

May 6, 2024

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 2025, 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 2025. 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 647 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 2023, several devices have been cleared for use in children, including the Neoasis incubator-based active noise control ANNE One, and the Orchid Safety Release Valve.

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 2025 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 2025 Agriculture, Rural Development, and FDA appropriations process moves forward.

Sincerely,

AANS/CNS Section on Pediatric Neurological Surgery  
AdvaMed  
American Academy of Pediatrics  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Surgeons  
American Pediatric Surgical Association  
American Society of Pediatric Nephrology  
American Society of Pediatric Neurosurgeons  
Children's Hospital Association  
Congress of Neurological Surgeons  
Cook Medical  
Elizabeth Glaser Pediatric AIDS Foundation  
Family Voices  
Green Sun Medical  
National Association of Pediatric Nurses Practitioners  
National Organization of Rare Disorders  
The Pediatric Orthopaedic Society of North America (POSNA)  
Scoliosis Research Society  
The Society of Thoracic Surgeons