



December 23, 2004

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 161
Rockville, MD 20852

RE: Docket number 2004D-0343 / Draft Guidance for Industry and FDA Staff – Hospital
Bed System Dimensional Guidance to Reduce Entrapment

Food and Drug Administration:

Thank you for the opportunity to comment on this draft document. Baretich Engineering provides consulting services to healthcare organizations in the areas of clinical engineering, facilities engineering, and safety management. We also provide incident investigation and expert witness services. Many of our activities are focused on patient safety.

We commend the FDA and other members of the Bed Safety Working Group for their efforts on behalf of patient safety. To support these efforts we offer the following comments:

1. The guidance article should specifically limit its application to the manufacture of new beds and clearly exclude its application to legacy beds. This will allow healthcare organizations to improve the safety of their beds over time in a cost-effective manner. Application of the guidance article to legacy beds would require massive expenditure of scarce capital resources for retrofitting or replacement. There is no evidence that the potential benefit to patient safety would justify this capital cost, especially in comparison with the many other opportunities that now exist for improving patient safety through capital investment.
2. The guidance article should eliminate all references to testing of beds by user facilities for compliance with dimensional guidelines. Such references are outside the FDA mandate to insure that devices manufactured and sold are safe and effective. Appropriate testing procedures, if necessary, will be developed through existing non-governmental mechanisms of demonstrated effectiveness. It is particularly inappropriate for the guidance article to call for unspecified testing procedures that are apparently under development but not available for public comment.

We would encourage FDA and the Bed Safety Working Group to continue its efforts to establish dimensional guidelines for application to new beds. This would be an important contribution to cost-effective improvements in patient safety.

Sincerely,

Matthew F. Baretich, P.E., Ph.D.
President

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