



November 29, 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Re: Draft Guidance for Industry and FDA Staff: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 System Dimensional Guidance to Reduce Entrapment
Division of Dockets Management (HFA-305)
Docket No. 2004D-0343

Dear Dr. Schultz:

On behalf of the American Society for Healthcare Engineering (ASHE), we welcome the opportunity to comment on the Food and Drug Administration's (FDA) *Draft Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment (Dimensional Guidance)*. ASHE is a personal membership group of the American Hospital Association (AHA) with 6,300 members in the health care engineering and facilities management professions.

A safe environment for patient care is a fundamental patient right, and preventing harm from reaching any patient, is a strategic goal of the AHA. A single patient death from bed rail related entrapment is one death too many. Greater awareness to this safety risk is needed, and ASHE has been an active participant on the Hospital Bed Safety Work Group (HBSW) since its inception. ASHE was a participating organization in the development of the brochure *A Guide to Bed Safety* and has been supportive of the development of the document *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospital, Long Term Care, and Home Care Setting (Clinical Guidance)*. ASHE participated in the HBSW subgroup on dimensional guidance and within that subgroup has engaged in the debate on scope and effectiveness of the *Dimensional Guidance* document. Through these discussions within the HBSW workgroup, ASHE has consistently argued for limiting the scope of the *Dimensional Guidance* document to only new bed systems – but in the introduction and appendix F of the *Dimensional Guidance* document, it is clear that FDA intends for these limitations to be applied retroactively to existing (legacy) hospital beds. **ASHE disagrees and**

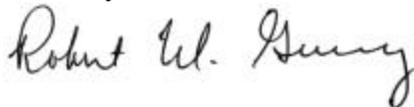
feels that the focus on legacy beds must be on individualized patient assessment rather than simply on the dimensions of bed rail gaps. Healthcare organizations should use the *Clinical Guidance* to first consider the patient population that is served and their risk for bed rail entrapment, and then, if appropriate, focus on the bed rail dimensions. Bypassing the patient assessment and simply focusing on the measurement of bed rail gaps will lead organizations directly into a solution and miss the critical first step of clinical assessment. Assessing the individual needs of the patient and, if indicated, re-evaluating the bed for entrapment potential, is a realistic way to manage this risk. But the *Dimensional Guidance* does not adequately establish the role that clinical assessment and clinical intervention plays in reducing the risk of entrapment. The *Clinical Guidance* is not referenced in the body of this document. In fact, the FDA website on bed rail entrapment reveals that the clinical guidance document was neither written nor endorsed by FDA.

Without a clear discussion of the critical role of clinical assessment, the specific dimensional limitations may be viewed as a model code, and be adopted by state or other agencies with the requirement for proactive measurement of existing beds for compliance with these new dimensional limitations. Establishing dimensional limitations and a measurement methodology to assure that new hospital beds meet these limitations is a forward thinking strategy. But implying that legacy beds that were not designed to these dimensional limitations should now be held to these limitations is unreasonable. In addition, by not limiting the scope of the dimensional limitations to new equipment only, this document creates the impression that reduction of the risk of entrapment is achieved solely through the identified dimensional limitations. ASHE has argued within the HBSW for limitation of the document scope to new beds only and remains **opposed to the application of those same dimensional limitations to existing (legacy) hospital beds**. ASHE recommends that the introduction and appendix F be revised to indicate that this document applies only to new hospital bed or rail design configurations.

Within the *Dimensional Guidance* document, a number of specific requests for comments are made. These requests tend to be technical in nature. Therefore each request is addressed in the attached detailed comments.

Thank you for the opportunity to comment on this important matter. If you have concerns or questions about these comments, please contact ASHE's Dale Woodin at dwoodin@aha.org or (312) 422-3812

Sincerely,



Robert Guerry, PE, CHFM
2004 ASHE President

Detailed Comments on the Draft Guidance for Industry and FDA Staff: Hospital Bed System Dimensional Guidance to Reduce Entrapment, Docket No. 2004D-0343, August 31, 2004

Submitted by: the American Society of Healthcare Engineers (ASHE)

We appreciate the opportunity to comment on this document. Given the size and scope of the document, we have included overall comments applicable to the entire document as well as responses to the specific request for comments. Each item is identified by page and citation. Comments plus specific recommended changes follow as appropriate.

