FDA’s Pediatric Device Consortia: National Program Fosters Pediatric Medical Device Development

**OBJECTIVES:** This article reports on the progress made in addressing pediatric medical device needs through the establishment of the Pediatric Device Consortia Grant Program. Pediatric practitioners should be aware of both the imperative for well-studied devices for children and the existence of recently created resources to help foster the development of such products.

**METHODS:** This article discusses some of the challenges associated with pediatric device development and describes the implementation of section 305 of the Pediatric Medical Device Safety and Improvement Act of 2007. This statute called for the creation of nonprofit consortia to facilitate the development, production, and distribution of pediatric medical devices.

**RESULTS:** A summary of the accomplishments of the pediatric device consortia is presented. Eleven million dollars have been awarded to 5 consortia since 2009. As of July 2012, they have collectively assisted in the development of 219 pediatric device ideas. The consortia provide innovators with both mentorship and services to help advance proposed pediatric device projects, including assistance with prototyping, identification of potential funding sources, preclinical and clinical trial design, and introductions to potential manufacturers.

**CONCLUSIONS:** Currently, 5 federally funded pediatric device consortia exist to help advance the development of potential pediatric devices. These consortia serve as a national resource for those with ideas for medical devices that may advance the health and well-being of children. *Pediatrics* 2013;131:981–985
Although some medical devices used in the pediatric population (defined by the US Food and Drug Administration’s [FDAs] Center for Devices and Radiologic Health as birth through age 21 years) are designed specifically for children, many others are borrowed or jury-rigged from adult applications, or other indications. As an example, stents initially developed for biliary disease have been routinely used to treat stenotic heart vessels in infants and children. Although such practice has often been born of necessity given the relative lack of availability of devices designed for and labeled for pediatric use, it has created a situation where the effectiveness and safety of medical devices used in pediatrics have often gone unstudied, and thus are unknown.

**LEGISLATIVE INITIATIVES**

Although the Best Pharmaceuticals for Children Act (1997), the Pediatric Rule in 1998, and the Pediatric Research Equity Act of 2003 tackled challenges in obtaining studies to advance pediatric drug research and aimed to ensure appropriate drug product labeling for children, advancement of medical devices for children was not addressed legislatively until September 2007. This date marked the passage of the Food and Drug Administration Safety and Innovation Act in June of 2012 reauthorized the Pediatric Device Consortia (PDC) Grant Program through fiscal year (FY) 2017.

**PEDIATRIC DEVICES: THE CHALLENGES AND RECENT RESPONSES**

Unlike the pharmaceutical industry, the medical device industry tends to consist of smaller companies with less financial resources that focus on producing either a single or a few products. Moreover, unlike drugs, the development of medical devices is typically an iterative process, with ongoing evolution and refinement over time with subsequent effect on and changes in patent protection. Once a device makes it on to the market, it may be replaced by a refined design within a relatively short period of time. Thus, incentives to extend periods of marketing exclusivity, which are effective in driving pediatric pharmaceutical studies, may not have similar applicability in the medical devices space.

The need for pediatric medical devices and the challenges of developing and evaluating such devices have been extensively reviewed by the FDA,1 the Institute of Medicine,5 the Government Accountability Office (GAO),6 and others. In brief, small market size, the need for multiple pediatric sizes in certain cases, the expense of trials, barriers to enrollment of children, ethical complexities, and a lack of pediatric device trials infrastructure have been identified as some of the major challenges. In addition, the potential for children to use devices over the long term means that such devices must be especially long-lasting and safe.

Some have suggested that the FDA’s regulatory approach to clearing or approving devices for children makes the development of pediatric devices prohibitive. The regulatory process currently used in evaluating pediatric devices is no different than that for adults. This regulatory process implements the legislative framework established by Congress. That framework sets forth device clearance and approval pathways that do not differ on the basis of whether a device is intended for use in an adult population or a pediatric population. Thus, even though the agency tries to exercise appropriate flexibility in interpreting and implementing the laws that have been established, the agency is bound to work within the established legislative framework.

Efforts within the FDA to ensure the development of safe and effective devices for children include publication of several guidances (eg, Premarket Assessment of Pediatric Medical Devices, issued May 14, 2004; Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and FDA Staff—Humanitarian Device Exemption Regulation: Questions and Answers, issued July 8, 2010) to provide advice to sponsors involved in the development of devices for children. The agency has also sponsored several public meetings on Pediatric Medical Device Development.
including the most recent workshop that was held in September 2012. The Center for Devices and Radiologic Health holds a monthly Pediatric Steering Committee meeting, and in 2010 created the position of Chief Pediatric Medical Officer within the Office of the Center Director.

Another limiting factor in pediatric device development is that clinicians with potential device ideas often lack the engineering, business, and regulatory background necessary to develop and commercialize products. Section 305 of the PMDSIA was enacted to assist in correcting this particular deficiency. The FDA Office of Orphan Product Development has been charged with implementing this section.

