



American College of Clinical Engineering  
5200 Butler Pike  
Plymouth Meeting PA 19462-1298

December 28, 2004

Food and Drug Administration  
Division of Dockets Management (HFA-305)  
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**Re: Draft Guidance for Industry and FDA Staff:  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 Sir/Madam:

On behalf of the American College of Clinical Engineering (ACCE), we appreciate the opportunity to comment on the Food and Drug Administration's (FDA) *Draft Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment (Dimensional Guidance)*. Founded in 1991, ACCE is fully committed to enhancing the profession of Clinical Engineering. With members in the United States and abroad, ACCE is the only internationally recognized professional organization for clinical engineers.

ACCE reviewed the presented draft document and acknowledges the efforts of the FDA's Hospital Bed Safety Work Group (HBSW) on such an important patient safety document. Many of ACCE members work in hospitals and have thus been closely involved in the initiatives related to reducing bed entrapments. ACCE is in full support of advocating and sustaining a safe patient care environment. ACCE would like to provide the following comments on the presented draft document:

- 1. The guidance document should apply to newly manufactured beds and should not encompass the legacy (existing) beds. With limited capital resources, hospitals need to very careful with their allocation on improving patient safety. The data from the existing guidance document does not presently provide enough evidence for hospitals to support the capital expenditures related to retrofitting the legacy beds. As stated above, this guidance document recognizes very important patient safety initiatives and should be applied to all newly manufactured beds.*

2004D-0343

- 2. The guidance document does not presently provide any explicit risk assessment procedures and tools for healthcare representatives to conduct testing on legacy beds. If legacy beds are, indeed, identified as at risk, no existing retrofits are available for the different legacy beds. To further support these patient safety initiatives, necessary training for all healthcare providers, clinical and technical, needs to be provided in conjunction with risk assessment procedures.*

Thank you for the opportunity to comment on this very important document. If you have any questions about this letter, please contact Izabella Gieras at [igieras@beaumontservices.com](mailto:igieras@beaumontservices.com) or 248-551-0549.

Sincerely,

A handwritten signature in cursive script, appearing to read "I Gieras".

Izabella Gieras  
President, ACCE