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Division of Dockets Management
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, Maryland 50852

RE: Docket Number: 2004N-0254

To Whom It May Concern:

On behalf of the 14,000 members of the American Thoracic Society (ATS), I would like to thank the Food and Drug Administration (FDA) for seeking community comment on how to improve the therapeutic medical devices options for pediatric patients. The members of the ATS provide unique expertise and experience in treating children with respiratory disease. We strongly endorse the need for FDA to take steps to increase therapeutic medical device options that are specifically designed, tested and have post-market data collection for children with respiratory diseases.

The ATS appreciates the FDA's interest in this important but long neglected children's health issue. The ATS especially wants to recognize the recent establishment of the Office of Pediatric Therapeutics (OPT) within the Office of the Commissioner of the Food and Drug Administration and the Pediatric Advisory Committee (PAC). These organizations will provide a platform for highlighting the unique medical needs of children. It is our hope and expectation that pediatric medical devices will be an important part of the agenda of both these groups. It is our hope that FDA, by bringing attention to this issue and by taking regulatory action, can improve the availability of medical devices specifically designed, studied and tested for children.

Children are not little adults. While children may suffer from many of the diseases of adults and often benefit from the therapies developed to treat adult diseases, there are fundamental differences in size, growth, chemistry and activity level that create a unique set of factors in dealing with medical devices for children.

Unmet Pediatric Pulmonary Device Needs

There several unmet needs in the pediatric pulmonary community. The ATS offers the following examples:

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Drug Deposition of Aerosolized Drugs

Drug deposition of aerosolized medicine is poorly studied in pediatric populations. While sufficient drug deposition studies exist for the adult population, studies in children under 5 years old and especially under 3 years old are sorely lacking. While the need is most pressing for bronchodilator drugs and steroids used to treat asthma, the recent interest in inhaled antibiotics will also create a need for studies in children. The drug deposition studies should be specific to the administering devices, including metered dose inhalers (MDIs), dry powdered inhalers, nebulizers and transtracheal administration.

Size and Shape of Tracheostomy Tubes

Device manufacturers have provided a wide range of tube sizes for tracheostomy tubes. However, the availability of tube shapes and studies on the optimal shape and size for various age groups is lacking. Studies need to be conducted to provide guidance to clinicians on the optimal size and shape of tracheostomy tubes in children. .

Care of Tracheostomies

As noted in the 1999 ATS statement Care of the Child with a Chronic Tracheostomy, there has been little research done on proper care of tracheostomies in children. The authors of the document state, "Many of the recommendations are by consensus in the absence of scientific data, and suggestions are made for areas of research." Considering the size of the pediatric patient population that has tracheostomies, it is imperative that evidence supported recommendations for the care and prevention of infection of tracheostomies be developed.

Non-Invasive Positive Pressure Ventilation – Mask Interface

Non-invasive ventilators are a significant therapeutic advancement in the treatment of sleep-disordered breathing and respiratory failure. However, children have not enjoyed the full benefit of this therapeutic advancement due to mask interface issues. To ensure proper use of non-invasive ventilators, the mask must fit the patient . This requires both proper mask size and proper headgear fit. Unlike an adult, the tissues of the face of a young child are highly plastic and are susceptible to remodeling from external pressure. Often the pressure required to keep non-invasive ventilator masks in place with proper fit can cause remodeling of the child's face. Such remodeling can lead to cosmetic and functional abnormalities of the nose, jaw and midface.

Currently, there is a dearth of FDA approved pediatric sized ventilator masks. The ATS notes that pediatric sized masks are available outside the United States.

The alternative to non-invasive ventilation is invasive ventilation through tracheostomies or intubation. Both of these more invasive options have higher

costs, greater length of stays, higher risks of infection, and long-term morbidity such as speech impairment and scarring of the airway.

More research is needed to create pediatric masks and headgear that assure proper fit without leading to face remodeling.

Non-Invasive Positive Pressure Ventilation – Triggering/cycling mechanisms

A related issue concerns the breathing cycle algorithms used in non-invasive positive pressure ventilators. The machines used in adult populations generally try to accommodate the breathing cycle of a 150-pound adult. Using non-invasive ventilators for children, especially neonates, requires significantly different timing and airflow rates to trigger the inhalation/exhalation breathing cycle.

Again, little research has been done by manufacturers or by clinicians to best adapt the breathing algorithms of these machines for pediatric applications. Research is needed to provide appropriate devices to adequately ventilate young children.

Home Pulse-Oximetry Monitoring for Children

Home pulse oximetry is often used by clinicians to assist adult patients in weaning from ventilator devices. However, pulse oximetry readings are very sensitive to motion, making continuous pulse oximetry readings in a child extremely difficult to obtain. The inability to collect accurate home pulse oximetry readings for children means clinicians often manage ventilator weaning in the absence of clinically important data.

Additional research is needed to develop pulse oximetry devices that can accurately provide home oxygen saturation readings that are not compromised by motion artifact.

The above are just a few of the more pressing examples of medical device challenges in the pediatric pulmonary community. In all these cases, research has been conducted to create evidence-based recommendation for the use of these devices in adults. However, follow up research for pediatric indications remains unaddressed.

Recommendations

The ATS offers the following recommendations to improve availability of medical devices that have been specifically designed and tested for pediatric patients. These recommendations closely follow the recommendations developed by our colleagues at the American Academy of Pediatrics:

- The FDA should establish a presumption that devices manufactured for adults should also be required to be designed for and tested for pediatric populations if

the indication occurs in those populations. Giving the FDA the authority to establish this presumption would likely require an act of Congress.

- Congress should also consider the creation of financial incentives, including grants or guaranteed loans for R&D to small companies, modifying the existing Humanitarian Device Exemption provision to allow for profit, and financial support for prototype development and the conduct of clinical trials, possibly through a network structure.
- The FDA should use the recent statutory requirement to exempt pediatric devices from user fees as an opportunity to create a system to identify and track pediatric devices, both those specifically intended for use in children and those devices labeled for adult or general use that are intended for conditions that occur in pediatric populations. Such a system could be used, for example, for FDA to identify devices that require only slight modifications or minimal additional testing to obtain a pediatric indication and to communicate the necessary data requirement to the manufacturer. This system could also be used to identify devices eligible for incentives or should be subject to a requirement to test in children.
- FDA should clarify for manufacturers acceptable data for determining safety and efficacy of pediatric devices.
- FDA should design studies of new medications so that the drugs or devices will be studied in ways that they will be used clinically.

On behalf of American Thoracic Society, I want to again thank the FDA for allowing us to comment on issues surrounding pediatric medical devices. We look forward to working with the FDA, our sister medical societies and the device manufacturers to develop new therapeutic medical devices for children.

Sincerely,



Sharon I.S. Rounds MD

American Thoracic Society