**THE VISION: PDC**

Section 305 of PMDSIA called for the establishment of a “non-profit consortium to facilitate the development, production, and distribution of medical devices” by the following:

- Encouraging innovation and connecting qualified individuals who have pediatric device ideas with potential device manufacturers
- Mentoring and managing pediatric device projects through the development process, which includes identifying projects, designing prototypes, and developing and marketing devices
- Connecting innovators and physicians with existing US government sources and nonfederal resources
- Assessing the scientific and medical merit of proposed pediatric device projects
- Giving assistance, as needed, in areas such as business development, personnel training, prototype development, and postmarket needs*

Overall, the PDC serve as providers of scientific and regulatory advice, physical and design resources, and business assistance to individuals attempting to develop medical devices for children. To be successful, a consortium needs to bring together a strong network of experts and organizations, working together to advance pediatric medical devices onto the market.

As mentioned above, the statute calls for the consortia to mentor and manage pediatric devices at various stages of development. Medical device development is often described in terms of stages or phases on the basis of the FDA’s Center for Devices and Radiologic Health’s “Total Product Life Cycle” (Fig 1). A device starts in the “concept” or idea phase. As a physical model of the device is developed, it enters the “prototype” phase. This phase is generally followed by a “preclinical” phase, which includes bench-top and animal testing. If successful, the “clinical” phase typically follows and consists of testing the device in humans. If clinical testing is successfully completed, a product generally enters the “manufacturing” phase, which refers to the design of production processes that ensure standardization of the device.

This phase is followed by the “marketing” phase, where results of study data are submitted to the regulatory agency for clearance or approval, as necessary. Once a device is cleared or approved, a device enters the “commercial use” phase where the device becomes available for purchase on the market. Finally, “obsolescence” occurs as new technologies evolve to replace the existing device. Progression from one stage to the next is not necessarily linear, and there is often fluidity between the various stages of development. One of the primary goals of the PDC is to help devices advance through the various stages of development.

**ESTABLISHMENT OF THE PDC**

Congress first appropriated federal dollars for the PDC grant program in FY 2009. In that year, the program, administered by the Office of Orphan Products Development, initially funded 3 consortia. Additional funds and an additional grant competition led to the program’s current support of 5 pediatric device consortia in FY 2012. Since its establishment, the PDC grant program has awarded a total of 11 million dollars. Applicants for funding were judged on the organizational capacity of their proposed...
consortiums to exert a sustained, powerful influence on the field of pediatric device development, as well as on a scientific assessment of potential device projects. The application review involved an assessment of each proposed consortium's ability to provide appropriate clinical, scientific, business, and regulatory advice. Those who received funding scored best in their abilities to serve as a national platform to advance the development of pediatric medical devices while supporting device projects whose outcomes could have a significant impact on the practice of medicine.

The 5 currently funded consortia are led by, and located in, the following institutions:

1. James Geiger, MD, and Andre Muelanaer, MD, and the University of Michigan–Pediatric Medical Device Institute (PMDI) Pediatric Device Consortium
2. Michael Harrison, MD, and the University of California, San Francisco, Pediatric Device Consortium
3. David Ku, MD, PhD, and Barbara Boyan, PhD, and the Atlanta Pediatric Device Consortium
4. Pedro del Nido, MD, and the Pediatric Cardiovascular Device Consortium at Children's Hospital, Boston
5. Pablo Garcia and the MISTRAL (Multidisciplinary Initiative for Surgical Technology Research–Advanced Laboratory) Consortium, at SRI International in Palo Alto, California

Each of the consortia differs in how they carry out the requirements of the statute. For example, each proposed pediatric medical device considered by the Michigan-PMDI undergoes a formal, highly structured assessment process. The University of California at San Francisco consortium holds twice-a-week open meetings where devices at various stages of development are discussed among a group of engineering and clinical experts. The Cardiovascular Consortium also holds a monthly Innovator’s forum and is focused on assisting clinical trial design for cardiovascular products. Anyone with an idea for a pediatric medical device product can seek advice and assistance from the above consortia. Depending on the device and its needs, the type of assistance provided by the consortium may vary. Examples of specific services include making models of proposed devices (ie, developing prototypes) and advising on issues such as intellectual property protection, preclinical and clinical trial design, and business strategy.

**ACCOMPLISHMENTS OF THE PDC**

As of July 2012 and according to quarterly updates filed to the FDA, the PDC have assisted in the development of 219 proposed pediatric medical devices, 132 of which are still being actively managed or mentored. Most (83%) of the active device projects supported by the consortia are in the early stages of device development, including the initial concept-generating stage, prototyping (designing models of a device idea), and preclinical (bench and animal testing) stages. Specifics about many of the devices being assisted by the consortia cannot be disclosed for confidentiality and proprietary reasons. However, the GAO's December 2011 report on pediatric medical devices included information on some of the medical device projects that have been supported by the consortia6 (Table 1). As of the most recent grantee reports available in September 2012, 3 of the 219 proposed devices assisted by the consortia were commercially available. These devices are the Geiger Pyloric Immobilizer (a surgical tool used in pyloromyotomy), the Arbriz (a computerized asthma-management tool), and the Dynamic Compressor System (an external brace for the treatment of pectus carinatum). The consortia have also advised on the design of several ongoing preclinical and clinical trials for pediatric devices and provided funding guidance for >100 proposed pediatric device projects.

