



Pediatric Device Consortia Grant Program



FDA's Office of Orphan Products Development and Pediatric Medical Device Development

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OOPD Programs and Pediatric Medical Device Development

OOPD Programs Supporting Pediatric Devices

- PDC Grants Program
- HUD Designations
- OPD Grants



Challenges to Device Development

- Time
- Sweat
 - Invention = 1% inspiration, 99% perspiration
(Thomas Edison)
- Money
- Regulation
- Reimbursement

Challenges to Pediatric Device Development – Device issues

- Small market size
- Need for multiple sizes to accommodate growth
- Timeline for Use

Challenges to Pediatric Device Development – Trial issues

- Expense of Trials
- Enrollment challenges for children
- Consent + assent
- Need parent AND child cooperation
- Ethical complexities
- Lack of pediatric device trial infrastructure

Challenges to Pediatric Device Development – Regulatory issues

- Legislative incentives for pediatric drug development may not translate well or apply to the development of pediatric medical devices

2007 Pediatric Medical Device Safety and Improvement Act

- Enhanced Federal response to Pediatric Device needs
- Track Pediatric Device Approval
- Incentivized Development
 - Humanitarian Device Exemption profit provision
 - Establishes non-profit consortia
- Permitted extrapolation of Adult data
- Enhanced post-market surveillance

Pediatric Device Consortia Grant Program

- \$14.6 Million awarded in first five years, 3 grant cycles
- PDC Grant Program reauthorized as part of 2012 FDASIA
 - Through 2017
 - \$5.25 Million/Year authorization by law
 - Currently, \$3 Million/Year by appropriation

Pediatric Device Consortia Grant Program

- OOPD is responsible for carrying out the program
 - Encompasses devices used in all pediatric diseases, not just rare diseases
- PDC program encompasses ALL aspects of pediatric device development, not just regulatory
- Not a direct research grant
 - Fund non-profit consortia that support pediatric device developers

Pediatric Device Consortia

- What is a consortium?
 - A network of individuals and organizations: business, clinicians, manufacturers, engineers, and others
 - An information source
 - Provides experienced regulatory, business planning, and device advising and development services to advance medical devices for pediatric patients.



Silos don't help Device Development for Kids



**ENGINEERING/
BASIC
SCIENCE**

LEGAL/IP

CLINICAL

BUSINESS REGULATORY



Begin with the end in mind -

And, realistically,

What will it take to get there?

The Valley of Death is littered with prototypes....



What is the market?

Inventors need someone who thinks like a regulator

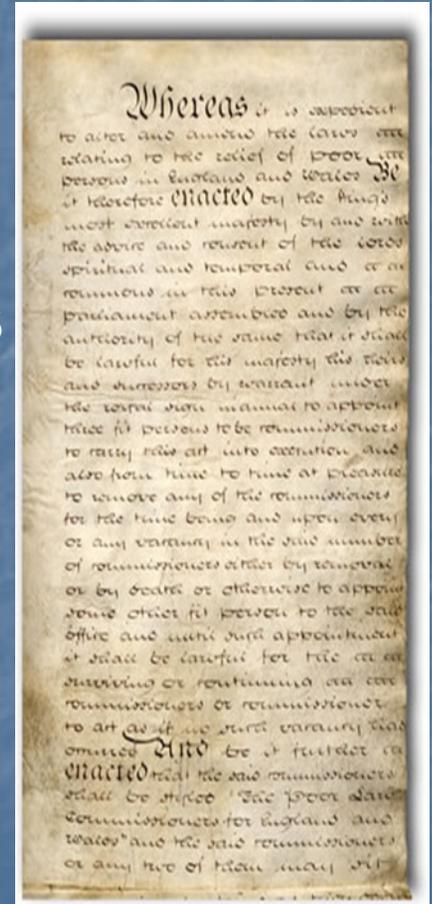


**What's the likely regulatory path
for clearance or approval?**

What the Law says...

About the Pediatric Device Consortia

- Connect Innovators with Potential Manufacturers and Potential Funding Sources
- Manage and Mentor Device Projects throughout the Development Cycle
- Assess Proposed Projects for Scientific and Medical merit
- Provide Business and Device Development Support



Recipients of 2013 PDC Grants



- **New England Pediatric Device Consortium, led by Rick Greenwald, Ph.D.**
- **Boston Pediatric Device Consortium, led by Pedro del Nido, M.D.**
- **National Capital Consortium for Pediatric Device Innovation, led by Peter Kim, M.D., Ph.D.**
- **Philadelphia Regional Pediatric Medical Device Consortium, led by Matthew Maltese, M.S., Ph.D.**
- **Atlantic Pediatric Device Consortium, led by David Ku, M.D., Ph.D., and Barbara Boyan, Ph.D.**
- **University of Michigan Pediatric Device Consortium, led by James Geiger, M.D.,**
- **Southern California Center for Technology and Innovation in Pediatrics, led by Yaniv Bar-Cohen, M.D. and Chester Koh, M.D.**

Progress in Advancing Pediatric Medical Devices

Over **260** pediatric device projects have been assisted in their development by the Pediatric Device Consortia since October 2009.

Impact of the Pediatric Device Consortia

- This doesn't mean that we have 260 devices coming to the market because of the program....
- The **vast majority** of projects assisted by the consortia are in the earliest stages of development— concept formation; prototyping; and early testing on the bench-top or in animals
- The consortia are currently managing >110 **ACTIVE** projects

What has come through the PDC FY '09-13 pipeline

- Pediatric devices available or remaining on the market:
 - Brace for pectus carinitum
 - Arbriz pediatric component to asthma management program
 - Geiger pyloric clamp for pyloric stenosis

What is coming through the PDC FY '09-13 pipeline

- Other devices in the works – not yet approved or cleared, but that have been reported in the press:
 - Stent for the treatment of tracheomalacia
 - Remotoscope for remote diagnosis of otitis media using a cell phone
 - Buzzy for pain relief

The Pediatric Device Consortia have :

- Helped secure additional funding for research
- Raised awareness about pediatric device development issues
- Gotten folks in the community involved
- Created opportunities for outreach, publications, and research

Other OOPD Medical Device Programs

- Humanitarian Use Device Program
- Orphan Products Grant Program

Orphan Products Grants Program

- >\$14 Million annual budget to fund **clinical** development of products for rare diseases
 - Phase 1 Studies
 - Up to \$200,000/year for up to 3 years
 - Phase 2 & 3 Studies
 - Up to \$400,000/year for up to 4 years
 - Humanitarian Use Device Program

Orphan Products Grants Success

- >50 Products partially funded by OOPD grants approved for marketing
- Development of Berlin Heart Device supported by an OPD Grant
- Practical goal: Advancing marketing approvals and relevant publications that impact care for rare diseases.

Orphan Products Grants Process

- ~100 applications per year
- Competitive grant program ~10-15 new grants funded per year
- Application and review similar to NIH grant application
- Request for Application (RA) at www.fda.gov/orphan or grants.gov
- Next Application date February 5, 2014

Requirements

- Eligibility
 - Academic and Industry sponsored research
 - Domestic or foreign, public or private, for-profit or nonprofit
 - Any entity except DHHS Federal agencies
- Requirements
 - Handout available at Registration desk, and online at www.fda.gov/orphan

Questions

Go to www.fda.gov/orphan for

- More information about Pediatric Device Consortia, Humanitarian Use Device Designations, or Orphan Product Grants;
- Updates about these Public Workshops;
- Or any needed follow-up

