

December 14, 2004

Dear Sir or Madam:

Thank you for the opportunity to comment on the FDA draft guidance: *Hospital Bed System Dimensional Guidance to Reduce Entrapment*.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 we feel that the introduction statement<sup>[3]</sup> 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 (fifty five) existing hospital beds will not pass is wasted with no risk reduction. The dimensional guidance has value to existing beds if it is clearly stated that the primary focus must first be clinical assessment of the patient 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 patient's need.

Sincerely,

Cindy Delancy  
Risk Manager

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[1] Bed entrapment occurs when a patient slips between the mattress and bed rail or when the patient becomes entrapped in the bed rail itself. Entrapment risk may increase when patients are frail or elderly or when patients have conditions that cause them to move about the bed or try to exit from the bed.

[2] The document states "...the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and **the assessment and modification of existing (legacy) hospital bed systems**". To review the document, go to <http://www.fda.gov/cdrh/beds/>

[3] "...the FDA believes the risk of entrapment can be reduced through the development of new hospital bed or rail design configurations and **the assessment and modification of existing (legacy) hospital bed systems**".