In the first 3 years, >9 million dollars of additional funding for pediatric device research was secured on the basis of advice, partner support, or facilitated interactions between device inventors and potential investors. Thus, the consortia leveraged the government's 9-million-dollar investment in the program to attract an equal amount of additional funding to advance pediatric device products.

The consortia have raised local and national awareness around the issue of pediatric medical device development. As a result, several accomplished clinical, engineering, and industry experts have volunteered their time and resources to engage in the development of specific medical device projects. Several conferences on the topic have been organized by the consortia, such as the Bioinnovation Summit in March of 2012 hosted by the University of Michigan–PMDI Consortium and PMDI's Pediatric Device Meeting in November of 2010. Consortia members have also published articles about specific pediatric medical devices and produced Web site resources on the topic of pediatric device development (http://pediatricdevicesatlanta.org/news-events, www.pediatricdevic consortium.org, and www.mistralpediatric.org).

In December 2011, the GAO issued a report on pediatric medical device development, including an analysis of the PDC program. The report concluded: “It is too early to determine if the FDAAA provisions authorizing demonstration grants for pediatric device consortia... have had a substantial impact on the number of approved pediatric devices.” However, the report went on to state: “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” and “the number of devices that the PDC have supported through the early phase of development and the positive feedback from stakeholders indicate that pediatric devices are being developed.”

CONCLUSIONS AND FUTURE DIRECTIONS
In the 3 years since appropriations of federal funding, the PDC grant program has established a national infrastructure for assisting individuals with pediatric device ideas and has advanced pediatric products along the development pathway. An increased awareness about the need for medical devices for children now exists. Funds appropriated to the PDC grant program have been leveraged by the consortia to attract additional funding for pediatric device development projects. Although much has been accomplished, there is still much more work to be done. An RFA (request for applications) for this program will be issued in the spring to announce future funding opportunities for this program. Prospective applicants will be able to access the RFA in the National Institutes of Health Guide for Grants and Contracts. With continued congressional appropriations, it is anticipated that the critical work of developing medical devices for children will continue with assistance from the PDC.

ACKNOWLEDGMENTS
We acknowledge the dedication of the FDA’s PDC Project Officers (Richard Barror, Francesca Joseph, Erica McNeilly, John Milto, and Karen Russell), who provide oversight and guidance to our consortia. A special thanks to the consortia leaders for their unfaltering efforts to advance the practice of pediatrics through device development.

REFERENCES

TABLE 1 Medical Device Projects Presented in Consortia Grant Applications and Funded in Fiscal Years 2009 and 2010

<table>
<thead>
<tr>
<th>Pediatric Device Consortia Grantees</th>
<th>Device Project</th>
<th>Condition Treated or Use</th>
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<tbody>
<tr>
<td>Michigan Pediatric Device Consortium</td>
<td>Bowel-lengthening device</td>
<td>Treats short bowel syndrome&lt;sup&gt;a&lt;/sup&gt;</td>
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<td></td>
<td>Nonthrombogenic and antiseptic catheters for infants</td>
<td>Treats clotting and infection problems with catheters in children</td>
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<td>MISTRAL Device Consortium</td>
<td>Pyloromyotomy surgical tool</td>
<td>Used in making laparoscopic pyloromyotomy safer and easier&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td></td>
<td>Esophageal atresia surgical tool</td>
<td>Treats esophageal atresia&lt;sup&gt;c&lt;/sup&gt;</td>
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<td>Neurosurgical articulated tools</td>
<td>Used to pediatric brain surgery</td>
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<td></td>
<td>NICU dashboard</td>
<td>Used to monitor and synthesize multiple pediatric vital sign inputs</td>
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<td></td>
<td>Catheter far-peripheral nerve blocks</td>
<td>Used to secure catheter placement in pediatric pain management</td>
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<td>Pediatric Cardiovascular Device Consortium</td>
<td>Septal cincher</td>
<td>Used to reduce the opening of a cardiac valve</td>
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<td>Biodegradable valve ring for children</td>
<td>Used in repair of cardiac valve</td>
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<td></td>
<td>Pediatric ultrasound imaging for diagnostics and surgical planning</td>
<td>Used for cardiac imaging</td>
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<tr>
<td></td>
<td>PediVAS pediatric circulatory assist device</td>
<td>Used in acute and temporary life support for infants and small children</td>
</tr>
<tr>
<td>University of California at San Francisco Pediatric Device Consortium</td>
<td>Magnetic Mini-Mover for pectus excavatum: third-generation magnetic implant device</td>
<td>Treats pectus excavatum (sunken chest)&lt;sup&gt;d&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Roboimplant (remotely operated bionic ortho implant) for scoliosis</td>
<td>Treats congenital and acquired spine disorders, such as early-onset scoliosis</td>
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Data are from the 2011 Government Accountability Office report.<sup>e</sup>
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Linda C. Ulrich, Francesca D. Joseph, Debra Y. Lewis and Robert L. Koenig
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