S 2041

Promoting Life-Saving New Therapies for Neonates Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Sep 16, 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. (Sep 16, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/2041

Sponsor

Name: Sen. Casey, Robert P., Jr. [D-PA]
Party: Democratic • **State:** PA • **Chamber:** Senate

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Cassidy, Bill [R-LA]	R · LA		Sep 16, 2015
Sen. Menendez, Robert [D-NJ]	D · NJ		Sep 16, 2015
Sen. Booker, Cory A. [D-NJ]	D · NJ		Oct 21, 2015
Sen. Capito, Shelley Moore [R-WV]	R · WV		Feb 24, 2016
Sen. Donnelly, Joe [D-IN]	D · IN		Feb 24, 2016
Sen. Heinrich, Martin [D-NM]	D · NM		May 16, 2016

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Sep 16, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 5182	Related bill	**May 13, 2016:** Referred to the Subcommittee on Health.

Summary (as of Sep 16, 2015)

Promoting Life-Saving New Therapies for Neonates Act of 2015

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 Act, 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

- **Sep 16, 2015:** Introduced in Senate
- **Sep 16, 2015:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.