

September 24, 2016

The Honorable Robert M. Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Califf:

We, families who have been touched by pediatric cancer and organizations dedicated to pediatric cancer research, request that you establish a new Pediatric Cluster for cancer (“Pediatric Cancer Cluster”) under the jurisdiction of the Oncology Center of Excellence to further promote international scientific exchange and to harmonize global pediatric cancer drug development.

The objective of the current Pediatric Cluster monthly teleconference calls coordinated by the Office of Pediatric Therapeutics is to enhance the science of pediatric trials and to avoid exposing children to unnecessary trials. This collaboration provides a forum for robust ethical and scientific evaluation and discussion of proposed pediatric studies. The Pediatric Cluster program has successfully addressed clinical and logistical issues related to studies required for pediatric drug development including: choice of comparator and efficacy endpoints; status of ongoing pediatric studies; results of pediatric studies; safety concerns, including clinical holds; and plans for long-term safety monitoring.

We request you now take a further step to strengthen this program by creating a separate Pediatric Cancer Cluster. A separate Pediatric Cancer Cluster would result in more in-depth and robust discussion and consideration of variations in pediatric cancer trials across different countries. Moreover, a Pediatric Cancer Cluster would improve the timing of studies between the United States and Europe.

Cancer drug development for children has never been affected by the Pediatric Research Equity Act. As a result, evaluation of cancer drugs for children occurs later in the drug development process in the United States. A Pediatric Cancer Cluster would create an opportunity for the FDA to collaborate with Europe earlier in the drug development process, when the EMA considers Pediatric Investigational Plans.

In addition, we request that this specialized Pediatric Cancer Cluster be directed out of the FDA’s Oncology Center of Excellence, where the pediatric oncology

critical scientific expertise exists to review the merits of potential studies of drugs as well as cell products, vaccines and in vitro diagnostics.

Thank you for working with us to establish a Pediatric Cancer Cluster within the Oncology Center of Excellence. For more information, please contact Nancy Goodman at nancygoodman@kidsvcancer.org.

Sincerely,

Abigail Alliance for Better Access to Developmental Drugs
Addi's Faith Foundation
Alex's Army Childhood Cancer Foundation
Along Comes Hope
Arms Wide Open Cancer Foundation
Bear Necessities Pediatric Cancer Foundation
Beat NB Cancer Foundation
Brooke's Blossoming Hope
CancerFree KIDS
Canines-N-Kids Foundation
Carson Leslie Foundation
CCAGCC
Chase After a Cure
Childhood Cancer Guides
Chris Lantos Foundation
Christina Renna Foundation Inc.
Coalition Against Childhood Cancer (CAC2)
Cody's Crew Foundation
CureSearch for Children's Cancer
Curewize Health Ltd.
Gold Rush Cure Foundation
Grandparents In Action
Hardy Family
Healing Hearts Respite Foundation
Jeff Gordon Children's Foundation
Julia's Grace Foundation
Kids v Cancer
Kraftlove
Lucy's Love Bus
Max's Ring of Fire
Michael Mosier Defeat DIPG Foundation
Mikey's Way Foundation
Noah's Light Foundation
Olivia Boccuzzi Foundation
Pat Mac's Pack
People Against Childhood Cancer

Princesses on a Mission
Rally Foundation for Childhood Cancer Research
Richi Childhood Cancer Foundation Inc.
Smashing Walnuts Foundation
Solving Kids' Cancer
St Baldrick's
Sublime Pool Service
Swiftly Foundation
Team Serena
The EVAN Foundation
The Max Cure Foundation, Inc.
The Nicholas Conor Institute