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# PEDIATRIC MEDICAL DEVICES

## Provisions Support Development, but Better Data Needed for Required Reporting

U.S. Government Accountability Office

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## Why GAO Did This Study

Medical devices can significantly improve, and save, the lives of children. Yet according to the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA), the development of pediatric devices lags years behind the development of devices for adults. The FDA Amendments Act of 2007 (FDAAA) provided incentives to develop devices for children, particularly devices that receive FDA's humanitarian device exemption (HDE), a process for devices that treat or diagnose rare diseases or conditions. FDAAA also authorized demonstration grants for nonprofit consortia to facilitate pediatric device development and required FDA to annually report the number of approved devices labeled for use in pediatric patients. Finally, FDAAA required GAO to report on pediatric device development. This report (1) describes barriers to developing pediatric devices, (2) describes how pediatric device consortia have contributed to the development of pediatric devices, and (3) examines FDA data on the number of pediatric devices approved since FDAAA was enacted. GAO examined FDA data and documents related to device approvals, reviewed relevant laws and regulations, and interviewed and reviewed documents from stakeholders and FDA officials.

## What GAO Recommends

GAO recommends that FDA collect reliable information to report data on pediatric medical devices by consistently using its existing pediatric electronic flag in its tracking system or otherwise developing internal controls. HHS concurred with GAO's recommendations.

View [GAO-12-225](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

# PEDIATRIC MEDICAL DEVICES

## Provisions Support Development, but Better Data Needed for Required Reporting

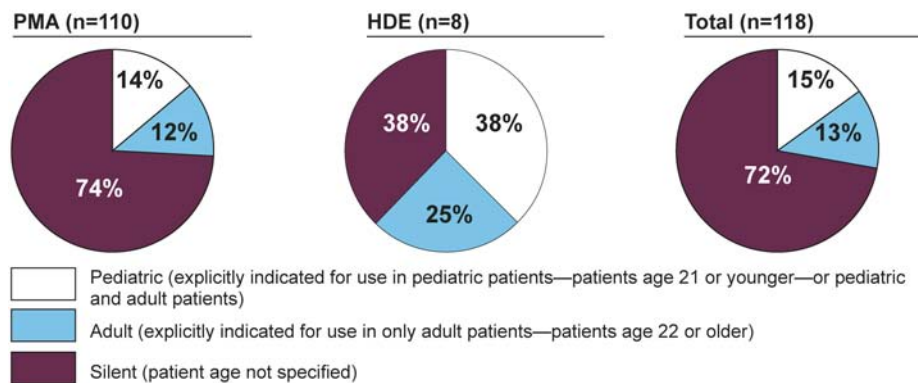
### What GAO Found

Certain characteristics unique to pediatric populations—including physiological differences from adult patients and challenges with recruiting pediatric participants for clinical trials—are barriers to developing medical devices for pediatric use cited by stakeholders. Given the unique characteristics of the pediatric population, and because the market for pediatric devices is smaller than the market for adult devices, there are limited economic incentives for manufacturers to develop pediatric medical devices.

FDAAA provisions authorized demonstration grants for pediatric device consortia—these consortia reported assisting over 100 pediatric device projects in the first 2 years of the program, fiscal years 2009 and 2010. FDA awarded grants totaling about \$5 million to four pediatric device consortia in these 2 years. Of the device projects assisted by the consortia, many projects were in early stages of development, such as the creation of a prototype and the preclinical testing of that prototype. Activities performed by the consortia included regularly scheduled forums where innovators could discuss new device ideas with a group of experts.

FDA lacks reliable internal data with which to identify all pediatric devices. FDAAA required FDA to annually report to congressional committees on the number of devices approved in the preceding year that were labeled for use in pediatric patients. While FDA created an electronic flag in its internal tracking system to identify such devices, FDA has not consistently used this flag and therefore lacks reliable and timely information needed for reporting. GAO's review of the indication for use statements of devices approved since FDAAA was enacted identified 18 devices—including 3 HDE devices and 15 premarket approval (PMA) devices—that were explicitly indicated for use in pediatric patients (patients age 21 or younger). However, the approved indication for use statements for most (72 percent) of the devices approved through the HDE or PMA processes did not specify the age of the intended patient population, so additional pediatric devices could exist.

**PMA and HDE Devices Approved in Fiscal Years 2008 through 2011 by Indicated Population**



Source: GAO.

Note: Totals do not add to 100 percent because of rounding.

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## Abbreviations

ADN	annual distribution number
CDRH	Center for Devices and Radiological Health
CHIP	Children's Health Insurance Program
CPT	current procedural terminology
CTS	Center Tracking System
FDA	Food and Drug Administration
FDAAA	FDA Amendments Act of 2007
HDE	humanitarian device exemption
HHS	Department of Health and Human Services
HUD	humanitarian use device
IRB	institutional review board
PMA	premarket approval
RVOT	right ventricular outflow tract

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**G A O**

Accountability \* Integrity \* Reliability

**United States Government Accountability Office**  
Washington, DC 20548

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December 20, 2011

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
Ranking Member  
Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
Chairman  
The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

Medical devices prevent premature death and significantly improve the quality of life for many children each year.<sup>1</sup> However, stakeholders from the pediatric community have raised concerns about the availability of devices developed and approved for pediatric use. In particular, concerns have been raised about challenges to developing and marketing pediatric medical devices. Designing and developing pediatric medical devices can be challenging because children's bodies are often smaller, are structured differently than adults, and change throughout childhood. According to the Food and Drug Administration (FDA), in 2011 the development of medical devices for children lagged 5 to 10 years behind the development of devices for adults. Some medical devices are designed specifically for pediatric patients and some are designed for patients above a certain age. Frequently, providers modify devices designed for adults for use in their pediatric patients.

FDA, an agency within the Department of Health and Human Services (HHS), is responsible for ensuring that medical devices, including pediatric medical devices, sold in the United States provide reasonable assurance of safety and effectiveness and do not pose a threat to public

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<sup>1</sup>Generally, medical devices include items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease. See 21 U.S.C. § 321(h). Throughout this report, the term device refers to a medical device that is not being regulated as a drug or a biological product.

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health. Before medical devices may be legally marketed in the United States, they are generally subject to FDA premarket review unless exempt by FDA regulations.<sup>2</sup> Under FDA's premarket approval (PMA) process, manufacturers must supply evidence providing reasonable assurance of safety and effectiveness to obtain FDA approval to market a device in the United States; we refer to devices approved through this process as PMA devices. To encourage development of devices that treat or diagnose rare diseases or conditions, devices that receive a humanitarian device exemption (HDE) are exempt from the effectiveness requirement of the PMA process. Under FDA's HDE process, manufacturers are instead required to show that the probable benefit outweighs the risk of using the device. In general, manufacturers of devices approved through the HDE process are allowed to recover certain development and production costs but may not make a profit on their device; we refer to devices approved through this process as HDE devices.

To encourage the development of pediatric medical devices, the FDA Amendments Act of 2007 (FDAAA) removed the profit prohibition for HDE devices that are used to treat children and meet other requirements,<sup>3</sup> and established a demonstration grant program for nonprofit consortia to stimulate pediatric medical device development.<sup>4</sup> Pediatric device consortia receiving these grants, administered by FDA, are expected to facilitate the development, production, and distribution of pediatric medical devices through activities such as connecting innovators and physicians to existing federal resources, assessing the scientific merit of proposed pediatric device projects, and providing assistance and advice as needed on business development. In addition, FDAAA required FDA to annually report to the Senate Committee on Health, Education, Labor, and Pensions and the House Committee on Energy and Commerce on

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<sup>2</sup>Devices are generally subject to one of two types of FDA premarket review—the 510(k) premarket notification process and the more stringent premarket approval process—unless exempt by FDA regulations. Under the 510(k) premarket review process, a medical device may be marketed in the United States after being cleared by FDA if FDA determines that the device is substantially equivalent to a legally marketed device that is not required to go through the premarket approval (PMA) process.

<sup>3</sup>Pub. L. No. 110-85, § 303(a)(3), 121 Stat. 823, 860-62 (2007) (codified in part at 21 U.S.C. § 360j(m)(6)).

<sup>4</sup>Pub. L. No. 110-85, § 305, 121 Stat. 823, 863-64 (2007).

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pediatric medical devices, including the number of devices approved in the preceding year that were labeled for use in pediatric patients.<sup>5</sup>

FDAAA also required GAO to report on pediatric medical device development.<sup>6</sup> In this report, we (1) describe barriers to developing pediatric medical devices, (2) describe how the demonstration grants for pediatric device consortia have contributed to the development of pediatric medical devices, and (3) examine FDA's data on the number of pediatric PMA and HDE devices approved since FDAAA was enacted.<sup>7</sup>

To describe the barriers to developing pediatric medical devices, we interviewed officials and reviewed documents from key pediatric medical device stakeholders, including the pediatric device consortia; manufacturer organizations, including the Medical Device Manufacturers Association and the Advanced Medical Technology Association; professional associations, such as the American Academy of Pediatrics, the Pediatric Orthopaedic Society of North America, and the American Thoracic Society; advocacy organizations, such as the Elizabeth Glaser Pediatric AIDS Foundation and the National Organization for Rare Disorders; and the two manufacturers of HDE devices approved for use in pediatric patients and exempted from the HDE profit prohibition. In addition, we interviewed officials from FDA and the National Institutes of Health who conduct work related to medical devices. We also conducted a literature review of government and independent reports and peer-reviewed publications and reviewed stakeholder testimonies and summaries regarding barriers to pediatric medical device development.<sup>8</sup> In addition, we examined policy papers written by key stakeholders, including FDA and professional associations.

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<sup>5</sup>Pub. L. No. 110-85, § 302, 121 Stat. 823, 859-60 (2007) (codified at 21 U.S.C. § 360e-1).

<sup>6</sup>Pub. L. No. 110-85, § 303(b), 121 Stat. 823, 862 (2007).

<sup>7</sup>In addition, FDAAA required that we describe the key characteristics of pediatric HDE devices granted exemption from the HDE profit prohibition. We discuss these devices in app. I.

<sup>8</sup>Reports we reviewed included, for example, Institute of Medicine, *Rare Diseases and Orphan Products: Accelerating Research and Development* (Washington, D.C.: The National Academies Press, October 2010), and American Academy of Pediatrics, *Summary of Pediatric Stakeholder Meetings* (Washington, D.C.: November 2004).



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To describe the contributions of the pediatric device consortia, we reviewed pediatric device consortia quarterly and annual reports submitted to FDA to assess the type and amount of assistance the consortia provided to device innovators and manufacturers described in the reports.<sup>9</sup> We also reviewed additional information provided by FDA and interviewed officials from FDA and the consortia and other relevant stakeholders.

To examine FDA's data on the number of pediatric PMA and HDE devices approved since FDAAA was enacted, we reviewed FDA procedures for tracking and reporting information on pediatric medical devices and analyzed FDA data and documents for approved PMA and HDE devices.<sup>10</sup> We compared FDA's procedures for tracking and reporting information on pediatric medical devices to standards described in *Standards for Internal Control in the Federal Government*—which specifies that information should be communicated to those who need it in a form and within a time frame that enables them to carry out their operational responsibilities.<sup>11</sup> Specifically, we examined the agency's ability to readily identify approved PMA and HDE devices labeled for use in pediatric patients and report on them in a timely manner. To do this and to determine the reliability of FDA's data on PMA and HDE devices labeled for use in pediatric patients, we interviewed FDA officials; reviewed laws, regulations, and guidance; and reviewed FDA data

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<sup>9</sup>We reviewed quarterly and annual consortia reports available through September 2011. These reports included information on the device projects assisted by the consortia that could be developed to enter the U.S. market through one of FDA's premarket review processes—PMA, HDE, or the 510(k) premarket review process.

<sup>10</sup>FDAAA required that we focus our report on medical devices that were approved for the U.S. market through the PMA and HDE processes. For additional information on devices cleared through the 510(k) premarket review process, see GAO, *Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process*, [GAO-09-190](#) (Washington, D.C.: Jan. 15, 2009), and the Related GAO Products section at the end of this report.

<sup>11</sup>These standards provide an overall framework for establishing and maintaining internal controls and for identifying and addressing major performance and management challenges and areas at greatest risk of fraud, waste, abuse, and mismanagement. See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999), and its supplemental guide, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: August 2001).

