



the injury prevention centre of Children's Hospital

December 5, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To whom it may concern,

Re: Draft Guidance for Industry and FDA Staff - Hospital Bed System Dimensional
Guidance to Reduce Entrapment

This letter is in response to the request for comments on the above document. As a pediatrician, I am submitting comments specific to pediatric patients, who often use hospital beds designed for adults. Although existing hospital bed entrapment guidelines and standards have not identified pediatric patients as one of the risk groups, pediatric patients are clearly at risk for entrapment in these beds due to their physical size and in some cases, pediatric patients have the same types of risk factors as the older patient (e.g. neurological and cognitive disabilities).

As background, children in Canadian hospitals are typically assigned a crib until age two, and thereafter a hospital bed, usually a hospital bed designed for adults (in many cases imported from the US), given the lack of a high quality "youth" hospital bed until the recent past. In my facility alone we have had two near-miss cases of entrapment involving Zone 3 in the past 4 years, involving children over two years of age who were assigned an adult bed. In both cases, the child's body slipped under the lowest rail and they were found cyanotic with the head/neck entrapped and the body hanging toward the floor. We have since eliminated adult beds from our facility, and have had a Canadian hospital bed manufacturer design a custom bed with all potential "spaces" similar to a standard crib. In terms of rationale for dimensions for the pediatric patient, we have used crib slat spacing standards and playground entrapment prevention standards as reference.

Adult hospital beds are also used in some US facilities for pediatric patients. I am not aware of the extent of this practice. Our contacts with Canadian hospital bed manufacturers have indicated that children over 6 years of age may use a typical (adult) hospital bed. Even for children greater than 6 years of age there would remain a significant theoretical risk of entrapment, due to body size. Older children with significant neurological and/or cognitive dysfunction and/or small stature would also be at risk.

1. Exclusions. I support eliminating exclusions for pressure reduction products. These are also used by our pediatric patients, and we have had several cases of non life-threatening entrapment in Zones 3, 5, and 6 on our surgical/burn ward.
2. More stringent dimensional limit at Zone 2. I support the recommendation of a dimensional limit of less than 2 1/3 inches (60 mm), which would better protect the pediatric patient.



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3. More stringent dimensional limit at Zone 3. I support the recommendation of a dimensional limit of less than 2 1/3 inches (60 mm), which would better protect the pediatric patient. Our two near-miss pediatric cases involved Zone 3.

4. Recommendation for a dimensional limit for Zone 5. I support the recommendation for Zone 5 of a dimensional limit of either less than 2 1/3 inches (60 mm) or greater than 12 1/2 inches (318 mm) and an angle of greater than 60 degrees in the V-shaped spaces between the rails. This would better protect the pediatric patient.

5. Recommendation for dimensional limits for Zone 6. I support the recommendation for a dimensional limit at the foot end of either less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees or greater than 12 1/2 inches (318 mm) between the end of the lower (foot) side rail and the side edge of the footboard. This would better protect the pediatric patient.

6. Recommendation for a dimensional limit for Zone 7. I support the recommendation of a dimensional limit of less than 2 1/3 inches (60 mm) for this zone, which would better protect the pediatric patient. The guidance for crib mattress fit would provide even greater protection (3cm).

7. Articulated bed positions. The guidance should apply to all bed positions. As has been seen with crib entrapments, there is clearly the potential for the development of entrapment gaps with changes in bed position.

8. Application of this guidance to all health care settings. This guidance should apply to all settings (acute care, long-term care, home care). Educational efforts should also be targeted toward health care providers and parents of children with disabilities, who may use after-market bed rails and other modifications, rather than a hospital bed which meets current standards.

I would encourage the Hospital Bed Safety Working group to involve the American Academy of Pediatrics and the National Association of Children's Hospitals and Related Institutions (NACHRI) in these and future discussions around bed entrapment.

Yours truly,

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