

**BAY**  
REGIONAL MEDICAL CENTER  
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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Re: Draft Guidance for Industry and FDA Staff:  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Thank you, for the opportunity to comment on the FDA draft guidance: **Hospital Bed System Dimensional Guidance to Reduce Entrapment.**

We understand and appreciate the intention of this document, to minimize the potential of patient entrapment in a hospital bed. But I believe the introduction statement and Appendix F will focus attention on proactive testing of existing beds with little or no actual risk reduction. In fact, this focus will stretch currently scarce resources that would be better spent on patient assessment and modification of the bed environment if warranted based on patient size and/or condition.

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.

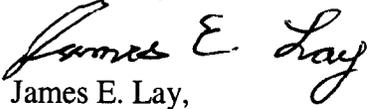
FDA must revise this draft document to clearly identify existing (legacy) beds are not inherently "unsafe" even though they do not meet the new dimensional limits established in this document. The focus on dimensional limits must be on new beds manufactured

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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.**

Respectfully submitted,

A handwritten signature in black ink that reads "James E. Lay". The signature is written in a cursive style with a large, stylized initial "J".

James E. Lay,  
Facilities Manager