

Highlights of [GAO-12-225](#), a report to congressional committees

### 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).

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## PEDIATRIC MEDICAL DEVICES

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

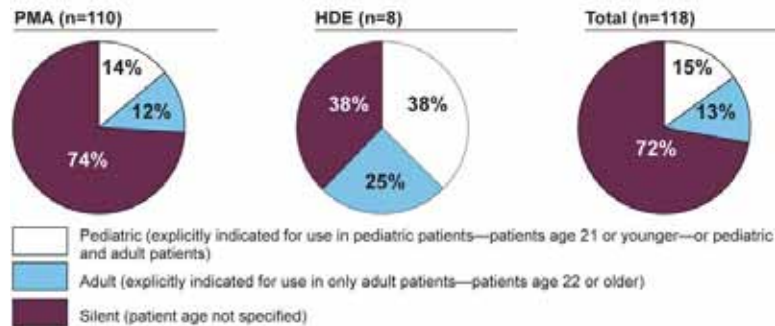
#### What GAO Found

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.

United States Government Accountability Office