

April 4, 2023

The Honorable Martin Heinrich
Chair
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 Andy Harris
Chair
Agriculture, Rural Development, FDA, and
Related Agencies Subcommittee
United States House of Representatives
Washington, DC 20515

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

Dear Chair Heinrich, Chair Harris, Ranking Member Hoeven, and Ranking Member Bishop:

As you begin to consider funding priorities for Fiscal Year 2024, 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 \$7 million in Fiscal Year 2024. 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.

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 metabolism rate. 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 five geographically dispersed consortia assisted with 611 pediatric medical device products in the past year. 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, 50 devices are now available to patients. As a direct result of their efforts in FY 2022, one device (EaseVRx) was granted a De Novo classification and three PDC supported devices received 510(k) clearance for use in pediatric patients: EvoEndo Single-Use Endoscopy System, Orchid Safety Release Valve, and InfraScanner.

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.

Continued funding for the PDC program is necessary to improve device availability for children; we urge you to include \$7 million for the PDC Grant Program in the FY 2024 Agriculture, Rural Development, and FDA appropriations bill. We thank you for your consideration of our request and look forward to working with you as the Fiscal Year 2024 Agriculture, Rural Development, and FDA appropriations process moves forward. Please contact Amanda Reiling (areiling@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 Orthopaedic Surgeons

American College of Surgeons

American Pediatric Surgical Association (APSA)

Children's Hospital Association

Congress of Neurological Surgeons

Elizabeth Glaser Pediatric AIDS Foundation

National Association of Pediatric Nurses Practitioners

National Organization of Rare Disorders

The Pediatric Orthopaedic Society of North America (POSNA)

Preceptis Medical, Inc.

Scoliosis Research Society