



**Texas Children's Hospital**  
www.texaschildrenshospital.org



**BAYLOR  
COLLEGE OF  
MEDICINE**

**Renal Service**

*Located in the Texas Medical Center*

6621 Fannin Street  
MC 3-2482  
Houston, Texas 77030  
Tel: 832/824-3800  
Fax: 832/825-3889

1015 W 132 111

Eileen D. Brewer, M.D.  
*Chief and Section Head*  
Ewa Elenberg, M.D.  
Daniel E. Ferg, M.D., Ph.D.  
Stuart L. Goldstein, M.D.  
L. Leighton Hill, M.D.  
Arundhati S. Kale, M.D.  
Rita D. Sheth, M.D.

August 13, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fisher's Lane  
Room 1061  
Rockville, Maryland 20852

Re: Docket Number 2004N-0254

Dear Center for Medical Devices and Radiological Health Director,

I am responding to your request for comments regarding the possible barriers to the availability of medical devices intended to treat or diagnose diseases and conditions that affect children. I am a pediatric nephrologist who serves as a special government employee and member of the CDRH advisory panel. I want to first thank you for your interest in children.

I forwarded the 3 questions posed in your request for comments to the medical and surgical division chiefs at Texas Children's Hospital, which is the largest pediatric hospital in the United States. While the specific device needs were obviously peculiar to each specialty, a number of themes emerged. I have distilled these for each question, and attached a copy of their individual responses for your review.

2004N-0254

@13

**1. What are the unmet medical device needs in the pediatric population (neonates, infants, children, and adolescents)? Are they focused in certain medical specialties and/or pediatric subpopulations?**

Almost every specialty responded that appropriately sized instruments are not readily available, or certainly no significant choice exists, for the entire range of patient sizes seen in pediatric sub-specialty settings. The major areas of deficits are:

1. Renal – Dialysis catheters, hemodialysis and continuous renal replacement therapy circuit tubing, hemodialyzers, blood pressure cuffs and ambulatory blood pressure monitors
2. Pulmonary – Bronchoscopy equipment, nasal and facial oxygen supplementation equipment, fiberoptic scooping devices
3. Cardiology – Intravascular stents and devices, cardiac assist device technology (artificial hearts, left-ventricular assist devices)

**2. What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical hindrances? Economic issues? Legal issues?**

The major barrier to development for all pediatric subspecialty equipment is economic. Just as existed with drug development for children, companies are unwilling to develop and formally study devices in children for fear of liability from a bad outcome coupled with lack of significant economic incentives or profit in the relatively small pediatric population. I have personally tried to work with catheter companies to develop smaller catheters for infants with multi-organ system failure who require dialysis and need a small but reliable vascular access. Manufacturers have told me the R&D and FDA regulations make such endeavors cost prohibitive, given the small market. Furthermore, conducting the appropriate studies to attain FDA device approval requires most often a multi-center pediatric effort in order to enroll sufficient patients. I have spearheaded such an effort with respect to pediatric CRRT. The Prospective Pediatric CRRT (ppCRRT) registry group is now conducting a four-center trial of an infant CRRT filter, which is available in Europe, Canada and Mexico, to attain FDA 510K approval. Gambro Renal Products is funding the study, which they could not previously get initiated since no collaborative group existed previously, and the contractual negotiations

between a company and separate institutions creates more burden on the whole development and testing process.

3. What could FDA do to facilitate the development of devices intended for the pediatric population? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors, and manufacturers to pursue clinical trials and/or marketing of pediatric devices?

The FDA may have a number of options to facilitate the device development process.

1. As with drugs, the FDA could extend patent exclusivity for certain device types developed for children. While we want to increase the choice when it comes to catheters for instance, other areas where no pediatric device exists may be appropriate for this type of patent protection.
2. Lower the cost of FDA application by identifying pediatric chronic illness populations as orphans, thereby making them subject to the orphan drug act. Many smaller companies have told me that a significant reduction in application costs would lower their threshold to enter into the pediatric market.
3. Encourage the FDA Centers and the NIH to support multi-center collaborative networks to expedite device testing and application in pediatric patients. Out ppCRRT registry is serving as a model to the adult nephrology community in this regard. These networks can decrease and simplify the contractual processes, provide the FDA with a quality control mechanism and foster rigorous scientific evaluation of the devices.

I have attached the specific responses I received at the end of this letter. Once again, thank you for your interest in improving the healthcare of children.

Sincerely,

  
Stuart L. Goldstein, MD  
Associate Professor of Pediatrics  
Baylor College of Medicine  
Medical Director, Renal Dialysis  
Texas Children's Hospital

E-mail comments received

**From George Mallory, MD,  
Pediatric Pulmonologist and Director Pediatric Lung Transplant Program at  
Texas Children's Hospital**

Let me address medical devices that have to be adapted with growth. This is, I believe, our biggest problem in pediatric pulmonology. With respect to endotracheal and tracheostomy tubes, we have very good choices now a days. With respect to nasal masks for nasal ventilation (BiPAP and CPAP), we often have the cheapest forms only since the more adaptable devices are more expensive and insurers almost always will not pay the hospital for in-patient and home care companies for out-patient uses. Not only that but these devices often need to change with growth so expense is a built-in part of treating growing children. Our current market forces penalize children, providers and manufacturers in this regard.

Bronchoscopes have moved from fiberoptic technology to video-chip devices. Obviously, adult scopes came first but Olympus is moving chip technology into the smaller scopes and all manufacturers need to be encouraged to spend the money on miniaturizing all such equipment, preferably with governmental incentives and not threats. It is more expensive and there will be less profit because the volume for pediatrics will not be so great. The government needs to find incentives along the lines of orphan drugs to encourage these devices.

**From Yadin David, Director of Biomedical Engineering at Texas Children's  
Hospital**

Hi Stu:

I'm delighted to see the attention this issue is getting at the FDA level. Over the years several issue regarding medical devices for pediatrics repeated themselves again and again. Here are some quick few comments I would like to share with you:

1. lack of market needs understanding by manufacturers. Pediatric device is not a "smaller" adult device.
2. the pediatric device is a smaller volume market and does not attract industry, perhaps government should exercise incentives to change that.
3. labeling for use and warnings affixed to devices and disposables are not appropriate for parents nor for children who may use them.
4. the environment of use maybe in noisy areas on one hand and in noise-free (like our NICU) on the other, however device features (like alarms) do not accommodate that.
5. sibling protection should be standard feature on devices, and finally,

6 I recommend we apply for a grant to develop resource center to support families who needs to use medical devices out side the hospital and do not have a point of information to go to.

**From David Wesson, MD, Chief of Pediatric Surgery at Texas Children's Hospital**

Stuart,

We reviewed this at our faculty meeting on Friday but didn't come up with anything apart from the 2 well know issues:

1. Devices for kids may not be profitable
2. It's hard to do research on children

David Wesson