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AAP brings need for pediatric medical devices to forefront

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As development of medical and surgical devices for children continues to lag, pediatricians, manufacturers and regulators are coming together to look for new solutions.

They proposed incentivizing manufacturers, streamlining the regulatory process, looking for new funding sources and more during a two-day meeting the Food and Drug Administration (FDA) held at the Academy's urging.

"Off-label use of medical devices in children continues to be a necessary and appropriate but unfortunate reality for pediatricians and pediatric surgical specialists," said AAP CEO/Executive Vice President (Interim) Mark D. Del Monte, J.D. "Our goal must be to significantly decrease the off-label use of devices in children so that children are … using devices designed for them and studied in pediatric populations."

The AAP-championed Pediatric Medical Device Safety and Improvement Act of 2007 assisted development by improving device tracking, creating an incentive for the development of pediatric devices, establishing Pediatric Device Consortia program, and improving post-market surveillance.

However, unlike pharmaceuticals, companies are not required to study medical devices in children, and development continues to lag behind devices for adults. Over the past decade, only about 9% of devices going through pre-market approval or humanitarian device exemption pathways were approved with pediatric indications for children under 18, , according to data presented by the FDA.

Pediatric device development poses numerous challenges. Adhering to regulations to get products approved can be timely and costly. The small number of children with certain conditions makes it difficult to perform studies and commercialize devices. If investors don't believe they will get a sufficient return, they won't provide the funding to get these projects off the ground.

"A large gap still exists between the idea and the clinical application for pediatric devices, mostly due to the significant development and regulatory costs with insignificant financial return," said Bob Kroslowitz, president and CEO of Berlin Heart Inc. and representative of AdvaMed, a trade association for the medical technology industry.

Throughout the meeting, experts discussed ways to optimize evidence generation through randomized controlled trials, extrapolation of adult data and use of real-world data.

The issues of marketability and funding generated discussion about involving venture capitalists in future talks, looking at other funding sources like philanthropic organizations and patient advocacy groups, offering incentives to manufacturers and improving insurance coverage. Some suggested using an orphan drug

model, which incentivizes development of drugs for rare conditions. Others called for more money for Pediatric Device Consortia that assist with these projects.

To overcome regulatory hurdles, some suggested adding more pediatric experts to FDA review teams, allowing expedited review and looking at ways to streamline the process without sacrificing quality or safety.

FDA Commissioner Scott Gottlieb, M.D., said the agency has been adding pediatric experts to advisory panels, collecting data on unmet needs and barriers, finding new ways to protect children in trials and incorporating real-world strategies to generate evidence. He committed to doing more.

“Today, more than ever, we recognize the unique needs of children and we’re working to encourage the development of safe, effective medical devices specifically for pediatric patients,” Dr. Gottlieb said. “… There are still far too few devices on the market designed specifically to treat, diagnose and cure disease in children.”

The FDA will be sending a report to Congress on proposed solutions. It will accept public comments until Sept. 14 at https://www.regulations.gov/document?D=FDA-2018-N-0404-0001.

Resources

- AAP policy "Off-Label Use of Medical Devices in Children"
- AAP Section on Advances in Therapeutics and Technology