

December 14, 2023

The Honorable Anna Eshoo 272 Cannon House Office Building Washington, DC 20515 The Honorable Michael McCaul 2300 Rayburn House Office Building Washington, DC 20515

Dear Representatives Eshoo and McCaul:

Founded in 1999, Children's Cancer Cause is a leading national advocacy organization dedicated to creating a brighter future for children with cancer, survivors, and their families. We policies and programs that aim to accelerate the development of safer, more effective cancer therapies for children and better address the unique needs and lifelong health challenges experienced by childhood cancer survivors and their families

We strongly support H.R. 6664, the Innovation in Pediatric Drugs Act of 2023. This bill would help speed therapies to children who need them—including children with pediatric cancer and other rare diseases—by making improvements to pediatric drug laws including the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) and by giving authority to the Food and Drug Administration (FDA to ensure that required pediatric drug studies are completed on time.

The biology of children with cancer is different from adults with cancer. Drugs to treat children must be developed that are tailored for children. The Innovation In Pediatric Drugs Act of 2023 builds upon the promise of the Research To Accelerate Cures and Equity (RACE) Act For Children to increase pediatric studies of novel therapeutics for pediatric cancers. The new bill is an important step to ensure that required studies are completed for children as they are currently done for adults.

Current law requires many drugs to be studied for pediatric use. However, despite this requirement, the FDA's existing authority to compel sponsors to follow the law in a timely manner has been proven insufficient. While the FDA is allowed to assess civil monetary penalties for late post-study requirements for adults, the law currently forbids the FDA from doing the same for children. Fortunately, the Innovation in Pediatric Drugs of 2023 would address this inequity by amending PREA to give FDA the authority it needs to ensure that legally required pediatric studies are completed in a timely way.



We applaud your efforts to help children receive lifesaving treatments, and thank you for joining with us in our vision of a long, healthy life for every child with cancer.

Sincerely,

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Steve Wosahla Chief Executive Officer Children's Cancer Cause