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systems.<sup>12</sup> Based on our examination, we generally found the data that FDA maintains on the number of approved PMA and HDE devices labeled for use in pediatric patients not to be sufficiently reliable for our purposes and, as a result, in order to identify pediatric devices, we reviewed FDA documents—the approval order, approved labeling, and summary of safety and effectiveness data—that FDA makes publicly available for each approved PMA and HDE device.<sup>13</sup> Each document contains the approved indication for use statement, which specifies the disease and population the device is intended to treat. However, the indication for use statement may not explicitly state if a device can be used in pediatric patients; in these cases, FDA may still consider the device to be labeled for use in pediatric patients based on other information in the labeling or summary documents. Given the extent of information and expertise needed to determine if a device is labeled for use in pediatric patients, for our analysis we considered pediatric devices to be those explicitly indicated for use in pediatric patients when the indication for use statement in these approval documents (1) specified a population that included patients age 21 years or younger, (2) stated that the device was for pediatric patients, or (3) stated that it was for skeletally immature patients.<sup>14</sup> We reviewed approval documents for PMA devices,

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<sup>12</sup>We also examined FDA's ability to readily identify additional information that FDAAA required FDA to annually report to congressional committees, including the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure and the number of approved devices that were exempted from the fee charged by FDA to review a PMA application because the device was intended solely for a pediatric population.

<sup>13</sup>To the extent possible, we compared FDA data on pediatric devices that the agency generated from its Center Tracking System with data generated from our PMA and HDE document review to corroborate or provide perspective on the data FDA provided.

<sup>14</sup>A device's approved indication for use statement describes the disease and population the medical device is intended to treat. Although the upper age limit used to define the pediatric population varies among experts, FDA issued guidance in 2004 stating that including adolescents up to the age of 21 years in the pediatric population is consistent with the definition found in several sources. We counted patients age 21 years or younger as pediatric patients in our review of the indication for use statements because the Food, Drug, and Cosmetic Act (as amended by FDAAA) defines pediatric patients, for purposes of provisions related to HDE devices, as those who are age 21 years or younger at the time of diagnosis or treatment. See 21 U.S.C. § 360j(m)(6)(E)(i). FDA has also concluded that for purposes of a provision requiring sponsors to submit information with PMA and HDE device applications, the term "pediatric patients" refers to patients who are age 21 years or younger at the time of diagnosis or treatment. See 75 Fed. Reg. 16,365, 16,366-67 (Apr. 1, 2010).

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including PMA supplements called panel-track supplements,<sup>15</sup> approved in fiscal years 2006 through 2011 and HDE devices approved in fiscal years 2001 through 2011.<sup>16</sup>

In addition, to determine how many humanitarian use device (HUD) designations—a required first step for FDA approval to market an HDE device—FDA granted for devices used to treat diseases that occur in pediatric populations since FDAAA was enacted, we analyzed data provided by FDA for all HUD requests submitted and designated in fiscal years 2001 through 2011. We interviewed FDA officials regarding methods for tracking HUD requests and designations and determined that the data were sufficiently reliable for our purposes. We also interviewed FDA officials and reviewed FDA data to identify the HDE devices exempted from the HDE profit prohibition and determined that these data were sufficiently reliable for our purposes.

We conducted this performance audit from February 2011 through December 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

Medical devices include items used for the diagnosis, cure, mitigation, treatment, or prevention of a disease. These devices range from simple tools like bandages and surgical clamps to complicated devices like pacemakers; unless exempt by FDA regulations, devices are generally

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<sup>15</sup>A PMA panel-track supplement is required if substantial clinical data are necessary to provide reasonable assurance of the safety and effectiveness to change the indication of an approved PMA device—for example, to add a pediatric population to a PMA device already approved for use in adults.

<sup>16</sup>We reviewed information for PMA devices (including PMA panel-track supplements) approved since fiscal year 2006 in order to include information for 2 years prior to enactment of FDAAA on September 27, 2007. This included a total of 81 devices approved before FDAAA was enacted and 110 devices approved after FDAAA was enacted. Because a much smaller number of HDE devices are approved each year, we included information for HDE devices approved since fiscal year 2001 listed on FDA's website as of October 2011, for a total of 23 HDE devices approved before FDAAA was enacted and 8 devices approved after FDAAA was enacted.

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subject to FDA premarket review. Pediatric patients may be among those a device is intended to treat and generally are defined as those age 21 years or younger. FDAAA included provisions to support and track pediatric device development.

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## Medical Device Premarket Review Process

Unless exempt by regulation, medical devices are generally subject to FDA premarket review before they may be legally marketed in the United States. The extent of the premarket review is generally correlated with the level of risk the device poses.<sup>17</sup> Applications to market medical devices are primarily submitted to and reviewed by FDA's Center for Devices and Radiological Health (CDRH).<sup>18</sup>

Under the PMA premarket review process, FDA reviews and makes approval decisions on applications for class III devices.<sup>19</sup> Among other things, PMA applications must include the indication for use—including the disease and population the medical device is intended to treat—and evidence (typically clinical data) providing reasonable assurance that the device is safe and effective. After an initial screening of an application and determination that the review should proceed, FDA's reviewers conduct a scientific review of the application and may refer applications to an external advisory committee composed of individuals with expertise in a particular medical specialty, such as cardiovascular or neurology—known as a medical specialty panel. FDA charges manufacturers a fee to

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<sup>17</sup>FDA categorizes medical devices into three classes based on the level of risk the device poses and the controls necessary to provide reasonable assurance of its safety and effectiveness. Class I devices include those with the lowest risk (such as forceps) and class III devices include those with the greatest risk (such as pacemakers). See 21 U.S.C. § 360c; 21 C.F.R. pts. 862-892 (2011).

<sup>18</sup>Although FDA's Center for Biologics Evaluation and Research also reviews medical device applications, including those for devices used in the testing and manufacturing of biological products, FDA officials noted that the majority of pediatric medical device applications are reviewed by CDRH and no pediatric HDE applications had, at the time of our review, been reviewed by the Center for Biologics Evaluation and Research.

<sup>19</sup>Some class III device types on the market before the enactment of the Medical Device Amendments of 1976 do not currently require PMA approval for marketing. FDA has been taking steps to address these device types; once this process is completed, all class III devices will be required to go through the PMA review process. For additional information, see GAO, *Medical Devices: FDA's Premarket Review and Postmarket Safety Efforts*, [GAO-11-556T](#) (Washington, D.C.: Apr. 13, 2011).

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review PMA applications, but PMA applications for devices intended solely for pediatric use are exempt from any fees.<sup>20</sup>

For devices that have been approved through the PMA process, a manufacturer that wants to add a pediatric population (or otherwise significantly change the approved indication for use) must submit and receive FDA approval for a PMA panel-track supplement.<sup>21</sup> FDA charges manufacturers a fee to review PMA panel-track supplements, but those intended solely for pediatric use are exempt.<sup>22</sup>

In 1990, Congress authorized FDA to exempt from the premarket review requirement to demonstrate effectiveness certain medical devices in order to provide an incentive for the development of devices that treat or diagnose rare diseases or conditions, including those in children.<sup>23</sup> Manufacturers of such devices still must show that the probable benefit outweighs the risk of using the device and that the device will not expose patients to unreasonable or significant risk of illness or injury. These devices, called HUDs, are intended to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States. In order to market an HUD in the United States, an HDE application must be submitted to and approved by FDA.

Obtaining HDE approval is a two-part process:

- A manufacturer must first request and obtain HUD designation from FDA's Office of Orphan Product Development. A device manufacturer requests HUD designation by providing a description of the rare disease or condition for which the device is to be used, the proposed indication or indications for use of the device, the reasons why such therapy is needed, and a description of the intended patient population along with data to support that there are fewer than 4,000 of these patients within the United States. The device manufacturer

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<sup>20</sup>For fiscal year 2012, the standard fee for a PMA application is \$220,050.

<sup>21</sup>Although FDA reviews and approves other types of PMA supplements, a panel-track supplement is required if the manufacturer wants to change the indication for use of an approved PMA device to add a pediatric population, according to FDA officials.

<sup>22</sup>For fiscal year 2012, the standard fee for a PMA panel-track supplement is \$165,038.

<sup>23</sup>Pub. L. No. 101-629, § 14(a), 104 Stat. 4511, 4524-25 (1990) (codified as amended at 21 U.S.C. § 360j(m)).

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must also provide a description of the device and scientific rationale for the use of the device for the rare disease or condition.

- Once the HUD designation is granted, the manufacturer can then seek device approval by submitting an HDE application. In addition to including the indication for use, the HDE application must include a detailed description of the device, along with evidence demonstrating device safety, and data and a rationale supporting the probable benefit of the device. Device labeling is also reviewed and must include a statement indicating that the device is a humanitarian device.<sup>24</sup> According to FDA guidance, criteria for HDE approval are focused on safety, probable benefit, and lack of a comparable device. FDA does not charge manufacturers a fee to review HDE applications.<sup>25</sup>

Manufacturers of HDE devices are allowed to recover certain development and production costs but are generally prohibited from making a profit on their device. Unless exempt, HDE applications must include a cost assessment to demonstrate that the amount charged for the HDE device does not exceed the cost of research and development, fabrication, and distribution. After FDA approval, in order for an HDE device to be used in patient care, it must be reviewed and approved by an institutional review board (IRB) to assess the safety of the device.<sup>26</sup>

If FDA review results in premarket approval, FDA issues an approval order to the manufacturer, which includes the approved indication for use statement. FDA also approves all printed material accompanying the device—known as the device labeling. The approval order, labeling, and a summary of safety and effectiveness data are available on FDA’s

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<sup>24</sup>The HDE device label must include the following statement: “Humanitarian Device. Authorized by Federal law for use in the [treatment or diagnosis] of [specify disease or condition]. The effectiveness of this device for this use has not been demonstrated.”

<sup>25</sup>See 21 U.S.C. § 379j(a)(2)(B)(i).

<sup>26</sup>The IRB is a committee that has been formally designated to approve, monitor, and review biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the research subjects. Although IRBs generally oversee clinical investigations, for HDE devices IRBs are required to review and approve the use of the device. The IRB may review each use of an HDE device or use discretion to determine general rules for use of the HDE device after initial review. If an HDE device is used in an emergency situation, subsequent written notice to the IRB must be provided. See 21 U.S.C. § 379j(m)(4).

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website; all three documents contain the approved indication for use statement.

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## Pediatric Populations for Medical Devices

Although the upper age limit experts use to define the pediatric population varies, for purposes of certain statutory provisions for PMA and HDE device applications, FDA considers pediatric patients as those who are age 21 years or younger at the time of diagnosis or treatment.<sup>27</sup> FDA issued guidance in 2004 that specifies age ranges for four main pediatric subpopulations: neonate, infant, child, and adolescent (see table 1).<sup>28</sup> According to FDA officials, the agency defined an additional subpopulation, transitional adolescents, for its internal application review purposes. These officials noted that in some cases patients in this age range may not require special considerations compared to adults.<sup>29</sup> A pediatric medical device may be indicated for use in more than one pediatric subpopulation.

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<sup>27</sup>21 U.S.C. § 360j(m)(6)(E)(i) and (ii) define pediatric patients as age 21 years or younger at the time of diagnosis or treatment and specifies categories of pediatric subpopulations. 21 U.S.C. § 360e-1(a), which requires sponsors of PMA and HDE applications and supplements to submit information on pediatric subpopulations and pediatric patients, uses the same definition of “pediatric subpopulations” but does not include a definition of “pediatric patients.” Because no other definition of “pediatric patients” is included in statute and because the definitions of “pediatric patients” and “pediatric subpopulations” in section 360j are consistent, FDA has concluded that the term “pediatric patients” for purposes of required information for PMA and HDE applications refers to patients who are 21 years of age or younger at the time of diagnosis or treatment. See 75 Fed. Reg. 16,365, 16,366-67 (Apr. 1, 2010).

<sup>28</sup>See FDA, *Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices*. (Rockville, Md.: 2004). FDA, in its guidance, recognized that factors other than a patient’s numerical age may often be appropriate to consider in defining a pediatric population.

<sup>29</sup>FDA developed this subpopulation for determining if certain devices indicated for patients in the age range should be considered differently than adults. FDA officials stated that they will issue guidance on pediatric subpopulations that will include the transitional adolescent category.

