

The Need for Children's Medical Devices

Children Are At Risk of Being Left Behind

Cutting-edge research and revolutionary technologies have led to the development of countless innovative medical devices, allowing patients to live longer, healthier lives. However, as science and medicine move forward, children are at risk of being left behind. Too few critical medical devices are designed specifically with children's needs in mind.

While children and adults suffer from many of the same diseases and conditions, their device needs can vary considerably due to differences in size, rates of growth, critical development periods, anatomy (e.g., organ size), physiological differences (e.g., breathing and heart rates), physical activity levels, etc. In addition, since there are many pediatric diseases for which no adult parallel exists, in some cases devices exclusively designed for children are needed.

Like adults, children deserve medical devices that are safe, effective and designed for their particular needs. Yet, to date, because the pediatric market is so small and pediatric diseases relatively rare, there has been little incentive for device manufacturers to focus their attention on children. Typically, pediatric providers must resort to "jerry-rigging" or fashioning make-shift device solutions for pediatric use. When that is not an option, providers may be forced to use more invasive treatment or less effective therapies.

Recent Efforts to Address Children's Device Needs

Over the past few years, several efforts have been launched to better identify barriers to the development of pediatric devices and to generate solutions for improving children's access to needed products:

- Beginning in June 2004, the American Academy of Pediatrics, the Elizabeth Glaser Pediatric AIDS Foundation, the National Organization for Rare Disorders (NORD), the National Association of Children's Hospitals, and the Advanced Medical Technology Association (AdvaMed) hosted a series of stakeholders meetings that yielded recommendations for improving the availability of pediatric devices.
- In October 2004, in response to a directive in the Medical Devices Technical Corrections Act of 2004, the Food and Drug Administration released a report that identified numerous barriers to the development and approval of devices for children.
- In July 2005, the Institute of Medicine (IOM) issued a report on the adequacy of post-market surveillance of pediatric medical devices, as mandated by the Medical Device User Fee and Modernization Act of 2002. The IOM found significant flaws in safety monitoring and recommended expanding the FDA's ability to require post-market studies of certain products and improving public access to information about post-market pediatric studies.

Legislative Action Is Needed

In our view, the solution to the lack of pediatric devices lies in a comprehensive approach that includes providing assistance to innovators, streamlining regulatory processes, elevating pediatric device issues at the FDA and NIH, and improving incentives for devices for small markets -- while still preserving the ability to ensure the safety of new products once on the market. We look forward to working with Congress to pass legislation to ensure that when it comes to medical devices, children have access to the very best of what science and medicine have to offer.

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