

October 9, 2014

The Honorable Margaret Hamburg, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20933

Dear Commissioner Hamburg:

As organizations dedicated to improving therapies for children, we write to thank the Food and Drug Administration (FDA) for its commitment to the Pediatric Device Consortia (PDC) and urge increased investment in this important program. We particularly want to thank the FDA Office of Orphan Product Development for their dedication to the success of this crucial effort from children.

Since it was originally authorized in the Food and Drug Administration Amendments Act of 2007, the PDC has stimulated a great deal of pediatric device activity despite a remarkably modest yearly federal investment. The PDC recognizes that the availability of safe and effective medical and surgical devices for children continues to lag behind devices for adults and that innovative strategies are needed to stimulate pediatric device development. The consortia have helped advance hundreds of pediatric device projects and have also been able to generate a significant amount of private investment to supplement the grants made by the PDC.

Congress recognized the importance of continuing the program and growing its funding level through its reauthorization of the program in the Food and Drug Safety and Innovation Act (FDASIA). FDASIA reauthorized the PDC at \$5.25 million, a level nearly double the currently budgeted level of \$3 million. In addition, the report accompanying the Fiscal Year (FY) 2016 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill that was passed by the Senate Appropriations Committee on May 22, 2014 contained language praising the PDC program and directing the FDA to “fund the program at the levels authorized by the Food and Drug [Administration] Safety and Innovation Act of 2012 (Public Law 112-144).”

Regardless of how the FY2015 congressional appropriations process progresses, it is clear that Congress believes that the PDC program is worthy of an increased investment by the FDA. The PDC is now a proven concept and is ready to be taken to scale. We strongly urge the FDA to include \$5.25 million in its proposed FY2016 budget for the PDC program.

Thank you for your commitment to the health and well-being of children. We look forward to continuing to work with you to strengthen the FDA’s efforts to improve access to safe and effective medical and surgical devices for the pediatric population. If you have any questions about this issue, please contact James Baumberger (jbaumberger@aap.org) at the American Academy of Pediatrics.

Sincerely,

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

American Academy of Neurology
American Academy of Pediatrics
American Association of Orthopaedic Surgeons
American Association for Pediatric Ophthalmology and Strabismus
American College of Cardiology
American Society of Pediatric Nephrology
American Thoracic Society
Cook Medical
Elizabeth Glaser Pediatric AIDS Foundation
Medtronic, Inc.
National Association of Pediatric Nurse Practitioners
National Organization for Rare Disorders
Pediatric Orthopaedic Society of North America
Scoliosis Research Society

cc. The Honorable Shaun Donovan, Director, White House Office of Management and Budget