HR 5858

RACE for Children Act

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Jul 14, 2016
Current Status: Referred to the House Committee on Energy and Commerce.
Latest Action: Referred to the House Committee on Energy and Commerce. (Jul 14, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/5858

Sponsor

Name: Rep. McCaul, Michael T. [R-TX-10]
Party: Republican • **State:** TX • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Butterfield, G. K. [D-NC-1]	D · NC		Jul 14, 2016
Rep. Duffy, Sean P. [R-WI-7]	R · WI		Jul 14, 2016
Rep. Van Hollen, Chris [D-MD-8]	D · MD		Jul 14, 2016
Rep. Lipinski, Daniel [D-IL-3]	D · IL		Nov 18, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Jul 14, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 S 3239	Identical bill	**Jul 14, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Jul 14, 2016)

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 requirements for assessing the use of medications in pediatric populations.

Applications and supplements to applications for certain drugs and biological products, including orphan drugs, that could be used to treat pediatric cancer must include an assessment of pediatric use. Upon request, the Food and Drug Administration (FDA) must meet with the sponsor of such a medication to discuss the plan for pediatric studies.

The FDA may require the sponsor of an approved medication that could be used to treat 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 bill limits waivers of pediatric assessment requirements for certain medications that could be used to treat a pediatric cancer for which there is a need for additional treatment options.
The FDA must meet with medication sponsors to discuss a deferral or waiver of the pediatric assessment requirement.

Actions Timeline

- **Jul 14, 2016:** Introduced in House
- **Jul 14, 2016:** Sponsor introductory remarks on measure. (CR E1133)
- **Jul 14, 2016:** Referred to the House Committee on Energy and Commerce.