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**Table 1: Pediatric Subpopulations for Medical Devices and Related Ages**

<b>Pediatric subpopulation</b>	<b>FDA guidance on approximate age range for this subpopulation</b>
Neonate (newborn)	Birth to 1 month
Infant	Greater than 1 month to 2 years
Child	Greater than 2 years to 12 years
Adolescent	Greater than 12 years to 21 years <sup>a</sup>

Source: GAO analysis of FDA information.

Notes: This table presents FDA's guidance on the approximate age ranges for four main pediatric subpopulations as reported in FDA's *Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices* (2004). According to FDA officials, for internal application review purposes, FDA uses slightly different age ranges for these main subpopulations—for example, 2 years to less than 12 years for children.

<sup>a</sup>For internal application review purposes, FDA identified another subpopulation, transitional adolescent, to include those age 18 to 21 years.

According to FDA officials, some pediatric devices are indicated for use in both pediatric and adult patients, such as devices with an indication for all patients with a given condition above a certain age. Additionally, a device's indication for use statement might not specify the age of the intended population, but based on additional clinical information that may be included in the approval documents, FDA might consider a device labeled for pediatric use. For example, the indication for use statement for an influenza diagnostic test might not specify a pediatric population, but FDA could consider the device labeled for patients of all ages. In addition, a device's indication for use statement might specify a minimum blood vessel size or body weight rather than a certain patient age, and if pediatric patients meet the criteria, the device could be considered labeled for pediatric use.

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## FDAAA Provisions on Pediatric Medical Device Development

To stimulate pediatric medical device development, FDAAA exempted HDE devices labeled for use in pediatric patients (including those for both pediatric and adult patients) from the HDE profit prohibition for applications approved on or after September 27, 2007, when FDAAA was signed into law.<sup>30</sup> In order to receive the exemption from the profit prohibition, HDE applications must include data to prove that the device

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<sup>30</sup>To qualify for the exemption from the HDE profit prohibition, the sponsor must submit an HDE application on or before October 1, 2012.



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can safely be used in a pediatric population and to support the number of individuals likely to use the device each year. Based on this information, FDA determines an upper limit on the number of devices that can be distributed or sold each year—to treat both pediatric and adult patients—known as the annual distribution number (ADN). Manufacturers may only receive profits from the sale of HDE devices exempt from the profit prohibition and indicated for pediatric or pediatric and adult use up to the ADN. In addition, FDAAA requires that FDA’s Pediatric Advisory Committee annually review all HDE devices granted exemption from the profit prohibition to ensure that the exemption remains appropriate for the pediatric populations for which it is granted.<sup>31</sup>

FDAAA also required PMA and HDE applications to include, if readily available, a description of any pediatric population or subpopulation(s) that suffer from the disease or condition that the device is intended to treat, diagnose, or cure and the number of affected pediatric patients. FDAAA further required FDA to annually report to congressional committees on the number of PMA and HDE devices approved in the preceding year (1) for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; (2) labeled for use in pediatric patients; and (3) exempt from user fees because the device was intended solely for pediatric use.<sup>32</sup>

To help connect individuals with ideas for pediatric medical devices with experienced professionals to assist them through the medical device development process, FDAAA also authorized demonstration grants for pediatric device consortia to promote pediatric device development.<sup>33</sup> Pediatric device consortia receive 2-year grants, administered by FDA, to conduct certain activities for device projects, such as mentoring and managing the development process, assessing the scientific merit of a proposed device, and providing assistance and advice as needed on

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<sup>31</sup>Pub. L. No. 110-85, § 303(a)(3), 121 Stat. 823, 861-62 (2007) (codified at 21 U.S.C. § 360j(m)(8)).

<sup>32</sup>Pub. L. No. 110-85, § 302, 121 Stat. 823, 859-60 (2007) (codified at 21 U.S.C. § 360e-1). The third requirement applies only to PMA devices since HDE devices are already exempt from user fees. In addition, the report is required to include the FDA review times for these devices.

<sup>33</sup>FDAAA also authorized the use of contracts. Pub. L. No. 110-85, § 305, 121 Stat. 823, 863-64 (2007).

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business development and navigating the regulatory process. In their demonstration grant applications, consortia were not only required to demonstrate their capability to develop pediatric devices—by having members with medical and scientific expertise in device development and relationships with manufacturers—but they were also required to identify two to five device projects that the consortia would directly support under the demonstration grant.<sup>34</sup> Grantees must submit quarterly and annual reports to FDA describing how they have used grant funds to support innovation and the phase of development for the devices for which they provided assistance.<sup>35</sup> Phases of development include, for example, concept, prototype (during which a model is developed), clinical (during which the device is tested), and marketing (during which the device goes through the regulatory process).<sup>36</sup>

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## Characteristics of the Population and Limited Economic Incentives Cited as Barriers to Pediatric Device Development

Certain characteristics unique to pediatric populations—including physiological differences in pediatric patients and challenges with recruiting pediatric participants for clinical trials—are barriers to developing pediatric medical devices that were cited by stakeholders.

- Pediatric patients are composed of different subpopulations with differences in size, growth rate, metabolism, heart rate, activity level, and other differences. For example, younger pediatric patients—neonates, infants, and children—have higher heart rates or respiratory rates than adults. This difference, as cited by some stakeholders, makes some devices used for adults, such as certain heart valves, not appropriate for use in young children; thus a device that has already been developed for an adult may have to be redesigned for a pediatric population. Another unique characteristic cited is the range of pediatric subpopulations and the difficulty in developing potentially different devices for each of these subpopulations. For example, a device that is developed for a toddler may not be appropriate for use in an adolescent, even if they have the same disease or condition. As

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<sup>34</sup>Directly supported device projects received a portion of the demonstration grant funding.

<sup>35</sup>Grantees are required to report on the directly supported projects that were proposed in the grant applications as well as on other device projects for which the consortia provided assistance, such as developing a prototype or assessing the scientific merit of a device project.

<sup>36</sup>FDA officials stated that the phases of development used in consortia reporting come from CDRH's Total Product Lifecycle approach to reviewing medical devices.

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a result, manufacturers may have to develop and test a different device for each subpopulation although the disease or condition may be the same.

- Recruiting pediatric patients to participate in clinical trials has also been cited as a challenge for manufacturers. Performing experimental procedures on children naturally raises concern for their safety, and it may be difficult to obtain parental consent on behalf of the child to conduct experimental procedures. This issue is compounded because the pediatric population is not just one population but rather many subpopulations. Therefore, manufacturers find it difficult to recruit enough children for each pediatric subpopulation over a reasonable time frame and within a manageable number of investigational sites to ensure enough test subjects to meet clinical trial requirements.

Given these unique characteristics of the pediatric population, as well as the fact that the market for pediatric devices is generally smaller than the market for adult devices, there are limited economic incentives for manufacturers to develop pediatric medical devices. Stakeholders indicated that the cost of developing pediatric medical devices relative to the potential revenue generated by sales in a small market is a significant barrier to the development of new pediatric medical devices.

Stakeholders also noted that the cost of research and development for pediatric medical devices can be the same as for adult devices while the market size is often smaller. Given these factors, stakeholders report that the return on the investment to develop and test pediatric medical devices usually falls below the profit goals of most medical device manufacturers.

Stakeholders noted that the FDAAA provision allowing pediatric HDE devices to earn a profit is one helpful step to encourage pediatric medical device development; however, they indicated that this provision is not enough to address the small market for pediatric devices and the resources necessary to study a device in a pediatric population. An official from one device manufacturer that had a pediatric HDE device approved since FDAAA was enacted told us that the ability to earn a profit for the HDE device, while helpful, was not part of this manufacturer's decision to develop and market it. Stakeholders noted that the maximum number of 4,000 individuals for HDEs limited the effectiveness of this incentive for development of devices for larger pediatric populations. Stakeholders also noted that incentives used for pediatric drug development would not necessarily work for pediatric medical device development. For example, patent protection for medical devices is not as meaningful an incentive as it is for the development of pediatric drugs

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because the typical life cycle for medical devices (about 18 months) is significantly shorter than the typical life cycle for a drug.<sup>37</sup>

Other barriers identified by stakeholders included an incomplete understanding of unmet pediatric device needs and issues related to the medical device regulatory process.

- Several stakeholders commented that there is no consistent inventory of the devices that need to be developed for pediatric populations. Although it is unclear who should maintain this inventory, FDAAA did require FDA to annually report on the number of devices approved in the preceding year that were labeled for use in pediatric patients or for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. FDA has reported to Congress that the pediatric device data contained in these reports may help identify areas of pediatric device research and development that need to be addressed.<sup>38</sup> However, FDA has issued only one of these reports to date.<sup>39</sup> Furthermore, some of the information from which FDA would develop these reports may not be as useful as possible in determining unmet need. Specifically, manufacturers are to include the information on pediatric subpopulations in their premarket approval applications if readily available; however, one manufacturer organization stated that it was unclear about the specific information requirements, and thus

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<sup>37</sup>Generally, it is possible to design a medical device in a number of different ways that could be marketed by different manufacturers. As noted by the medical device industry, the typical “life cycle” or the amount of time before competitors begin selling an alternative product of a device is 18 months. The Best Pharmaceuticals for Children Act authorizes FDA to provide an incentive of an additional 6 months of market exclusivity to drug manufacturers that conduct pediatric studies requested by FDA. See 21 U.S.C. § 355a; 42 U.S.C. § 284m.

<sup>38</sup>See Department of Health and Human Services, Agency for Healthcare Research and Quality, Food and Drug Administration, and National Institutes of Health, *Report to Congress on the Plan for Expanding Pediatric Medical Device Research and Development* (Washington, D.C.: 2009).

<sup>39</sup>FDA issued a report for PMA and HDE devices approved in fiscal year 2008.

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manufacturers may not be submitting useful information for tracking unmet pediatric device needs.<sup>40</sup>

- Stakeholders also cited as barriers to pediatric device development certain issues related to the medical device regulatory process in general. For instance, it was reported that the amount of time that it will take to get through the regulatory process cannot always be predicted, which limits the ability to appropriately budget for development. One manufacturer organization also noted that FDAAA authorized FDA to consider published data from adult studies and studies in different age groups when determining effectiveness for pediatric device approvals; this manufacturer organization commented that where appropriate, FDA should also use scientific evidence other than randomized controlled studies, such as well-documented case histories, to show probable benefit or demonstrate effectiveness.<sup>41</sup> Recognizing the need to discuss the ways scientific research data can be used for pediatric medical device applications, FDA announced in November 2011 that it would hold a public workshop to discuss the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.<sup>42</sup>

Stakeholders also noted barriers that were unique to HDE devices, including pediatric HDE devices. One manufacturer organization stated that FDA has provided no general guidance to manufacturers regarding the type or level of evidence that must be developed to demonstrate that an HDE device meets the probable benefit standard. According to the organization, this lack of guidance ultimately hinders the use of the HDE program as a pathway to market devices that treat or diagnose diseases and conditions that affect fewer than 4,000 patients, including pediatric patients. According to stakeholders, difficulties in obtaining insurance coverage for HDE devices are also a barrier to development because HDE devices are approved by demonstrating safety but not effectiveness.

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<sup>40</sup>FDA officials stated that the agency was working on draft guidance for tracking pediatric device information; however, at the time of our review, FDA had not issued this guidance. In addition, FDA is working to finalize a proposed rule regarding the requirement for submission of information on pediatric subpopulations that suffer from a disease or condition that a device is intended to treat, diagnose, or cure. See 75 Fed. Reg. 16,365 (Apr. 1, 2010).

<sup>41</sup>Pub. L. No. 110-85, § 302, 121 Stat. 823, 860 (codified at 21 U.S.C. § 360e-1(b)).

<sup>42</sup>See 76 Fed. Reg. 67,463 (Nov. 1, 2011).

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Although the two manufacturers' representatives we spoke with reported experiencing frustration with the HDE approval process, they noted that overall, their interaction with FDA reviewers was positive in that FDA responded to their questions in a timely manner and provided specific guidance where necessary.

