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December 23, 2004

Daniel G. Schultz, M.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Draft Guidance for Industry and FDA Staff:
Hospital Bed System Dimensional Guidance to Reduce Entrapment
Division of Dockets Management (HFA-305)
Docket No. 2004D-0343

Dear Dr. Schultz:

Thank you, for the opportunity to comment on the FDA draft guidance: "Hospital Bed System Dimensional Guidance to Reduce Entrapment."

As written, this guidance will create an expectation of hospitals and long term care facilities inspecting all of their existing (legacy) hospital beds for compliance with these dimensional limitations. Our understanding is that pilot testing of existing beds has revealed that most if not all-existing beds will not meet these dimensional limitations. So the extensive time and effort that will be required to determine that our 415 existing hospital beds will not pass is wasted with no risk reduction. Our primary focus should be clinical assessment of the patient's physical condition to establish that they are vulnerable to the risk of bed entrapment. At that point, the focus of the clinical and support staff should be the assessment of the hospital bed system with a clear plan for addition or modification of that system to meet that specific patient's needs.

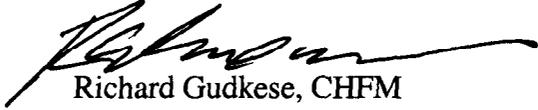
FDA must revise this draft document to clearly identify existing (legacy) beds are not inherently "unsafe" even though they do not meet the new dimensional limits established in this document. The focus on dimensional limits must be on new beds manufactured after the implementation of this document. The focus on legacy equipment is patient assessment first, with risk mitigation efforts based on meeting that specific patient's need.

My fear with this type of document is that we continue to focus limited resources on a problem, which is well down the list of priorities. The attractiveness of this implied requirement (as with others) is that this is a very tangible type of measurement. Easy to measure requirements does not translate into safe patients. Less tangible,

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but in my opinion a standard that will have a much greater effect on the health and safety of patients is, as one example; USP <797>. USP <797> focuses on what needs to be addressed in Health Care.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Richard Gudkese', written in a cursive style.

Richard Gudkese, CHFM
Facilities Management Consulting