

March 27, 2018

The Honorable John Hoeven
Chair, Agriculture, Rural Development, and
FDA Subcommittee
United States Senate
Washington, DC 20510

The Honorable Jeff Merkley
Ranking Member, Agriculture, Rural
Development, and FDA Subcommittee
United States Senate
Washington, DC 20510

The Honorable Robert Aderholt
Chair, Agriculture, Rural Development, and
FDA Subcommittee
United States House of Representatives
Washington, DC 20515

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

Dear Chairman Hoeven, Chairman Aderholt, Ranking Member Merkley, and Ranking Member Bishop:

We are writing to request \$6 million in funding in the Fiscal Year (FY) 2019 Agriculture, Rural Development, and Food and Drug Administration (FDA) appropriations bill for the Pediatric Device Consortia (PDC) Grant Program at the Office of Orphan Products Development (OOPD) at FDA. This amount is consistent with what Congress appropriated for the program last year. Continued funding of this program is critical for child health and we urge you to continue robust funding of this program.

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.

In addition, 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.

The PDC have been remarkably successful – the seven consortia have assisted in advancing the development of more than 1096 proposed pediatric medical devices. 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, eighteen 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 \$150 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.

The current round of grant proposals includes leveraging real-world evidence for regulatory evaluation of pediatric medical devices across their total product lifecycle. This will be the first opportunity to use real-world evidence for pediatric medical devices.

Examples of devices supported by the PDC include the TIVA device for needle-free direct blood draws; the JustRight Surgical Vessel Sealing System that seals blood vessels and vascular bundles during surgical procedures; and the Lifeflow Rapid Infusion Device for rapid infusion of fluids to a patient's system in emergency situations.

We believe that funding for the PDC program is necessary to effectively continue improving device availability for children. For these reasons, we ask that in the FY 2019 Agriculture, Rural Development, and FDA appropriations bill, you include \$6 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 2019 Agriculture, Rural Development, and FDA appropriations process moves forward.

Sincerely,

AdvaMed, the Advanced Medical Technology Association
American Academy of Pediatrics
American Association of Orthopaedic Surgeons
American Association for Pediatric Ophthalmology and Strabismus (AAPOS)
American College of Cardiology
American Society of Pediatric Nephrology
American Thoracic Society
Cook Medical
Elizabeth Glaser Pediatric AIDS Foundation
Georgia Institute of Technology
National Association of Pediatric Nurse Practitioners
National Organization for Rare Disorders
Pediatric Orthopaedic Society of North America
Scoliosis Research Society