Finally, stakeholders stated that individuals with innovative ideas for new pediatric medical devices do not necessarily know what steps to take to bring their ideas for pediatric medical devices to the market, and it would be helpful to connect these individuals with manufacturers and to help them navigate the device development and regulatory process. Individuals with ideas for medical devices range from engineers to clinicians, who often need to work together to develop and manufacture a pediatric medical device. In addition, it is necessary to have funds to sustain development and an understanding of how to navigate the regulatory process. A commonly cited example of the challenges faced by pediatric device innovators is the experience developing the titanium rib, which took about 14 years to develop before it was approved for the market in part because its inventor, a physician who saw the need for such a device, did not have the information or resources to navigate the development and regulatory process.<sup>43</sup> FDA officials and other stakeholders reported that the pediatric device consortia have helped to address this barrier. In addition, FDA officials reported that other efforts by FDA to organize early meetings before device manufacturers submit applications to clarify required clinical information and meetings with groups such as the pediatric orthopedic surgeons have also helped device innovators navigate the device development and regulatory process.

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<sup>43</sup>FDA approved the Vertical Expandable Prosthetic Titanium Rib for market through the HDE process in August 2004.

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## Pediatric Device Consortia Have Assisted over 100 Device Projects; Many Were in Early Development

The pediatric device consortia reported assisting 107 pediatric device projects—that is, projects to develop new pediatric devices—in the first 2 years of the demonstration grant program. In order to facilitate the development and approval of pediatric medical devices, FDA awarded grants totaling about \$5 million to four pediatric device consortia in fiscal years 2009 and 2010 (see table 2).<sup>44</sup> The consortia receiving these grants provided assistance that included review of projects by clinical experts to evaluate the devices' usefulness in a clinical environment and help connecting innovators with manufacturers as well as potential sources of additional federal grant funding.<sup>45</sup> The consortia also conducted other activities to support pediatric medical device development and connect individuals who have ideas for medical devices with information and resources, such as lectures, forums, and relevant conferences.<sup>46</sup>

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<sup>44</sup>Although the pediatric device consortia grant program was authorized as a demonstration grant program under FDAAA, appropriations were not designated for the program in committee reports until fiscal year 2009.

<sup>45</sup>Federal grant funding included grants through the National Institutes of Health.

<sup>46</sup>In 2011, FDA awarded grants for fiscal years 2011 and 2012 totaling \$5 million to three pediatric device consortia; the grant period for these awards had not yet started at the time of our review. Two of the grantees—Michigan Pediatric Device Consortium-PMDI and University of California at San Francisco Pediatric Device Consortium—had previously received pediatric device consortia grants; the third grantee—Atlanta Pediatric Device Consortium—had not previously received a pediatric device consortium grant. FDA also awarded an additional \$500,000 to MISTRAL Device Consortium.

**Table 2: Summary of Pediatric Device Consortia Grant Amounts and Funded Activities, Fiscal Years 2009 and 2010**

<b>Pediatric device consortia grantees (location)</b>	<b>Grant amounts<sup>a</sup> (in thousands)</b>	<b>Number of device projects assisted</b>	<b>Examples of activities to facilitate pediatric device development</b>
Michigan Pediatric Device Consortium (Ann Arbor, MI)	\$2,311	63	Hired postgraduate professionals with medical, dental, doctorate, or masters degrees for a 1-year fellowship to focus on bringing device innovations to the market
MISTRAL Device Consortium <sup>b</sup> (Menlo Park, CA)	500	17	Organized two teleconferences on issues surrounding neonatal intensive care units for the purposes of developing new devices
Pediatric Cardiovascular Device Consortium (Boston, MA)	1,102	9	Held monthly forums for device innovators to discuss new device innovations with experts such as engineers and scientists
University of California at San Francisco Pediatric Device Consortium (San Francisco, CA)	1,087	18	Held weekly forums to discuss new device innovations <sup>c</sup>
<b>Total</b>	<b>\$5,000</b>	<b>107</b>	

Source: GAO analysis of FDA information.

Notes: The total number of device projects assisted by the consortia is not proportional to the amount each consortium received in grant funding. Some device projects were more complex and needed more consortium resources than others. In addition, some consortia received funding outside of the demonstration grants to support their projects. This table presents grant funding for fiscal years 2009 and 2010 and the number of device projects assisted using those funds.

<sup>a</sup>Grant award amounts were rounded to the nearest thousand.

<sup>b</sup>Information presented for MISTRAL Device Consortium is for activities supported with funds from a grant made in fiscal year 2010.

<sup>c</sup>This innovator forum is scheduled two times per week and is open to anyone with a device idea or who wants to learn about device development. A 1-hour agenda is created where ideas are heard and consulted on. In addition, expert speakers are also brought in who can speak on manufacturing a device or taking a device through the regulatory process.

For the device projects assisted by the consortia, the phase of development varied. Although the consortia assisted a total of 107 device projects, 34 were inactive or were device projects that the consortia were no longer assisting at the time of our review.<sup>47</sup> Of the 73 active device projects, about half (36) were in the prototype phase (see table 3).<sup>48</sup> In

<sup>47</sup>In some cases inactive device projects stopped receiving consortia support because they could not obtain outside funding or there were complex development challenges.

<sup>48</sup>Active projects were those that were reported in the most recent consortia reports available at the time of our review, supplemented by additional information provided by FDA. Projects that we considered inactive were those that the consortia had mentored or supported at some point with grant funds but that were no longer receiving consortia assistance at the time of our review.



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order to monitor the progress of the device projects the pediatric consortia assisted, FDA requires each consortium to report on the development phase of each device project—including the directly supported device projects included in the grantees' applications as well as other device projects that received consortia assistance—on a quarterly and annual basis. Throughout the grant period, device projects were presented to the consortia and consortia members determined the kind of assistance to provide for development of these devices. The assistance provided depended on the device's phase of development. For example, for a device in the concept phase a consortium could assess its scientific merit to see if there is a need for the device or if it makes sense to develop it; for devices that were further along, a consortium could help produce prototypes. For devices in the marketing phase, the consortia could consult on next steps, including working with FDA, a step which the developer needs to take to market a device. As of the most recent grantee reports available in September 2011, 3 of the 107 devices that were assisted by the consortia were commercially available and 1 had received HUD designation.

**Table 3: Number of Device Projects by Development Phase That Were Mentored or Supported by the Pediatric Device Consortia**

<b>Phase of development</b>	<b>Total</b>
<b>Active</b>	
Concept (development of an idea for a device)	8
Prototype (the design and development phase where a model is used to conceive the concept)	36
Preclinical (testing a prototype in laboratories or animals)	20
Clinical (testing the device in humans)	4
Manufacturing (production of the device)	2
Marketing (includes the regulatory process and putting the device on the market)	0
Commercial use (use of the device by the general public)	3
<b>Active total<sup>a</sup></b>	<b>73</b>
<b>Inactive total<sup>b</sup></b>	<b>34</b>
<b>Total inactive and active</b>	<b>107</b>

Source: GAO analysis of FDA information.

Notes: The table presents the total number of device projects assisted by all four consortia. Data presented cover device projects that were assisted with funds from grants made in fiscal years 2009 and 2010.

<sup>a</sup>Active projects were those that were reported as supported with funds from grants made in fiscal year 2010 in the most recent consortia reports available at the time of our review in 2011, supplemented by additional information provided by FDA.

<sup>b</sup>Projects that we considered inactive were those that the consortia had mentored or supported at some point during their grant periods but that were no longer receiving consortia assistance with fiscal year 2010 funds. In some cases, inactive device projects stopped receiving consortia support because they could not obtain outside funding or there were complex development challenges.

Of the 107 device projects assisted by the consortia, 13 were directly supported—that is, they were identified in the grant awards to receive a portion of the grantee’s demonstration grant funding. Table 4 lists these directly supported device projects, which were identified by the grantees in their applications and selected by FDA to receive support through the consortia grants. FDA’s evaluation criteria included (1) the significance of the device to address pediatric needs, (2) how well the project was designed, (3) the likelihood for marketing success, (4) the expertise and training of project leaders, and (5) evidence that the institution where the consortium was located supported the project.

**Table 4: Medical Device Projects Presented in Consortia Grant Applications and Funded in Fiscal Years 2009 and 2010**

<b>Pediatric device consortia grantees</b>	<b>Device project</b>	<b>Condition treated or use</b>
Michigan Pediatric Device Consortium	Bowel lengthening device	Treats short bowel syndrome <sup>a</sup>
	Nonthrombogenic and antiseptic catheters for infants	Treats clotting and infection problems with catheters in children
MISTRAL Device Consortium	Pyloromyotomy surgical tool	Used in making laparoscopic pyloromyotomy safer and easier <sup>b</sup>
	Esophageal atresia surgical tool	Treats esophageal atresia <sup>c</sup>
	Neurosurgical articulated tools	Used in pediatric brain surgery
	NICU dashboard	Used to monitor and synthesize multiple pediatric vital sign inputs
	Catheter for peripheral nerve blocks	Used to secure catheter placement in pediatric pain management
Pediatric Cardiovascular Device Consortium	Septal cincher	Used to reduce the opening of a cardiac valve
	Biodegradable valve ring for children	Used in repair of cardiac valve
	Pediatric ultrasound imaging for diagnostics and surgical planning	Used for cardiac imaging
	PediVAS pediatric circulatory assist device	Used in acute and temporary life support for infants and small children
University of California at San Francisco Pediatric Device Consortium	MAGNETIC MINI-MOVER for pectus excavatum: 3rd generation magnimplant device	Treats pectus excavatum (sunken chest) <sup>d</sup>
	ROBOIMPLANT (remotely operated bionic ortho implant) for scoliosis	Treats congenital and acquired spine disorders, such as early onset scoliosis

Source: GAO analysis of FDA information.

Notes: This table presents information on the device projects that were directly supported under the pediatric device consortia grants—that is, they were proposed in the grantees’ applications and selected by FDA to receive support under the grants. All device projects were developing devices for use in pediatric patients.

<sup>a</sup>Short bowel syndrome represents a loss of sufficient length of intestine to allow for the absorption of nutrients.

<sup>b</sup>Laparoscopic pyloromyotomy is a minimally invasive surgery that makes an incision in the pylorus—the region of the stomach that connects to the small intestine.

<sup>c</sup>Esophageal atresia is a congenital medical condition that causes the esophagus to end rather than connecting normally to the stomach.

<sup>d</sup>Pectus excavatum is also known as sunken chest and is a congenital chest wall deformity in which several ribs and the sternum grow abnormally, producing a concave, or caved-in, appearance in the anterior chest wall.

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## FDA Lacks Reliable Information to Readily Identify All Pediatric PMA and HDE Devices

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### FDA Has Not Consistently Collected Reliable and Timely Information Needed to Report on Pediatric Devices

Although FDAAA required FDA to annually report to congressional committees on the number of PMA and HDE devices approved in the preceding year that were labeled for use in pediatric patients, the agency lacks reliable information to readily identify all such pediatric devices. Under standards for internal control in the federal government, relevant, reliable, and timely information should be available for external reporting purposes; however, FDA has not consistently collected reliable and timely information needed to report on pediatric devices.<sup>49</sup> In response to FDAAA, FDA developed an electronic flag within its Center Tracking System (CTS) in 2008, to help CDRH internally identify PMA and HDE devices that were labeled for use in pediatric patients.<sup>50</sup> According to FDA officials, the agency's medical device reviewers should check the pediatric flags during the PMA and HDE process based on all of the information available in the application. However, FDA officials reported that these electronic flags are not consistently applied, and that the agency does not provide formal training or guidance to its device reviewers regarding proper implementation of the pediatric flags. Therefore, information from FDA's tracking system is not sufficiently reliable to identify PMA and HDE devices labeled for use in pediatric patients.

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<sup>49</sup>See [GAO/AIMD-00-21.3.1](#) and [GAO-01-1008G](#).

<sup>50</sup>CTS is a web-based system used by CDRH for tracking premarket documents through the review process. According to FDA officials, the agency started using CTS in 2004 and implemented the pediatric flags in 2008.

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In the absence of reliable information from its internal tracking system that could be retrieved in a timely manner to identify approved PMA and HDE devices labeled for use in pediatric patients, FDA reported that staff completed labor-intensive file reviews—which included examining voluminous application files as well as discussion with FDA reviewers—to complete its first annual report.<sup>51</sup> This report, which covered devices approved in fiscal year 2008, did not specify the criteria FDA used to identify devices labeled for use in pediatric patients in its manual data collection process. An FDA official involved in the preparation of the fiscal year 2008 report told us that FDA staff considered devices to be labeled for pediatric patients if FDA officials determined that the devices were for patients younger than 18 years of age; however, this criterion was not explicit in the report. Instead, FDA's report noted that a committee report described pediatric medical devices as those used to treat or diagnose diseases or conditions in patients from birth through age 21.<sup>52</sup> Further, in the absence of documented criteria used to prepare the fiscal year 2008 report, FDA officials involved in preparing the combined fiscal years 2009-2010 report at the time of our review were not aware of the specific criteria used for the fiscal year 2008 report and, as a result, created their own criteria and labor-intensive file review for identifying and reporting on approved PMA and HDE devices labeled for use in pediatric patients. As of October 2011, the combined fiscal years 2009-2010 report had not been issued; FDA officials reported that it was in the agency's internal review and clearance process.

