

American Academy  
of Pediatrics  
DEDICATED TO THE HEALTH OF ALL CHILDREN™



ELIZABETH GLASER  
PEDIATRIC AIDS  
FOUNDATION



AdvaMed  
Advanced Medical Technology Association



Helping Cardiovascular Professionals  
Learn. Advance. Heal.



Medtronic



stryker®

POSNA



AMERICAN SOCIETY OF  
PLASTIC SURGEONS



NORD  
National Organization for Rare Disorders



We help the world breathe  
PULMONARY • CRITICAL CARE • SLEEP



AMERICAN ACADEMY OF  
OTOLARYNGOLOGY-  
HEAD AND NECK SURGERY

AAOS  
AMERICAN ASSOCIATION OF  
ORTHOPAEDIC SURGEONS

Johnson & Johnson

March 28, 2012

The Honorable Daniel K. Inouye  
Chairman  
Committee on Appropriations  
U.S. Senate  
Washington, D.C., 20510

The Honorable Thad Cochran  
Ranking Member  
Committee on Appropriations  
U.S. Senate  
Washington, D.C. 20510

The Honorable Herb Kohl  
Chairman  
Subcommittee on Agriculture,  
Rural Development, and Food and  
Drug Administration Appropriations  
U.S. Senate  
Washington, DC 20510

The Honorable Roy Blunt  
Ranking Member  
Subcommittee on Agriculture,  
Rural Development, and Food and  
Drug Administration Appropriations  
U.S. Senate  
Washington, DC 20510

Dear Chairmen Inouye and Kohl and Ranking Members Cochran and Blunt:

As you begin to deliberate funding for the Fiscal Year 2013 Agriculture, Rural Development, and Food and Drug Administration (FDA) appropriations bill, we write to ask you to include \$6 million in funding for the Pediatric Device Consortia program in the Office of Orphan Products Development at the FDA.

We recognize the realities of the current fiscal environment and appreciate your duty as stewards of American taxpayer dollars to use those funds most efficiently. And, we support the promotion of medical device innovation here in the United States. The Pediatric Device Consortia program at FDA has helped to foster job growth and increased the commercial availability of pediatric medical devices in the United States.

According to the FDA, the five FDA-funded Pediatric Device Consortia have assisted in advancing the development of **135 proposed pediatric medical devices**. In its December 2011 report, the Government Accountability Office (GAO) found, “Although stakeholders identified barriers to developing and receiving FDA approval to market pediatric medical devices, programs such as the pediatric device consortia can foster an environment for device innovators to share ideas and advance the development of pediatric medical devices.”

The Atlanta Pediatric Device Consortium, which received funding under this program in 2012, brings together the resources of Georgia Institute of Technology’s College of Engineering, Children’s Healthcare of Atlanta Pediatric Hospital, and Emory University. The Atlanta Consortium is helping identify and support novel technologies, developing commercialization plans for pediatric device projects, and providing a mechanism for generating external funding. Similarly, Pediatric Device Consortia in California such as the UCSF Pediatric Device Consortium and the MISTRAL Consortium at Stanford University and SRI International have enabled pediatric medical devices not previously approved for use in the United States to become commercially available and have advanced the progress of numerous pediatric medical device projects.

The work of the Pediatric Device Consortia is critical because while adult populations routinely benefit from cutting edge research and technological advances that allow them to live longer, healthier lives, children’s medical devices can lag 5 or 10 years behind those manufactured for adults. Since the pediatric market is so small and pediatric diseases relatively rare, there has been little incentive for device manufacturers to focus their attention on children. The result is far fewer products available for children in need of medical care.

That is why in 2007 Congress enacted the *Pediatric Medical Device Safety and Improvement Act* as part of the *Food and Drug Administration Amendments Act*. As part of that innovative initiative for children, Congress authorized \$6 million for Demonstration Grants for Improving Pediatric Device Availability, known as the Pediatric Device Consortia program.

We applaud the Subcommittee’s past support of the Pediatric Device Consortia program and ask that you include \$6 million in the Fiscal Year 2013 Agriculture Appropriations bill. As patient advocates and industry leaders, we are strongly invested in the success of this program, and we are excited by the innovative opportunities being cultivated through these consortia. The Pediatric Device Consortia program is a huge step forward in getting life-saving and life-improving pediatric devices to the patients that need them.

Thank you for your consideration, and we look forward to working with you as the Subcommittee moves forward with the appropriations process for Fiscal Year 2013.

Sincerely,

AdvaMed (the Advanced Medical Technology Association)  
American Academy of Cardiology  
American Academy of Otolaryngology—Head and Neck Surgery  
American Academy of Pediatrics  
American Association of Orthopaedic Surgeons  
American Psychiatric Association  
American Society of Plastic Surgeons  
American Thoracic Society  
Elizabeth Glaser Pediatric AIDS Foundation  
Johnson & Johnson  
Medtronic  
National Association of Pediatric Nurse Practitioners  
National Organization for Rare Disorders  
Pediatric Orthopaedic Society of North America  
Cook Medical  
Stryker