

April 20, 2022

The Honorable Tammy Baldwin
Chairwoman
Agriculture, Rural Development, FDA, and
Related Agencies Subcommittee
United States Senate
Washington, DC 20510

The Honorable John Hoeven
Ranking Member
Agriculture, Rural Development, FDA, and
Related Agencies Subcommittee
United States Senate
Washington, DC 20510

The Honorable Sanford Bishop
Chairman
Agriculture, Rural Development, FDA, and
Related Agencies Subcommittee
United States House of Representatives
Washington, DC 20515

The Honorable Andy Harris
Acting Ranking Member
Agriculture, Rural Development, FDA, and
Related Agencies Subcommittee
United States House of Representatives
Washington, DC 20515

Dear Chairwoman Baldwin, Chairman Bishop, Ranking Member Hoeven, and Acting Ranking Member Harris:

As you begin to consider funding priorities for Fiscal Year 2023, we urge you to fund the Pediatric Device Consortia (PDC) Grant Program at the Office of Orphan Products Development (OOPD) at the Food and Drug Administration (FDA) at \$9 million in Fiscal Year 2023. Recognizing the significant achievements of the PDC and the ongoing needs of children, Congress has provided meaningful increases in funding for the program several times over the past five years. Additional funding will allow FDA to support additional consortia, expanding the reach of the program to more geographic areas of the country.

Medical devices for children often lag five to ten years behind those for adults. Pediatric populations pose significant challenges for device manufacturers as there are many factors that limit children's access to safe and effective medical devices, including differences in size, weight, and metabolic rate.

To address the need for improved pediatric medical devices, Congress created the PDC Program and has renewed it since its inception in 2007. The PDC Program provides grants to non-profit pediatric medical device consortia, which assist scientists and innovators, particularly small businesses, with technical and financial resources to improve the number of medical devices available to children.

Often, a pediatric surgeon, pediatrician, or a scientist has an idea for a new or improved pediatric medical device. However, being unfamiliar with the process of developing and seeking approval for a medical device, they may not know where to start. The PDC funded through this competitive grant program help connect these individuals to the support networks and resources they need to navigate the sometimes complex and lengthy medical device approval process.

Since their inception in 2009, the PDC have been remarkably successful. The nine consortia have assisted in more than 2,500 proposed pediatric medical device projects. Most of the devices supported by the consortia are in the early stages of development, including concept formation, prototyping, and preclinical (animal and bench testing) stages, however, 46 devices are now available to patients.

Because of its innovative model for success, Congress's investment in the PDC Grant Program has enabled the consortia to leverage FDA's investment to raise more than \$750 million since 2009 in federal

and non-federal sources of funding to support advancement of, and research towards the consortia's pediatric medical device projects.

One example of a device supported by the PDC is the AireHealth™ nebulizer. The AireHealth™ nebulizer received 510(k) clearance with an indication for use to nebulize liquid medications for inhalation by a patient. The AireHealth™ nebulizer may be used in adults or children 5 years of age and older for use inpatient and outpatient (home) settings.

We believe that additional funding for the PDC program is necessary to improve device availability for children. For these reasons, we ask that in the FY 2023 Agriculture, Rural Development, and FDA appropriations bill, you include \$9 million for the PDC Grant Program.

We thank you for your consideration of our request and look forward to working with you as the Fiscal Year 2023 Agriculture, Rural Development, and FDA appropriations process moves forward. Please contact Cosette Audi (caudi@pedaids.org) or Madeline Curtis (mcurtis@aap.org) with any questions.

Sincerely,

AdvaMed

American Academy of Pediatrics

American Association of Neurological Surgeons

American Association of Neurological Surgeons/Congress of Neurological Surgeons Section on Pediatric Neurological Surgery

American Association of Orthopaedic Surgeons

American College of Surgeons

American Pediatric Surgical Association

American Society of Pediatric Nephrology

Children's Hospital Association

Congress of Neurological Surgeons

Cook Medical

Elizabeth Glaser Pediatric AIDS Foundation

National Association of Pediatric Nurse Practitioners

National Organization for Rare Disorders

Pediatric Orthopaedic Society of North America

PhotoniCare

Preceptis Medical

Scoliosis Research Society