 2017
Rep. Jenkins, Lynn [R-KS-2]	R · KS		Jun 21, 2017
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Jun 21, 2017
Rep. Poliquin, Bruce [R-ME-2]	R · ME		Jun 21, 2017
Rep. Tipton, Scott R. [R-CO-3]	R · CO		Jul 13, 2017
Rep. Mooney, Alexander X. [R-WV-2]	R · WV		Jul 25, 2017
Rep. Paulsen, Erik [R-MN-3]	R · MN		Jul 25, 2017
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Jul 28, 2017
Rep. Kind, Ron [D-WI-3]	D · WI		Jul 28, 2017
Rep. Maloney, Sean Patrick [D-NY-18]	D · NY		Sep 5, 2017
Rep. Moore, Gwen [D-WI-4]	D · WI		Sep 5, 2017
Rep. Smith, Jason [R-MO-8]	R · MO		Sep 5, 2017
Rep. Hudson, Richard [R-NC-8]	R · NC		Sep 25, 2017
Rep. Norcross, Donald [D-NJ-1]	D · NJ		Sep 25, 2017
Rep. Veasey, Marc A. [D-TX-33]	D · TX		Sep 27, 2017
Rep. Frelinghuysen, Rodney P. [R-NJ-11]	R · NJ		Oct 3, 2017
Rep. King, Peter T. [R-NY-2]	R · NY		Oct 12, 2017
Rep. Roskam, Peter J. [R-IL-6]	R · IL		Oct 12, 2017
Rep. Price, David E. [D-NC-4]	D · NC		Oct 24, 2017
Rep. Rush, Bobby L. [D-IL-1]	D · IL		Oct 24, 2017
Rep. Marshall, Roger [R-KS-1]	R · KS		Oct 31, 2017
Del. Plaskett, Stacey E. [D-VI-At Large]	D · VI		Nov 7, 2017
Rep. Eshoo, Anna G. [D-CA-18]	D · CA		Nov 7, 2017
Rep. Ruiz, Raul [D-CA-36]	D · CA		Dec 18, 2017

## Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 26, 2017

## Subjects & Policy Tags

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### Policy Area:

Health

### Related Bills

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No related bills are listed.

### Summary (as of May 24, 2017)

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#### **Promoting Life-Saving New Therapies for Neonates Act of 2017**

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

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- **May 26, 2017:** Referred to the Subcommittee on Health.
- **May 24, 2017:** Introduced in House
- **May 24, 2017:** Referred to the House Committee on Energy and Commerce.