S 456

RACE for Children Act

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 27, 2017
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. (Feb 27, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/456

Sponsor

Name: Sen. Bennet, Michael F. [D-CO]
Party: Democratic • **State:** CO • **Chamber:** Senate

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Gardner, Cory [R-CO]	R · CO		Feb 27, 2017
Sen. Rubio, Marco [R-FL]	R · FL		Feb 27, 2017
Sen. Van Hollen, Chris [D-MD]	D · MD		Feb 27, 2017
Sen. King, Angus S., Jr. [I-ME]	I · ME		Aug 2, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 27, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 HR 1231	Identical bill	**Mar 3, 2017:** Referred to the Subcommittee on Health.

Summary (as of Feb 27, 2017)

Research to Accelerate Cures and Equity for Children Act or the RACE for Children Act

This bill amends the Federal Food, Drug, and Cosmetic Act to expand Food and Drug Administration (FDA) requirements for sponsors of certain drugs and biological products for adult cancer to assess the use of their medications in pediatric populations. (Currently, applications for FDA approval of new medications or new uses of medications must include pediatric assessments of safety and effectiveness for claimed indications, with exceptions.) The pediatric assessment for medications, including orphan drugs, that are used to treat cancer in adults and target a molecule germane to pediatric cancer must assess the safety and effectiveness of the medication for pediatric cancer. The bill limits waivers of pediatric assessments for medications that target a molecule germane to a pediatric cancer for which there is a need for additional treatment options.

The FDA may require the sponsor of an approved medication that targets a molecule germane to pediatric cancer to complete a pediatric assessment if: (1) the medication is used for a substantial number of pediatric cancer patients, or (2) there is reason to believe the medication would have a meaningful therapeutic benefit over existing therapies for pediatric cancer patients.

The FDA committee that reviews requests for pediatric studies must implement a plan to achieve earlier submission of pediatric studies. (Currently, completion of pediatric clinical studies requested by the FDA extends the patents or marketing exclusivity period for a medication by six months, with exceptions.)

The FDA must act within 120 days on proposed pediatric study requests and proposed amendments to requests.

Actions Timeline

- **Feb 27, 2017:** Introduced in Senate
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