In addition, FDA does not have readily available, reliable information to identify other pediatric information that FDAAA required the agency to report annually. Specifically, FDA officials said that the agency does not have reliable information to readily identify and report on the number of PMA and HDE devices approved each year for which there is a pediatric subpopulation that suffers from the disease or condition that the device is

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<sup>51</sup>See FDA, *Report to Congress: Premarket Approval of Pediatric Uses of Devices—FY2008* (March 2009), accessed October 31, 2011, [www.fda.gov/downloads/MedicalDevices/.../UCM268801.pdf](http://www.fda.gov/downloads/MedicalDevices/.../UCM268801.pdf).

<sup>52</sup>The report, H.R. Rep No. 110-225, was associated with a version of FDAAA that did not become law.

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intended to treat, diagnose, or cure.<sup>53</sup> Furthermore, FDAAA required FDA to annually report the number of PMA devices exempt from a user fee because they were solely intended for pediatric use. Although the agency reported that none of the devices approved in fiscal year 2008 were exempt from a user fee for this reason, FDA officials stated that as a result of our inquiry they reevaluated some of the PMA applications for which user fees were paid and identified certain PMA applications from other years that may not have properly received the user fee exemption. FDA officials said they were in the process of providing refunds to applicants that should have been exempt from the user fee.

Without readily available information on the approved PMA and HDE devices labeled for use in pediatric patients or the number of approved devices for which a pediatric subpopulation might be indicated, FDA cannot easily identify and aggregate data to complete statutorily required reporting in a consistent and timely manner. The inconsistent information presented in these reports makes it more difficult for policymakers, industry stakeholders, and innovators to identify what opportunities and needs exist for devices to diagnose and treat pediatric patients.

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### Fifteen PMA and 3 HDE Devices Have Been Explicitly Indicated for Use in Pediatric Patients since FDAAA Was Enacted

While the indication for use statement for most approved PMA and HDE devices did not identify the age of the intended population, our review identified 18 devices approved since FDAAA was enacted that were explicitly indicated for use in pediatric patients.<sup>54</sup> Specifically, our review found that 15 PMA and 3 HDE devices approved since FDAAA was enacted have indication for use statements explicitly stating that the devices are for patients that include patients age 21 or younger, pediatric patients, or skeletally immature patients. However, the approved indication for use statements for most of the 118 PMA and HDE devices approved since FDAAA was enacted do not specify the age of the intended patient population. Specifically, the indication for use statement

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<sup>53</sup>In April 2010, FDA issued a proposed rule and a direct final rule implementing the FDAAA requirement for HDE and PMA device applications and supplements to include this information, if readily available. However, FDA withdrew the direct final rule after receiving significant adverse comments. According to FDA officials, the agency is in the process of reviewing the comments before issuing a final rule. See 75 Fed. Reg. 16,347 (Apr. 1, 2010); 75 Fed. Reg. 16,365 (Apr. 1, 2010); 75 Fed. Reg. 41,986 (July 20, 2010).

<sup>54</sup>See apps. II and III for additional information on PMA and HDE devices approved before and after FDAAA was enacted that were explicitly indicated for use in pediatric patients.

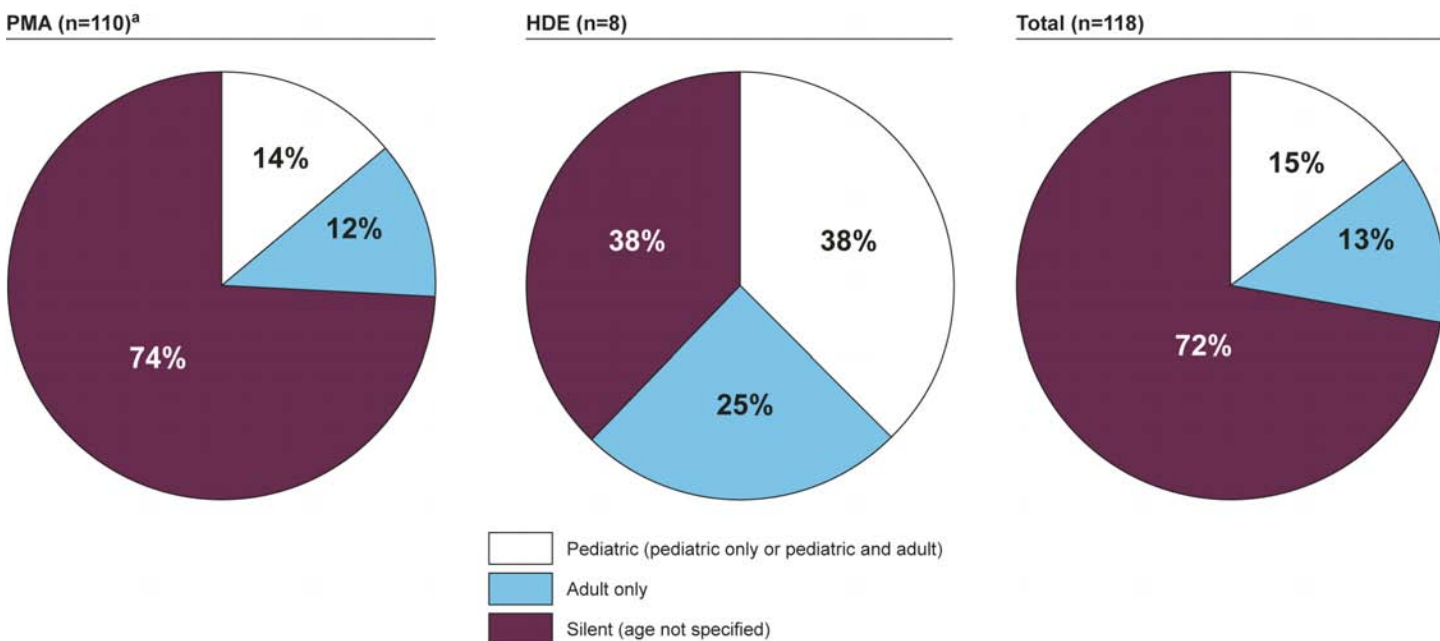
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was silent on the age of the intended patient population for 75 percent of PMA devices and 38 percent of HDE devices approved during that time (see fig. 1). Given that a device's indication for use statement may not explicitly state the age of the intended patient population or specify if it is for pediatric patients, additional pediatric devices could exist because other labeling and clinical information can be used to determine if the device can be used in pediatric patients.<sup>55</sup>

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<sup>55</sup>Based on our review of additional labeling information, at least 1 HDE device and 8 original PMA devices approved since fiscal year 2008 with indication for use statements that were silent on the age of the intended patient population were approved based on clinical studies that included one or more subjects age 21 or younger and did not include contraindications stating that the device should not be used in pediatric patients. At least 12 additional devices with indication for use statements that were silent on the age of the intended patient population included contraindication statements stating that the device should not be used in or was not tested in patients under age 18—that is, the device could potentially be used in patients age 18 to 21 years and older.

**Figure 1: PMA and HDE Devices Approved in Fiscal Years 2008 through 2011 by Indicated Patient Population**



Source: GAO analysis of FDA documents.

Notes: Totals do not add to 100 percent because of rounding.

In this figure, devices approved through FDA's premarket approval (PMA) and humanitarian device exemption (HDE) processes were considered to be for pediatric patients if they were explicitly indicated for use in pediatric patients—that is, if the approved indication for use statement (1) specified a population that included patients age 21 years or younger, (2) specifically stated it was for pediatric use, or (3) stated it was for skeletally immature patients. Devices explicitly indicated for use in pediatric patients include those explicitly indicated for use in pediatric patients or those for both pediatric and adult patients.

Adult only devices are those explicitly indicated for use in adult patients—that is, (1) if the indication for use statement specified a population that only included patients age 22 or older or (2) if the indication for use statement did not specify an age, but specifically stated it was for adult use.

Silent means devices for which the indication for use statement did not specify the age of the intended patient population.

<sup>a</sup>PMA devices include original and panel-track supplement devices.

Of the 18 PMA and HDE devices explicitly indicated for use in pediatric patients since FDAAA was enacted, most were explicitly indicated for adolescents. The majority of those indicated for adolescents were indicated for patients age 18 and older. Nine devices (50 percent) were indicated solely for patients age 18 or older—the age group FDA



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considers to be transitional adolescents for internal application review purposes—and 2 of those were indicated solely for patients age 21 or older.<sup>56</sup> Two devices were explicitly indicated for children and none were explicitly indicated for neonates or infants (see table 5). In addition, the most common medical specialties of devices explicitly indicated for use in pediatric patients were microbiology (39 percent); cardiovascular (22 percent); anesthesiology and ear, nose, and throat (11 percent each); and clinical chemistry, ophthalmology, and gastroenterology (6 percent each).<sup>57</sup>

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<sup>56</sup>FDA officials told us that during their premarket review they consider some devices indicated for patients age 18 to 21 years—transitional adolescents—the same as adult devices. However, because patients age 21 years or younger are considered pediatric under the definition in 21 U.S.C. § 360j(m)(6)(E)(i), devices labeled for patients age 19, 20, or 21 are considered pediatric devices for certain purposes.

<sup>57</sup>We identified each device's medical specialty based on data from FDA's product code classification database—which contains device names and product codes assigned based upon the medical device product classification designated under 21 C.F.R. Parts 862-892. The database did not include the medical specialty for some device product codes; for these we used information on the medical specialty provided by FDA.

**Table 5: Approved PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients since FDAAA Was Enacted, by Pediatric Subpopulation**

Device type	Pediatric subpopulation <sup>a</sup>						Pediatric subpopulation not specified <sup>c</sup>
	Neonate	Infant	Child	Adolescent		Pediatric subpopulation not specified <sup>c</sup>	
				Twelve years to less than 18 years	Transitional adolescent (18 to 21 years) <sup>b</sup>		
PMA (n=15)	0	0	2	4	12	3	
HDE (n=3)	0	0	0	1	2	1	
<b>Total (n=18)</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>5</b>	<b>14</b>	<b>4</b>	

Source: GAO analysis of FDA documents.

Notes: This table presents PMA and HDE devices approved in fiscal years 2008 through 2011. FDAAA was enacted September 27, 2007; no devices approved through FDA's premarket approval (PMA) and humanitarian device exemption (HDE) processes were approved in fiscal year 2007 after FDAAA was enacted. We considered PMA and HDE devices to be for pediatric patients if they were explicitly indicated for use in pediatric patients—that is, if the approved indication for use statement (1) specified a population that included patients age 21 years or younger, (2) specifically stated it was for pediatric use, or (3) stated it was for skeletally immature patients. Devices explicitly indicated for use in pediatric patients include those explicitly indicated for use in pediatric patients or those for both pediatric and adult patients.

<sup>a</sup>A device can be indicated for more than one pediatric subpopulation. For purposes of this table, pediatric subpopulation ages are those that FDA uses for internal tracking purposes: neonate (birth to 28 days), infant (29 days to <2 years), child (2 years to <12 years), adolescent (12 years to <18 years), and transitional adolescent (18 years to <=21 years).

<sup>b</sup>Nine of the devices were explicitly indicated solely for transitional adolescents and adults, seven of which were indicated for patients age 18 or older and two of which were indicated for patients age 21 or older.

<sup>c</sup>The indication for use statement for four devices did not specify the pediatric subpopulation, but one was indicated solely for pediatric patients and three were indicated for both pediatric and adult patients according to the approved indication for use statement.

Although three HDE devices approved since FDAAA was enacted were explicitly indicated for use in pediatric patients, the number per year may increase in the future, as the number of HUD requests and designations per year for devices intended to treat diseases that occur in pediatric patients increased after FDAAA was enacted.<sup>58</sup> Because HUD designation is the first step to obtaining HDE approval, increasing HUD

<sup>58</sup>These three HDE devices explicitly indicated for use in pediatric patients—those age 21 or younger—or both pediatric and adult patients accounted for 38 percent of HDE devices approved after FDAAA was enacted. In the 7 fiscal years before FDAAA was enacted, six HDE devices (26 percent of approved HDE devices) were explicitly indicated for use in pediatric patients or both pediatric and adult patients.

