

**Memorandum**

**To:** Division of Dockets Management (HFA-305)

**From:** Elaine Jastram  
Associate Executive Director, Membership Division

**Date:** August 26, 2004 

**Subj:** Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children

On July 22, 2004, Ms. Theresa Toigo asked the American College of Emergency Physicians to comment on "Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children." To that end, we asked the Pediatric Emergency Medicine Committee of ACEP to provide comments. Their comments are noted below:

Currently, there are significant deficits in the development of medical devices for the pediatric population. Several areas that would benefit immediately from a focused development of age-appropriate devices include pediatric trauma patients (age appropriate spinal immobilization, transport immobilization devices that protect the child and are safe in ambulances or other transport vehicles), special needs children (portable ventilators, immobilization devices, transport devices) and orthopedic patients (crutches, walkers for children who break extremities and are under 8 years of age...crutches don't work in this age group). In addition, the pediatric population could benefit from advances in both invasive and noninvasive airway management devices. These are small suggestions for a population that has received very little attention, and if focused on, could provide tremendous advances for ill and injured children.

The barriers to development of new pediatric devices include regulations, a lack of research in the various age groups, and a lack of economic benefit to corporations that undertake projects in these arenas. The pediatric population does not have the economic resources to support extensive research and pay a premium price for new devices. In addition, the liability issues for testing, developing, and supporting a product/device are staggering. If a product fails, the financial losses to the developer could be devastating.

Changes in the regulatory, legal, and research arenas would advance the goal of exploration and development of new pediatric devices. A collaboration between medical providers and developers of medical devices that focused on needs assessment, potential designs, and modification for various age groups that could be safely conducted in a reasonable manner without fear of litigation would advance medical care for all children.

We apologize for our delay in responding to your request.

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