

November 8, 2021

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 Jeff Fortenberry
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 Ranking Member Fortenberry:

On behalf of the 20 undersigned organizations, we write to thank you for your long-standing support of the Pediatric Device Consortia (PDC) Grant Program at the Office of Orphan Products Development (OOPD) at the Food and Drug Administration (FDA). We are grateful to the Senate for providing \$7 million—the FY21 funding level—for the PDC program in its FY 2022 Agriculture/FDA bill. As you work to finalize funding levels in FY22, we urge you to adopt the Senate level funding amount of \$7 million.

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. 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.

Since their inception in 2009, the PDC have been remarkably successful. The nine consortia have assisted in more than 2,000 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, 36 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 \$500 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.

Funding for the PDC program is necessary to effectively continue improving device availability for children. For these reasons, we respectfully ask that the FY 2022 final appropriations bill include \$7 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 2022 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 (APSA)
American Society of Pediatric Nephrology
Children's Hospital Association
Children's National Hospital
Congress of Neurological Surgeons
Cook Group, Inc.
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, Inc.
Scoliosis Research Society
The Pediatric Orthopaedic Society of North America