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November 17, 2004

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

Re: Docket No. 2004D – 0343
Hospital Bed System Dimensional Guidance to Reduce Entrapment

Dear FDA:

Please accept this letter as representative of concerned comment over the FDA draft guidance proposed as, *Hospital Bed System Dimensional Guidance to Reduce Entrapment*.

It is understood and appreciated that the intent of this document is to minimize the potential of patient entrapment in a hospital bed. However, the introduction statement "...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,**" and the language contained in Appendix F will focus attention on proactive testing of existing beds with little or no actual risk reduction. While, in fact, it has been demonstrated that approximately three injuries occur to maintenance workers performing these tests contrasted to every possible patient adversely impacted.

As written, this guidance will create an expectation of hospitals and long term care facilities inspecting all of their existing hospital beds for compliance with these stated dimensional limitations. Current understanding is that pilot testing of existing beds has revealed that most if not all existing beds will not meet these dimensional limitations. Therefore, the time and effort used to determine that our 352 existing hospital beds will not pass is wasted with no beneficial 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.

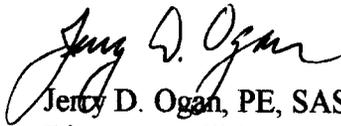
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FDA is respectfully requested, therefore, to revise this draft document to clearly identify existing beds are not inherently "unsafe" even though they do not meet the dimensional limits established in this document. The focus on dimensional limits **must be** on new beds manufactured after the implementation of this document. The focus on existing bed equipment should involve patient assessment first, with risk mitigation efforts based on meeting that patient's specific and unique needs.

Thank you for the opportunity to express our opinions.

Very truly yours,



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