

March 17, 2016

The Honorable Jerry Moran
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 Sam Farr
Ranking Member, Agriculture, Rural Development,
and FDA Subcommittee
United States House of Representatives
Washington, DC 20515

Dear Chairman Moran, Chairman Aderholt, Ranking Member Merkley, and Ranking Member Farr:

We are writing to request \$5.25 million in funding in the Fiscal Year (FY) 2017 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, as authorized under the *Food and Drug Administration Safety and Innovation Act* (FDASIA) pays untold dividends.

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 Pediatric Device Consortia 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 Pediatric Device Consortia have been remarkably successful – the nine consortia have assisted in advancing the development of more than 570 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 eight 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 private sources of funding. In fact, the Pediatric Device Consortia has raised *three times* the amount of federal investment in private funding.

Examples of devices supported by the Consortia include the “Buzzy” device for relief from pain associated with needlesticks; the Rhinoguard to assist in nasotracheal intubation for children undergoing maxillofacial surgery or dental procedures; and an external compressor brace for pectus carinitum, a deformity of the chest.

Medical devices for children often lag 5-10 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 reauthorized the PDC Grant Program in 2012 as part of FDASIA at \$5.25 million annually to provide grants to non-profit pediatric medical device consortia, which would assist scientists and innovators, particularly small businesses, with technical and financial resources to improve the number of medical devices available to children. We believe that funding for this demonstration grant program is necessary to effectively continue building new models in pediatric device development with the hopes of replicating those models as successes are realized. For these reasons, we ask that in the FY 2017 Agriculture, Rural Development, and FDA appropriations bill, you include \$5.25 million for the Pediatric Device Consortia Grant Program.

We thank you for your consideration of our request and look forward to working with you as the Fiscal Year 2017 Agriculture, Rural Development, and FDA appropriations process moves forward.

Sincerely,

AdvaMed, the Advanced Medical Technology Association
American Academy of Otolaryngology—Head and Neck Surgery
American Academy of Pediatrics
American Association of Orthopaedic Surgeons
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