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Deputy Director, FDA CDRH  
Division of Dockets Management (HFA-305)  
Food and Drug Administration, 5630 Fishers Lane, rm. 1061,  
Rockville, MD 20852

Re: Docket No. 2004N-0254 (Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children)

Dear Ms. Kahan,

As an SGE bioethicist and former medical device engineer, I comment on this issue from multiple vantage points. Decisions about pediatric medical device development often focus on several factors, the most ethically significant of which is level of seriousness of the disease (e.g., life-threatening). Other factors include: the prevalence of the condition to be treated in the pediatric population; the population size (n) of the age ranges of the children likely to be treated with the device; and the availability, suitability, efficacy, and adverse event profile of alternative interventions for the condition. Large net profit potential and large market potential are key variables for corporate R&D. If a pediatric population is small, it has the potential to be reduced to smaller subpopulations when one factors in mental/physical/physiological maturity and comorbidities. This shrinks market potential.

In developing devices for children, there are a multitude of factors to reflect upon including, the patient's stage of immunity and neurological/organ system development; small body size (BMI, BSA) and the often technical inability to 'simply' miniaturize an adult device; impact of patient growth (including rapid growth spurts); compliance issues with children (especially when they are in settings of limited psychosocial support); ability of children to operate and maintain their device by themselves versus the need for adult assistance; possible hormonal effects during puberty; and the ability of children to modify/restrict their activity level to foster safe and effective device function.

As an example, in some cases (e.g., pulmonary devices for aerosol delivery), specific pediatric formations and delivery systems are needed due to inherent

2004N-0254

anatomical, physiologic, pathophysiologic, and technical considerations in children versus adult patients (Resp Care 2000;45:646-651).

From a financial perspective, one wonders how many parents could afford medical devices for their children if insurance companies and Medicaid did not cover the costs. In the case of implants, cost estimates must reflect upon the surgery, the implant, and post-surgery care.

From a research ethics/clinical trial perspective, children are a “vulnerable” population and the regulatory requirements for such trials are viewed by many in industry as burdensome. Heightened regulatory and media spotlights often make pediatric clinical trials “too hot to handle” for some manufacturers, so they continue with projects that are adult-focused. Because children give “assent” rather than informed consent, clinical trials in this population involve more parties (the child and his/her parents). These are more people to deal with, more potential risk due to the emotional bond between parent and child (creating increased fear of litigation), and potentially a corporate “*Is it worth it?*” attitude.

If industry does not fund this research, and government research monies continue to shrink, the potential for increased pediatric devices seems remote.

*In addressing these multiple matters one must ask, What is the motive for device development? Corporate profit? Relief of patient suffering? Some of both? Are smaller corporate profits justified when the benefit is improved patient quality of life? What about the value of emotional benefits to families when their children recover or experience reduction in symptoms? Are companies and their shareholders willing to accept smaller profits when they are due to such benefits? When is net profit unacceptably low or high? These are values-based questions that require the diligent attention of medical industry personnel, preferably with the input of pediatric patients and their parents, as well as bioethicists.*

Easing research ethics requirements is likely not the answer, as the protection of human subjects is critical, especially when these subjects cannot make informed choices (then can only assent) and they often have serious or life-threatening conditions with limited medical and surgical options.

Thank you for the opportunity to comment on this important topic.

Sincerely,



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