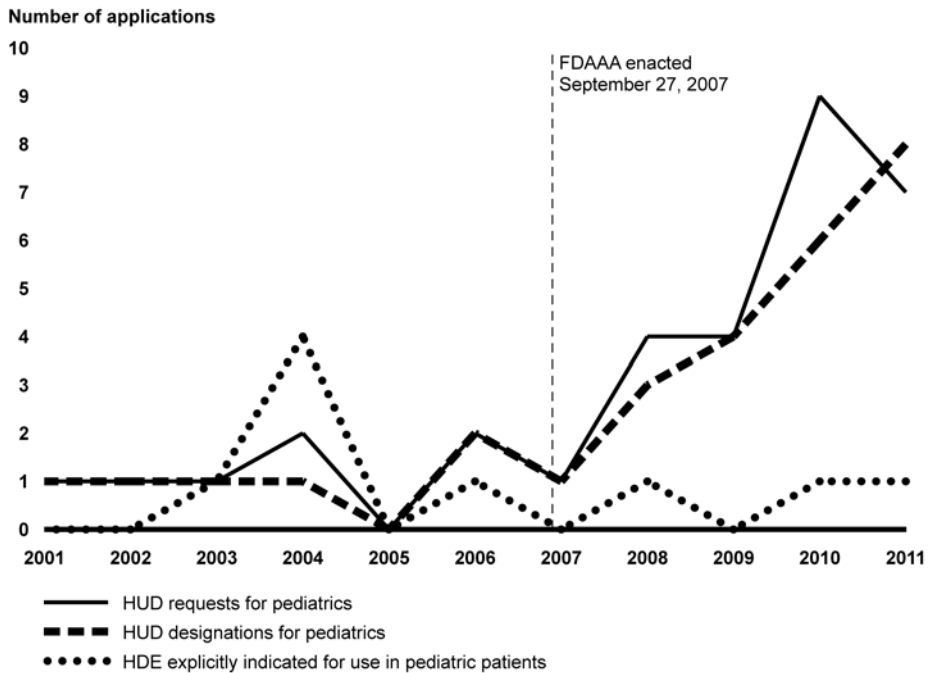
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designations indicate potential for future pediatric HDE devices.<sup>59</sup> According to FDA, the agency received about one HUD request per year on average for devices intended to treat a disease that occurs in pediatric patients before FDAAA was enacted and about five requests per year on average in the years after the law was enacted. Likewise, FDA granted about one HUD designation for devices intended to treat a disease that occurs in pediatric patients per year prior to FDAAA and almost five such HUD designations per year in the years after (see fig. 2).

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<sup>59</sup>The length of time between HUD designation and HDE device approval for HDE devices approved in the past decade ranged from 4 months to 7.5 years, with an average across the decade of about 2 years. However, to qualify for exemption from the HDE profit prohibition, the sponsor must submit an HDE application on or before October 1, 2012.

**Figure 2: HUD Requests, HUD Designations, and Approved HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2001 through 2011**



Source: GAO analysis of FDA data.

Notes: Some humanitarian use device (HUD) designations during a particular fiscal year may be from HUD requests submitted in an earlier fiscal year. FDA identified HUD requests and designations for pediatrics based on each device's indication for use statement, which includes the disease the device is intended to treat, diagnose, or cure.

We considered devices approved through FDA's humanitarian device exemption (HDE) process to be for pediatric patients if they were explicitly indicated for use in pediatric patients—that is, if the approved indication for use statement (1) specified a population that included patients age 21 years or younger, (2) specifically stated it was for pediatric use, or (3) stated it was for skeletally immature patients. Devices explicitly indicated for pediatric use include those explicitly indicated for use in pediatric patients or those for both pediatric and adult patients.

Since FDAAA was enacted, two of the three HDE devices explicitly indicated for use in pediatric patients (patients age 21 years or younger) were granted the exemption from the HDE profit prohibition.<sup>60</sup> One of

<sup>60</sup>An additional HDE device was approved for use in patients age 18 years and older (and therefore includes pediatric patients age 18 through 21 years), but the manufacturer did not request and receive exemption from the HDE profit prohibition for a pediatric device. FDA officials reported that the agency internally tracks HDE devices that have been approved for use in pediatric patients and granted exemption from the profit prohibition.

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these two exempted devices, the Medtronic Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Valve Delivery System (Melody® TPV) was approved in January 2010 for use in treating pediatric and adult patients with a blocked or leaky pulmonary heart valve that has previously been replaced to correct congenital (birth) heart defects and with a vessel size above a certain threshold.<sup>61</sup> In September 2011, FDA's Pediatric Advisory Committee reviewed the Melody TPV and determined that the HDE profit prohibition exemption remained appropriate.<sup>62</sup> The ELANA (Excimer Laser Assisted Non-Occlusive Anastomosis) Surgical KitHUD was approved in March 2011 for use in neurosurgery during intracranial vascular bypass procedures in patients 13 years of age or older who meet certain criteria. (See app. I for more information on the two devices.)

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## Conclusions

It is too early to determine if the FDAAA provisions authorizing demonstration grants for pediatric device consortia or allowing manufacturers to earn a profit on pediatric HDE devices have had a substantial impact on the number of approved pediatric devices; however, the provisions show potential for more pediatric devices in future years. 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 number of devices that the pediatric device consortia have supported through the early phases of development and the positive feedback from stakeholders indicate that pediatric devices are being developed. Further, the increase in the number of HUD requests and designations for devices that treat pediatric populations since FDAAA was enacted indicate potential for development of additional pediatric HDE devices in the near future. Over the past 10 years, it has taken a few years for a manufacturer to submit an HDE application and receive FDA market approval after receiving HUD designation; therefore the profit

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<sup>61</sup>The Melody TPV includes two parts—the Melody Transcatheter Pulmonary Valve (the valve) and Ensemble Transcatheter Valve Delivery System (the delivery system). The manufacturer refers to both parts together as Melody TPV.

<sup>62</sup>FDAAA requires that FDA's Pediatric Advisory Committee annually review all HDE devices granted exemption from the profit prohibition to ensure that the exemption remains appropriate for the pediatric populations for which it is granted. See Pub. L. No. 110-85, § 303(a)(3), 121 Stat. 823, 861-62 (2007) (codified at 21 U.S.C. § 360j(m)(8)).

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eligibility incentive for pediatric HDE devices may have induced an increase in the number of pediatric HUD requests.

Although the future for pediatric device development may be promising, FDA lacks reliable and timely information on pediatric devices approved for the U.S. market. To meet statutory reporting requirements, FDA must have data systems in place to produce timely, reliable information to readily identify and track devices the agency has approved for use in pediatric patients. Without a systematic database to identify medical devices approved for use in pediatric patients, FDA cannot provide data so that policymakers, innovators, and physicians may understand the extent of medical device availability and needs for further development.

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## Recommendation for Executive Action

We recommend that the Commissioner of FDA collect reliable information to report data related to pediatric medical devices. Specifically, FDA should take steps to consistently collect information using its existing pediatric electronic flag or otherwise develop internal controls to readily and reliably collect and report information on devices for pediatric use.

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## Agency Comments

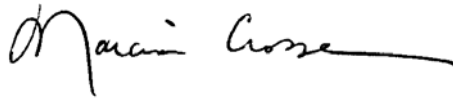
We received comments on a draft of this report from HHS, which are reproduced in appendix IV. The department agreed with our recommendation that FDA collect reliable information related to pediatric medical devices and commented that FDA is in the process of modifying and updating its current tracking system, related data quality controls, and training program requirements for pediatric medical device premarket submissions. The department further stated that when this process is complete, FDA's pediatric information collection efforts will satisfy the department's pediatric device operations and oversight needs, including the development of the annual pediatric report.

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We are sending copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff have any questions about this report, please contact me at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



Marcia Crosse  
Director, Health Care

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# Appendix I: Summary of HDE Devices Granted Exemption from the HDE Profit Prohibition

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The Food and Drug Administration Amendments Act of 2007 (FDAAA) also required that we describe the key characteristics of devices approved through the humanitarian device exemption (HDE) process that were granted exemptions from the HDE profit prohibition because they were labeled for use in pediatric patients. This appendix describes the conditions and the indicated patient populations of the two pediatric medical devices that were granted exemption from the HDE profit prohibition—Medtronic Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Valve Delivery System (Melody® TPV) and ELANA (Excimer Laser Assisted Non-Occlusive Anastomosis) Surgical KitHUD.<sup>1</sup> We also describe when each device was approved for the U.S. market and what is known about profits made by the manufacturers of each device. In addition, we describe what is known about the costs and insurance coverage and off-label use of the Melody TPV device—the one HDE device exempt from the HDE profit prohibition that was sold and in use in the United States at the time of our review.

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## Summary of Pediatric HDE Devices Exempt from the HDE Profit Prohibition

To describe the key characteristics of each device, we interviewed officials from Medtronic, Inc., and Elana, Inc.—manufacturers of the Melody TPV and ELANA devices, respectively—and examined manufacturer-provided documentation, such as billing code information, related to the Melody TPV device. We also interviewed officials from the Food and Drug Administration (FDA) who manage the HDE process and examined FDA documents for each device, including approval documents and an annual report for the Melody TPV—which manufacturers granted exemption from the HDE profit prohibition are required to submit annually to FDA. (Table 6 provides key characteristics of the two pediatric HDE devices granted exemption from the HDE profit prohibition.)

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<sup>1</sup>The Melody TPV includes two parts—the Melody Transcatheter Pulmonary Valve (the valve) and Ensemble Transcatheter Valve Delivery System (the delivery system). The manufacturer refers to both parts together as Melody TPV.



**Appendix I: Summary of HDE Devices Granted  
Exemption from the HDE Profit Prohibition**

**Table 6: Characteristics of the Two Pediatric HDE Devices Granted Exemption from the HDE Profit Prohibition**

	<b>Medtronic Melody® Transcatheter Pulmonary Valve and Ensemble® Transcatheter Valve Delivery System (Melody TPV)</b>	<b>ELANA (Excimer Laser Assisted Non-Occlusive Anastomosis) Surgical KitHUD</b>
Manufacturer	Medtronic, Inc., United States	Elana, Inc., Netherlands
Summary of indication for use	The Melody device is used to repair a blocked or leaky pulmonary heart valve that has previously been replaced to correct congenital (birth) heart defects. The Melody device is put in place without using open heart surgery and while the heart is beating, and can delay the need for more invasive open heart surgery.	The ELANA device is intended to allow neurosurgeons to reroute blood flow around an aneurysm or a tumor in the brains of patients at greater risk of stroke during standard bypass surgery. (Standard bypass surgery in the brain requires clipping the artery to halt blood flow during the procedure, and this standard surgery is not considered safe for about 1,000 patients annually for whom temporarily shutting off their blood flow would put them at high risk of stroke.)
Approved indication for use – including population	Indicated for use as an adjunct to surgery in the management of <b>pediatric and adult patients</b> with the following clinical conditions: Existence of a full (circumferential) Right Ventricular Outflow Tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted and Dysfunctional RVOT conduits with a clinical indication for intervention, and either Regurgitation: ≥ moderate regurgitation, or Stenosis: mean RVOT gradient ≥ 35 mmHg.	Indicated for creating arteriotomies during an intracranial vascular bypass procedure in <b>patients 13 years of age or older</b> with an aneurysm or a skull base tumor affecting a large (> 2.5 mm), intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity.
Medical specialty	Cardiovascular	Cardiovascular <sup>a</sup>
HUD designation date	7/10/2007	9/26/2003
HDE application: date filed and date approved	HDE application filed: 8/29/2008 HDE approved: 1/25/2010	HDE application filed: 12/5/2008 HDE approved: 3/10/2011
Annual distribution number <sup>b</sup>	2,996	1,000
Number of devices sold in the United States since HDE approval	695 <sup>c</sup>	4 <sup>d</sup>
Marketing in other countries	European Union: September 2006 Canada: December 2006	European Union: January 2006 Canada: November 2007
U.S. list price	\$30,500 (combined) \$24,000 (valve) \$6,500 (delivery system)	Not available
Profit from device	Not available	Not available

Source: GAO analysis of FDA and manufacturer information.

