The Pediatric Device Consortia Grant Program Fact Sheet

What: **A statutory grant program dedicated to stimulating the development and availability of medical devices for children through the establishment of pediatric device development consortia. As of FY 2011, a total of $8 Million dollars have been awarded.**

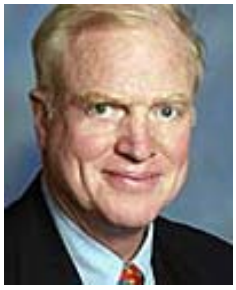
Why: **The development of medical devices for children currently lags five to ten years behind the development of devices for adults. Children differ from adults in terms of their size, growth, development, and body chemistry.**

When: **Most recently, three, two-year grants were awarded in September 2011.**

Who/ Where: **The program is administered by the FDA's Office of Orphan Products Development. Contact in OOPD: Linda.Ulrich@fda.hhs.gov For general information: www.fda.gov/orphan**

THE 2011/2012 CYCLE CONSORTIA GRANTEES ARE:






- **James Geiger, MD and Andre Muelenaer, MD and the Michigan Pediatric Device and Pediatric Medical Device Institute Consortium, $1,100,000 /year.**
- **Michael Harrison, MD and the UCSF Pediatric Device Consortium, $500,000/ year.**
- **Barbara Boyan, PhD and the Atlanta Pediatric Device Consortium, $900,000/year.**

The Law: **The Pediatric Medical Device Safety and Improvement Act of 2007 established demonstration grants for non-profit consortia to stimulate pediatric device development.**

- **A consortium receiving a grant or contract under Section 305 will facilitate the *development, production, and distribution* of medical devices by**
    - **Encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers.**
    - **Mentoring and managing device projects through the development process.**
    - **Connecting innovators and physicians to existing Federal and non-Federal Resources.**
    - **Assessing the scientific and medical merit of proposed pediatric device projects.**
    - **Providing assistance as needed on business development, personnel training, prototype development, post-market needs and other activities**
- **Each consortium will coordinate with the FDA Commissioner and device companies to facilitate applications for approval or clearance of devices labeled for pediatric use.**
- **Each consortium will coordinate with the NIH as well.**