



Thompson Health System
Facility Services
350 Parrish Street
Canandaigua, NY 14424

December 22, 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RE: Draft Guidance for Industry and FDA Staff: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 Systems Dimensional Guidance to Reduce Entrapment
Division of Dockets Management (HFA-305)
Docket No. 2004D-0343

Dear Dr. Schultz,

On behalf of Thompson Health (TH) I welcome the opportunity to comment on the Food and Drug Administration's (FDA) Draft Guidance for Industry and FDA Staff: Hospital Bed Systems Dimensional Guidance to Reduce Entrapment (Dimension Guidance). (TH) is a 113 bed medical center with a 190-bed long-term care unit located in Canandaigua, NY.

Providing a safe healing environment for patient is a priority for (TH). A review of the Dimension Guidance identified a need to provide additional training and provide additional measures to prevent entrapment. A focus group reviewed and identified appropriate measures including training, additional equipment and modifications to some existing bed rails. Risk assessment identified the need.

The measures include increase use of patient bed alarms, addition cushioned bed rail covers, and modification to a limited number of legacy bed rail systems. The actions are the result of Risk Assessment of existing beds and patient population utilizing the FDA draft guidance.

2004D-0343

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Requiring retroactive legacy bed modifications is not in the best interest of the healthcare industry and patient safety. The cost to retrofit all legacy beds in this facility will exceed \$100,000 without providing additional safety for AT RISK patients. I fully support and applaud the efforts of the FDA Dimension Guidance by providing the guidelines for NEW hospital beds. However I do not agree with the retroactive application of the identified limitations to legacy beds and the focus on legacy beds must be on the individual patient assessment rather than simply on the bed rail gaps. Clinical guidance to first consider the patient population that is served and their risk for bed rail entrapment, and then if appropriate focus on bed rail dimensions is my recommendation for legacy beds.

I recommend that the Hospital Bed Systems Dimensional Guidance to Reduce Entrapment apply only to new hospital bed rail design configurations.

Sincerely,

Alan C. Scrivener

Maintenance Manager

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