Notes: Humanitarian use devices (HUD) are approved for the U.S. market through FDA's humanitarian device exemption (HDE) process.

<sup>a</sup>We identified each device's medical specialty based on data from FDA's product code classification database—which contains device names and product codes assigned based upon the medical device product classification designated under 21 C.F.R. Parts 862-892. Although the database indicated a medical specialty of cardiovascular for the ELANA Surgical KitHUD, FDA officials reported that upon further review they determined that the product code assigned for the device is technically inaccurate. To correct this technical inconsistency, FDA will issue a corrected product code for this product in the near future. The corrected medical specialty for the device should be neurology, according to FDA officials.

<sup>b</sup>FDA determines an upper limit on the number of devices that can be distributed each year—to treat both pediatric and adult patients—known as the annual distribution number (ADN). Manufacturers may only receive profits on devices exempt from the profit prohibition up to the ADN.

<sup>c</sup>Number of Melody TPV devices sold from January 26, 2010, through August 31, 2011. According to the manufacturer, 386 devices (56 percent) were sold for use in patients age 21 or younger.

<sup>d</sup>According to the manufacturer, the ELANA Surgical KitHUD was first sold in the U.S. market in November 2011.

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## Survey of Physicians and Hospitals That Have Used the Melody TPV

To obtain information regarding costs of the Melody TPV device as well as insurance coverage for and off-label use of the device, we surveyed 36 physicians at the 25 children's hospitals and pediatric units of medical centers (which we collectively refer to as children's hospitals) that according to the device's manufacturer, had used the Melody TPV at least 10 times.<sup>2</sup> We received complete responses from 27 physicians at 20 children's hospitals for an overall response rate of 75 percent of physicians and 80 percent of hospitals in our sample.<sup>3</sup>

Almost all (93 percent) of the 27 respondents reported that their hospital purchased the Melody TPV at the manufacturer's list price of \$30,500.<sup>4</sup> All but 2 physicians reported that their hospital purchased the two components—the valve and the delivery system—of the Melody TPV device separately. A physician that we spoke with said his hospital kept several valves and several of each size delivery system in stock and

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<sup>2</sup>We also interviewed officials from the Centers for Medicare & Medicaid Services and America's Health Insurance Plans regarding public and private health insurance coverage of HDE devices, respectively.

<sup>3</sup>We fielded our survey from August 19, 2011, through October 3, 2011. At this time, the Melody TPV device was the only HDE device exempt from the HDE profit prohibition that was on the U.S. market. For questions regarding cost and insurance coverage for the device, someone other than the physician—such as a purchasing department representative—may have provided information on behalf of the physician.

<sup>4</sup>Thirty-three percent of respondents stated that they were not sure if the price they reported included all rebates or discounts their institution received for their most recent Melody TPV order. We did not further examine whether the reported prices included all rebates or discounts, and therefore additional rebates or discounts for these devices may have existed.

purchased more as needed. Twenty-four of the 25 physicians at children's hospitals that purchased the components separately reported paying the list price for each component—\$24,000 for each Melody Transcatheter Pulmonary Valve and \$6,500 for each Ensemble Transcatheter Valve Delivery System.

Many physicians we surveyed reported that they experienced at least some difficulty obtaining health insurance coverage for the Melody TPV device regardless of the type of insurance held by the patient (see table 7).<sup>5</sup> Twenty-five of the 27 responding physicians reported experiencing difficulty obtaining coverage for patients with private health insurance at least some of the time, with 3 of those physicians reporting that it was always difficult.<sup>6</sup> For Medicaid and Children's Health Insurance Program (CHIP) coverage, 4 physicians reported that the device was not covered at all by this type of insurance. Additionally, 18 of the 22 responding physicians who reported receiving reimbursement for the device through Medicaid or CHIP also reported difficulty obtaining that coverage at least some of the time, with 4 of those reporting that it was always difficult. Most responding physicians (19 of 27) reported not treating any patients covered by Medicare, but 4 of those who did treat patients with Medicare coverage said that obtaining Medicare coverage for the device was always difficult.<sup>7</sup> Further, 7 of the 27 responding physicians reported that health insurance coverage influenced their clinical decision to use the device. For example, 3 physicians reported that delay or denial of insurance coverage for the Melody TPV device has led them to conduct open heart surgery in patients for whom use of the device would otherwise have allowed them to delay this more invasive surgery.

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<sup>5</sup>We did not determine if issues in obtaining coverage were specifically related to off-label use.

<sup>6</sup>According to officials from America's Health Insurance Plans, private health insurers often determine coverage for HDE devices on a case-by-case basis.

<sup>7</sup>According to officials at the Centers for Medicare & Medicaid Services, the agency has not issued any national guidance to state Medicaid programs regarding coverage of HDE devices. In addition, officials reported that in most cases Medicare coverage for HDE devices is determined on a case-by-case basis.

**Table 7: Number of Physicians Reporting Difficulty Obtaining Insurance Coverage for Melody TPV Device, by Insurance Type and Extent of Difficulty Experienced**

Type of health insurance	Number of physicians reporting difficulty obtaining insurance coverage for Melody TPV							
	Melody TPV not covered by this type of insurance	No patients with this type of insurance	Never difficult	Sometimes difficult	About half the time difficult	Most of the time difficult	Always difficult	At least sometimes difficult
Private health insurance	0	0	2	11	9	2	3	25
Medicaid/Children's Health Insurance Program	4	1	4	10	2	2	4	18
Medicare <sup>a</sup>	0	19	2	0	0	0	4	4

Source: GAO.

Notes: This table presents the responses from 27 physicians who responded to GAO's 2011 Survey of Physicians Who Use the Melody TPV device.

<sup>a</sup>Two physicians did not respond to the question regarding Medicare insurance.

Consistent with what stakeholders reported about challenges to obtaining insurance coverage for HDE devices in general, physicians we surveyed reported challenges obtaining health insurance coverage for the Melody TPV device. These included comments about the time required to discuss coverage with the insurers to obtain reimbursement, insurers' lack of familiarity with the medical device, challenges because insurers consider the medical device experimental, and problems because the Melody TPV procedure did not have a current procedural terminology (CPT) code at the time of our survey.<sup>8</sup>

About half (52 percent) of physician respondents reported that they have implanted the Melody TPV device in a pediatric or adult patient for an indication other than the indication on the label of the device—an off-label indication—since it was approved for the U.S. market in February 2010. However, all but 1 of those physicians said they used it off-label 20 percent of the time or less across instances when they implanted the device in pediatric patients. Further, 29 percent of responding physicians

<sup>8</sup>CPT is a uniform coding system maintained by the American Medical Association used to identify and bill for medical procedures and services under public and private health insurance programs. Officials from the device manufacturer said they implemented new CPT codes for outpatient and inpatient use of the Melody TPV device in July and October 2011.

stated that they never used the device for an off-label indication in pediatric patients. In addition, each instance of off-label use should have been for an indication approved by the hospital's institutional review board (IRB). For example, 1 physician reported that he routinely implanted the Melody TPV for one of three IRB-approved protocols, two of which were for an off-label indication but all were for pediatric patients.<sup>9</sup>

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<sup>9</sup>The three protocols approved by the hospital's IRB were (1) in accordance with the approved indication for use, (2) transcatheter use outside the parameters of the approved indication for use, and (3) for surgical use instead of a conduit. The physician reported that the hospital used the second two off-label protocols in a small percentage of cases.

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# Appendix II: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients since Fiscal Year 2006

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Of the 118 devices approved through FDA's premarket approval (PMA) and HDE processes in the 4 years since FDAAA was enacted, 18 (15 percent) were explicitly indicated for use in only pediatric patients—those age 21 or younger—or both pediatric and adult patients. Of the 86 PMA and HDE devices approved in the 2 years before FDAAA was enacted, 21 were explicitly indicated for use in only pediatric patients or both pediatric and adult patients (see table 8). Of these, few devices were explicitly indicated for use in patients under age 18—that is, in each fiscal year, most devices that explicitly indicated a pediatric population were indicated for use in patients age 18 years and older.<sup>1</sup>

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<sup>1</sup>Five of the PMA devices approved in the 2 years before FDAAA was enacted were indicated solely for use in patients age 18 or older. An additional six PMA devices approved before FDAAA was enacted were indicated solely for use in patients age 21 or older. Six of the PMA devices and one of the HDE devices approved in the 4 years after FDAAA was enacted were indicated solely for use in patients age 18 or older. An additional two PMA devices approved after FDAAA was enacted were indicated solely for use in patients age 21 or older. We consider these to be explicitly indicated for use in pediatric patients because the minimum age includes patients age 21 years or younger.

**Appendix II: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients since Fiscal Year 2006**

**Table 8: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2006 through 2011**

Device type	Pre-FDAAA		Post-FDAAA <sup>a</sup>				Total pre- FDAAA	Total post- FDAAA
	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011		
<b>PMA<sup>b</sup></b>								
Pediatric only	1	1	0	1	0	0	2	1
Pediatric and adult	13	5	2	2	3	7	18 <sup>c</sup>	14 <sup>d</sup>
All pediatric PMA	14	6	2	3	3	7	20	15
<b>HDE</b>								
Pediatric only	1 <sup>e</sup>	0	0	0	0	0	1	0
Pediatric and adult	0	0	1	0	1	1	0	3 <sup>f</sup>
All pediatric HDE	1	0	1	0	1	1	1	3
<b>Total pediatric</b>	<b>15</b>	<b>6</b>	<b>3</b>	<b>3</b>	<b>4</b>	<b>8</b>	<b>21</b>	<b>18</b>

Source: GAO analysis of FDA documents.

Notes: We considered pediatric devices approved through FDA's premarket approval (PMA) and humanitarian device exemption (HDE) processes to be those explicitly indicated for use in pediatric patients when the approved indication for use statement (1) specified a population that included patients age 21 years or younger, (2) specifically stated it was for pediatric use, or (3) stated it was for skeletally immature patients. Devices explicitly indicated for use in pediatric patients include those explicitly indicated for use in pediatric patients or those for both pediatric and adult patients. Additional medical devices for which the indication for use was silent on the age of the patient population may have been approved for pediatric use during this time period.

<sup>a</sup>The FDA Amendments Act of 2007 (FDAAA) was enacted September 27, 2007, but no PMA or HDE devices were approved after FDAAA was enacted in fiscal year 2007.

<sup>b</sup>PMA devices include original and panel-track supplement devices.

<sup>c</sup>Five of the PMA devices approved in the 2 years before FDAAA was enacted were indicated solely for use in patients age 18 or older. An additional six were indicated solely for use in patients age 21 or older. We consider these to be explicitly indicated for use in pediatric patients because the minimum age includes patients age 21 years or younger.

<sup>d</sup>Six of the PMA devices approved in the 4 years after FDAAA was enacted were indicated solely for use in patients age 18 or older. An additional two PMA devices were indicated solely for use in patients age 21 or older. We consider these to be explicitly indicated for use in pediatric patients because the minimum age includes patients age 21 years or younger.

<sup>e</sup>The HDE device approved in fiscal year 2006 was indicated for fetuses whose gestational age is between 16 and 26 weeks. We considered this device to be explicitly indicated for use in pediatric patients.

<sup>f</sup>One of the HDE devices approved in the 4 years after FDAAA was enacted was indicated solely for use in patients age 18 or older.

