

March 26, 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:

We are writing to thank you for providing \$7 million in funding for the Pediatric Device Consortia (PDC) Grant Program at the Office of Orphan Products Development (OOPD) at the Food and Drug Administration (FDA) for Fiscal Year 2021. As you begin to consider funding priorities for Fiscal Year 2022, we urge you to increase funding for this important program to \$9 million. Recognizing the significant achievements of the PDC and the ongoing needs of children, Congress has provided modest increases in funding for the program several times over the past five years. Additional funding will allow FDA to support additional consortia in additional geographic areas of the country.

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.

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 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.

Examples of devices supported by the PDC include the bili-hutTM-- a portable neonatal phototherapy system that leverages a bassinet-like design to treat hyperbilirubinemia, commonly known as neonatal jaundice. The EyeBox, another device supported by the PDC, measures and analyzes eye movements as an aid in the diagnosis of concussion.

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 2022 Agriculture, Rural Development, and FDA appropriations bill, you include \$9 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 Agriculture, Rural Development, and FDA appropriations process moves forward.

Sincerely,

American Academy of Pediatrics

American Association of Orthopaedic Surgeons

American Thoracic Society

Children's National Hospital

Cook Medical

Elizabeth Glaser Pediatric AIDS Foundation

National Association of Pediatric Nurse Practitioners

National Organization for Rare Disorders

The Pediatric Orthopaedic Society of North America

Pediatric Specialists of Virginia

Scoliosis Research Society