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November 24, 2004

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

Docket No. 2004D-0343

Dear Sir/Madam:

The Evangelical Lutheran Good Samaritan Society is pleased to have the opportunity to provide comments on the Food and Drug Administration (FDA) draft guidance for **Hospital Bed System Dimensional Guidance to Reduce Entrapment** for manufacturers of hospital beds and hospital bed accessories.

As participants in the Hospital Bed Safety Work Group since its inception, we are grateful to the FDA for its continued leadership with this initiative.

Page 7 - Request for Comments: 1. Exclusions (framed flotation therapy products and bed systems using powered air mattress replacements)

Should FDA reconsider these exclusions and recommend the application of dimensional limits for all entrapment areas to these products?

[If "Yes" would it limit the availability of the equipment to providers?

If "No" would it increase liability of the users of these products?]

There is no categorical answer to this question relating to all items noted for possible exclusion. What should guide the FDA's decision are the relative risks of each bed type as identified by reported entrapment incidents. These products provide significant clinical benefits to patients in various health care settings; our particular interest is, of course, long term care. If the FDA decides not to change the exclusions, the agency should make note in the final guidance and other documents related to entrapment that exclusion from the list does not necessarily mean that the product is free of risk and that caution is advised to identify and address areas of potential entrapment for each patient. This applies to framed flotation therapy products, powered air mattress replacements, and mattress overlays. A particular bed configuration may meet the dimensional guidance but with the addition of a mattress overlay, that configuration changes and every caution must be raised to manufacturers and providers that risk must be reassessed.

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Pages 15-16 - Request for Comments 2 and 3: More stringent dimensional limit at Zone 2 and Zone 3: Should FDA modify its recommendation to recommend a dimensional limit of less than 2 1/3 inches (318mm)?

Yes, the limits should be decreased based on FDA's data. There was much detail in the published guidance document that gave detailed background information substantiating the recommended change. If the data is substantive, the change is warranted; we can only defer to the FDA on that point. However, the data must be substantive and compelling because of the impact this will have not only on manufacture of new equipment but also of existing equipment – to do otherwise is **not** a “least burdensome” approach. These two zones are in the group identified as posing the greatest potential risk and therefore any data-based change would be most warranted in these two areas.

Pages 20 - 22 - Request for Comments 4, 5, and 6: Recommendations for a dimensional limit for Zones 5, 6 and 7. Should FDA recommend dimensional limits for these additional zones as specified at each respective section in the guidance?

Yes, but conditionally. The HBSW recommended focusing on Zones 1-4 as the zones that the data indicated presented the greatest risks. Therefore we recommend focusing first on zones 1-4, which are more frequently identified in entrapment reports to the FDA. Directing manufacturers to focus design changes on all zones simultaneously (and all zones to include articulated bed positions) may reduce the timeliness and effectiveness of the design changes that would reduce potential entrapments at zones 1-4.

Page 23 - Additional Request for Comments 7: Articulated bed positions. Should FDA apply these dimensional limits to articulated positions?

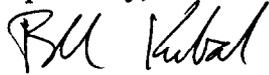
Yes. In our experience, hospital beds are used more frequently in articulated positions, usually in the semi-fowlers position, than in the flat deck position. To not write guidance for manufacturers to address the risk of potential entrapment zones on beds in articulated positions would place an unnecessary burden on caregivers to prevent entrapment when a bed is articulated for patient comfort or when the bed must be articulated for clinical reasons. If there is a need to prioritize (and “staging” if necessary) the focus between Zones 1-4, Zones 5-7 and articulated bed positions, we would recommend placing the Zones 5-7 emphasis last among those three. Thus the most important areas to focus on are Zones 1-4 and those zones to include articulated bed positions. As we remember it, that's where the data and our experience tell us the greatest risks lie.

Page 22 - Request for Comments 8: Application of this guidance to all health care settings. Is there a reason why this guidance document should not apply to hospital beds used in all care settings?

No. Even the asking of this question is a little surprising. Everything the HBSW has done since 1999 and every product and guidance document developed had as a basic assumption that the issue being addressed was entrapment risk in hospital beds in all care settings. The data indicates that entrapments have occurred in all patient care settings, including hospitals, nursing homes, and private homes. Therefore, the guidance should apply to all.

Allow us an additional comment: the "Background" section at the beginning of the document includes reference to the work of the HBSW; this is helpful but it should go further to identify some of the other products of the work group that provide a broader context for the reader (e.g. Brochure, Clinical Guidance Document, Mitigation Document that is forthcoming, the Kit). It was important for the HBSW to understand all of these products as integrated; it will be important for all stakeholders to understand them similarly as well going forward.

Respectfully,

A handwritten signature in black ink, appearing to read "Bill Kubat". The signature is written in a cursive, slightly slanted style.

Bill Kubat
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Ev. Lutheran Good Samaritan Society
Sioux Falls, South Dakota