# Appendix III: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2008 through 2011

Device name, number <sup>a</sup>	Date approved	Summary of indication for use	Pediatric subpopulation (if available) <sup>b</sup>	Medical specialty
<b>Devices approved through the Food and Drug Administration's (FDA) premarket approval (PMA) process</b>				
Propel sinus implant, P100044	8/11/2011	Indicated for use in patients 18 years of age or older following ethmoid sinus surgery to reduce the need for postoperative intervention.	Transitional adolescent, adult	Ear, nose, and throat
Vitros Immunodiagnostic Products Anti-HBe Reagent Pack, Calibrator and Controls, P100001	7/20/2011	Indicated for the in vitro qualitative detection of antibodies to hepatitis B e antigen (anti-HBe) in human adult and pediatric (2 to 21 years old) serum from individuals who have symptoms of chronic hepatitis and those who have recovered from hepatitis B infection.	Child, adolescent, transitional adolescent, adult	Microbiology
Solseta Injectable Gel, P100014	5/27/2011	Indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, and antimotility medications).	Transitional adolescent, adult	Gastroenterology/Urology
Vitros Immunodiagnostic Products HBeAg Reagent Pack, Calibrator and Controls, P090028	5/11/2011	Indicated for the in vitro qualitative detection of hepatitis B e antigen (HBeAg) in human adult and pediatric (2 to 21 years old) serum from individuals who have symptoms of hepatitis or who may be at risk for hepatitis B virus infection.	Child, adolescent, transitional adolescent, adult	Microbiology
Cobas HPV Test, P100020	4/19/2011	Indicated to screen patients 21 years and older with ASC-US (atypical squamous cells of undetermined significance) cervical cytology test results to determine the need for referral to colposcopy or to assess the presence or absence of high-risk Human Papillomavirus genotypes 16 and 18, and for other uses in women 30 years and older.	Transitional adolescent, <sup>c</sup> adult	Microbiology
Oraquick HCV Rapid Antibody Test, P080027 <sup>d</sup>	6/25/2010	Indicated for the qualitative detection of antibodies to hepatitis C virus in venipuncture whole blood specimens from individuals 15 years or older.	Adolescent, transitional adolescent, adult	Microbiology



**Appendix III: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2008 through 2011**

<b>Device name, number<sup>a</sup></b>	<b>Date approved</b>	<b>Summary of indication for use</b>	<b>Pediatric subpopulation (if available)<sup>b</sup></b>	<b>Medical specialty</b>
Alair Bronchial Thermoplasty System, P080032	4/27/2010	Indicated for the treatment of severe persistent asthma in patient 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long-acting beta agonists.	Transitional adolescent, adult	Anesthesiology
Esteem Totally Implantable Hearing System, P090018	3/17/2010	Indicated for patients with hearing loss who meet the following criteria: (1) 18 years of age or older, (2) stable bilateral sensorineural hearing loss, (3) moderate to severe sensorineural hearing loss defined by Pure Tone Average, (4) unaided speech discrimination test score greater than or equal to 40 percent, (5) normally functioning eustachian tube, (6) normal middle ear anatomy, (7) normal tympanic membrane, (8) adequate space for Esteem implant determined via a high resolution computerized tomography (CT) scan, and (9) minimum 30 days of experience with appropriately fit hearing aids.	Transitional adolescent, adult	Ear, nose, and throat
Architect Core Reagent Kit, Architect Core Calibrator and Architect Core Controls, P080023	4/10/2009	Indicated for the qualitative detection of antibodies to hepatitis B core antigen in human adult and pediatric serum and plasma and neonatal serum. It is intended as an aid in the diagnosis of acute, chronic, or resolved hepatitis B virus infection in conjunction with other laboratory results and clinical information.	(No age provided, indicated for pediatric and adult patients)	Microbiology
REPEL-CV Bioreabsorbable Adhesion Barrier, P070005	3/6/2009	Indicated for reducing the severity of postoperative cardiac adhesions in pediatric patients who are likely to require reoperation via sternotomy.	(No age provided, indicated for pediatric patients)	Cardiovascular
Freestyle Navigator Continuous Glucose Monitor, P050020	3/12/2008	Indicated for continually recording interstitial fluid glucose levels in people ages 18 and older with diabetes mellitus for the purpose of improving diabetes management.	Transitional adolescent, adult	Clinical chemistry
Architect Core-M Reagent Kit, Architect Core Calibrator and Architect Core Controls, P060035	11/6/2007	Indicated for the qualitative detection of IgM antibodies to hepatitis B core antigen in human adult and pediatric serum and plasma and neonatal serum. It is intended as an aid in the diagnosis of acute, chronic, or resolved hepatitis B virus infection in conjunction with other laboratory results and clinical information.	(No age provided, indicated for pediatric and adult patients)	Microbiology

**Appendix III: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2008 through 2011**

<b>Device name, number<sup>a</sup></b>	<b>Date approved</b>	<b>Summary of indication for use</b>	<b>Pediatric subpopulation (if available)<sup>b</sup></b>	<b>Medical specialty</b>
<b>PMA panel-track supplement devices</b>				
Meditec MEL 80 Excimer Laser, P060004-S001	3/28/2011	Indicated for primary lasik treatments for (1) the reduction or elimination of naturally occurring hyperopia, (2) in patients who are 21 years of age or older, and (3) with documentation of stable manifest refraction over the past year.	Transitional adolescent, <sup>c</sup> adult	Ophthalmic
Oraquick HCV Rapid Antibody Test, P080027-S001 <sup>d</sup>	2/18/2011	A single-use immunoassay for the qualitative detection of antibodies to hepatitis C virus in fingerstick whole blood specimens and venipuncture whole blood specimens from individuals 15 years or older.	Adolescent, transitional adolescent, adult	Microbiology
Navistar & Celsius Thermacool Catheters, P030031-S011	2/6/2009	Indicated for catheter-based cardiac electrophysiological mapping (stimulating and recording), for the treatment of (1) type I atrial flutter in patients age 18 or older, (2) recurrent drug/device refractory sustained monomorphic ventricular tachycardia due to prior myocardial infarction in adults, and (3) drug refractory recurrent symptomatic paroxysmal atrial fibrillation.	Transitional adolescent, adult	Cardiovascular
<b>Devices approved through FDA's humanitarian device exemption process (HDE)</b>				
ELANA Surgical KitHUD, H080005	3/10/2011	Indicated for creating arteriotomies during an intracranial vascular bypass procedure in patients 13 years of age or older with an aneurysm or a skull base tumor affecting a large (> 2.5 mm), intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity.	Adolescent, transitional adolescent, adult	Cardiovascular <sup>e</sup>
Medtronic Melody Transcatheter Pulmonary Valve and Ensemble Transcatheter Valve Delivery System, H080002	1/25/2010	Indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions: Existence of a full (circumferential) Right Ventricular Outflow Tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted and Dysfunctional RVOT conduits with a clinical indication for intervention, and either Regurgitation: ≥ moderate regurgitation, or Stenosis: mean RVOT gradient ≥ 35 mmHg.	(No age provided, indicated for pediatric and adult patients)	Cardiovascular

**Appendix III: PMA and HDE Devices Explicitly Indicated for Use in Pediatric Patients, Fiscal Years 2008 through 2011**

<b>Device name, number<sup>a</sup></b>	<b>Date approved</b>	<b>Summary of indication for use</b>	<b>Pediatric subpopulation (if available)<sup>b</sup></b>	<b>Medical specialty</b>
NeuRx RA/4, H070003	6/17/2008	Indicated for use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but who lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day. For use only in patients 18 years of age or older.	Transitional adolescent, adult	Anesthesiology

Source: GAO analysis of FDA data and documents.

Notes: We considered pediatric devices to be those explicitly indicated for use in pediatric patients when the approved indication for use statement (1) specified a population that included patients age 21 years or younger, (2) specifically stated it was for pediatric use, or (3) stated it was for skeletally immature patients. Devices explicitly indicated for use in pediatric patients include those explicitly indicated for use in pediatric patients or those for both pediatric and adult patients.

<sup>a</sup>FDA assigns a number to each device application that denotes the type of device (P=PMA, H=HDE), year the application was received, and number assigned chronologically in the order it was received. FDA also assigns PMA supplements, including panel-track supplements, a supplement number (S).

<sup>b</sup>For purposes of this table, pediatric subpopulation ages are those that FDA uses for internal tracking purposes: neonate (birth to 28 days), infant (29 days to <2 years), child (2 years to <12 years), adolescent (12 years to <18 years), and transitional adolescent (18 years to <=21 years).

<sup>c</sup>Two PMA devices are indicated solely for use in patients age 21 or older—we consider these devices to be indicated for use in pediatric patients because the minimum age includes pediatric patients.

<sup>d</sup>The original application and a panel-track supplement for the Oraquick HCV Rapid Antibody Test were both approved for use in pediatric patients after the FDA Amendments Act of 2007 was enacted.

<sup>e</sup>We identified each device's medical specialty based on data from FDA's product code classification database—which contains device names and product codes assigned based upon the medical device product classification designated under 21 C.F.R. Parts 862-892. Although the database indicated a medical specialty of cardiovascular for the ELANA Surgical KitHUD, FDA officials reported that upon further review they determined that the product code assigned for the device is technically inaccurate. To correct this technical inconsistency, FDA will issue a corrected product code for this product in the near future. The corrected medical specialty for the device should be neurology, according to FDA officials.

# Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

Márcia Crosse, Director  
Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

DEC 09 2011

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft report entitled, "PEDIATRIC MEDICAL DEVICES: Provisions Support Development, but Better Data Needed for Required Reporting" (GAO-12-225).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "PEDIATRIC MEDICAL DEVICES: PROVISIONS SUPPORT DEVELOPMENT, BUT BETTER DATA NEEDED FOR REQUIRED REPORTING" (GAO-12-225)**

The Department appreciates the opportunity to review and comment on this draft report.

**GAO Recommendation**

*We recommend that the Commissioner of the Food and Drug Administration (FDA) collect reliable information to report data related to pediatric medical devices. Specifically, FDA should take steps to consistently collect information using its existing pediatric electronic flag or otherwise develop internal controls to readily and reliably collect and report information on devices for pediatric use.*

**FDA Response**

We recognize that medical devices—including devices designed for the pediatric population—are critical to the improvement and advancement of healthcare, often serving as life-saving delivery systems. We agree with the GAO recommendation that FDA collect reliable information to report data related to pediatric medical devices. FDA is in the process of modifying and updating its current tracking system, related data quality controls, and training program requirements for pediatric medical device premarket submissions. When this process is complete, FDA's pediatric information collection efforts will satisfy our pediatric device operations and oversight needs, including the development of the annual Pediatric Report to Congress.

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Rebecca Abela; Carolyn Fitzgerald; Cathleen Hamann; Shirin Hormozi; Lisa Motley; and Dan Ries made key contributions to this report.

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# Related GAO Products

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*Medical Devices: FDA Should Enhance Its Oversight of Recalls.* [GAO-11-468](#). Washington, D.C.: June 14, 2011.

*Medical Devices: FDA's Premarket Review and Postmarket Safety Efforts.* [GAO-11-556T](#). Washington, D.C.: April 13, 2011.

*High-Risk Series: An Update.* [GAO-11-278](#). Washington, D.C.: February 2011.

*Food and Drug Administration: Overseas Offices Have Taken Steps to Help Ensure Import Safety, but More Long-Term Planning Is Needed.* [GAO-10-960](#). Washington, D.C.: September 30, 2010.

*Food and Drug Administration: Opportunities Exist to Better Address Management Challenges.* [GAO-10-279](#). Washington, D.C.: February 19, 2010.

*Food and Drug Administration: FDA Faces Challenges Meeting Its Growing Medical Product Responsibilities and Should Develop Complete Estimates of Its Resource Needs.* [GAO-09-581](#). Washington, D.C.: June 19, 2009.

*Medical Devices: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments.* [GAO-09-370T](#). Washington, D.C.: June 18, 2009.

*High-Risk Series: An Update.* [GAO-09-271](#). Washington, D.C.: January 2009.

*Medical Devices: FDA Should Take Steps to Ensure That High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process.* [GAO-09-190](#). Washington, D.C.: January 15, 2009.

*Health-Care-Associated Infections in Hospitals: Number Associated with Medical Devices Unknown, but Experts Report Provider Practices as a Significant Factor.* [GAO-08-1091R](#). Washington, D.C.: September 26, 2008.

*Medical Devices: FDA Faces Challenges in Conducting Inspections of Foreign Manufacturing Establishments.* [GAO-08-780T](#). Washington, D.C.: May 14, 2008.

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*Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk.* [GAO-08-147](#). Washington, D.C.: January 31, 2008.

*Medical Devices: Challenges for FDA in Conducting Manufacturer Inspections.* [GAO-08-428T](#). Washington, D.C.: January 29, 2008.

*Medical Devices: FDA's Approval of Four Temporomandibular Joint Implants.* [GAO-07-996](#). Washington, D.C.: September 17, 2007.

*Food and Drug Administration: Methodologies for Identifying and Allocating Costs of Reviewing Medical Device Applications Are Consistent with Federal Cost Accounting Standards, and Staffing Levels for Reviews Have Generally Increased in Recent Years.* [GAO-07-882R](#). Washington, D.C.: June 25, 2007.

*Medical Devices: Status of FDA's Program for Inspections by Accredited Organizations.* [GAO-07-157](#). Washington, D.C.: January 5, 2007.



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