

April XX, 2019

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

The Honorable Jeff Merkley
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 Chairman Hoeven, Chairman Bishop, Ranking Member Merkley, and Ranking Member Fortenberry:

We are writing to thank you for including \$6 million 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 and to urge you to maintain this level of funding in FY 2020. 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 nine consortia have assisted in advancing the development of more than 1294 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, 25 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 \$195 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, and information gathered through this initiative can inform the FDA’s efforts to further incorporate real-world evidence into the agency’s work.

Examples of devices supported by the PDC include the HydroPICC device for short-or-long-term peripheral access to the central venous system for intravenous therapy and the EyeBox device for measuring and analyzing eye movements as an aid in the diagnosis of concussion within one week of a head injury.

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 2020 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 2020 Agriculture, Rural Development, and FDA appropriations process moves forward.

Sincerely,

American Academy of Pediatrics

American Association of Pediatric Ophthalmology and Strabismus

American College of Cardiology

American Society of Pediatric Nephrology

American Thoracic Society

Child Neurology Foundation

Child Neurology Society

Cook Medical

Elizabeth Glaser Pediatric AIDS Foundation

Georgia Tech

National Association of Pediatric Nurse Practitioners

National Organization for Rare Disorders

Pediatric Orthopaedic Society of North America

Scoliosis Research Society