Overall Comments

Introduction

Page 1

Delete the portions of paragraph one that include use of these new dimensional limitations in the assessment of the compliance of existing (legacy) bed systems. Pilot testing of various tools and testing methodologies on existing beds has shown that these existing beds will not meet these new limitations. In the *FDA Talk Paper T04-34*, issued August 31, 2004, the final paragraph states that “Once the guidance is final, the Hospital Bed Safety Work Group will provide detailed measurement tools and test methods that manufacturers and healthcare facilities can use to assess the risk of existing bed systems. The group will also provide healthcare facilities and homecare providers with information on how to modify systems to reduce the risk of entrapment.” **Clearly the FDA is creating the expectation of testing of legacy equipment to these new dimensional limitations to ensure they are “safe” from entrapment risk.** This implies that existing beds are inherently unsafe until they are proven to be safe (tested to new dimensional limitations) utilizing measurement tools and testing methods that have not yet established.

Recommended revision:

Manufacturers may use this guidance when designing new beds to help ensure compliance with applicable FDA regulations such as the Quality System Regulation to assist in ensuring that their devices are safe when used as labeled ~~and to assess current hospital bed systems. In addition, this guidance may be used by healthcare facilities as part of a bed safety program to help identify entrapment risks that may exist with current hospital bed systems.~~

APPENDIX F

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The role of an appendix is to clarify or provide information in support of the document. Appendix F establishes a position, “Like HBSW, 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” rather than clarifying a position already established in the body of the document. **If the FDA “believes” in the “assessment and modification of existing (legacy) hospital bed systems”, then why is that belief buried in an appendix?** That belief should be stated in the introduction or opening paragraphs of the document.

Appendix F attempts to describe the “big picture” issue of reduced entrapment risk. This general discussion is in stark contrast to the specific, technical nature of the body of the document. The appendix offers other HBSW documents to aid in the assessment of entrapments risks. Of these listed documents, FDA’s website identifies that for the *Clinical Guidance* document “This guidance provides recommendations to caregivers to assess their patients’ need and use for bed rails, and was not written nor endorsed by the Food and Drug Administration”.

ASHE believes that the FDA is internally conflicted in its attempt to establish new dimensional guidance for new hospital beds while at the same time subtly establishing operational expectations for healthcare facilities to test and modify existing beds. Its web statement of “not written nor endorsed” along with its belief statement buried in an appendix all point to unclear scope and purpose. ASHE recommends this scope and purpose be clarified to focus only on new hospital bed systems.

Recommended revision:

This draft guidance provides recommendations for the hospital bed equipment industry to aid in the design of new bed systems. ~~Industry, health care facilities and care givers may also use it as a guide to evaluate the potential entrapment risks associated with a healthcare facility’s current and future hospital bed systems as part of a bed safety program. Members of the HBSW are developing procedures for the measurement and assessment of hospital bed systems.~~

The issue of hospital bed patient entrapment is complex. Reducing the risk of entrapment involves a multi-faceted approach that includes bed design, clinical assessment and monitoring, as well as meeting patient, resident, and family needs for vulnerable patients in all health care settings hospitals, long term care facilities, and at home. Many beds now in use may no longer have the original mattress or bed rails, and thus, may present an entrapment hazard by increasing or creating gaps or spaces between components of the bed.

The HBSW developed three documents entitled:

"A Guide to Bed Safety"

"Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings"

"A Guide for Modifying Bed Systems and the Use of Accessories to Reduce the Risk of Entrapment" (to be finalized upon publication of this Guidance in final).

These publications are intended to help caregivers and health care providers assess the individual patient's needs, consider and address entrapment risks, and recommend mitigation strategies.

Facilities are encouraged to consult the three HBSW documents identified to optimize bed safety in their facilities.

Every effort should be made to reduce the risk of patient entrapment in hospital bed systems. Like HBSW, 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.~~

Healthcare facilities should check with their bed system manufacturers to ensure that their hospital beds, mattresses, rails, and accessories are compatible. Healthcare facilities are encouraged to contact their equipment suppliers for entrapment mitigating solutions that may already be available. When evaluating the safe use of a hospital bed, component or accessory, manufacturers and caregivers should recognize that the risk for entrapment may increase if a hospital bed system is used for purposes, or used in a care setting, not intended by the manufacturer.

Healthcare facilities should assess current hospital bed system combinations that are used in their facilities. Reassessment should be done 1) when there is reason to believe that some components are worn (e.g., rails wobble, rails have been damaged, mattresses are softer) and could cause increased spaces within the bed system, 2) when accessories such as mattress overlays or positioning poles are added or removed, or 3) when components of the bed system are changed or replaced (e.g., new bed rails or mattresses).

The HBSW considered various aspects of the care environment in which hospital beds are used. The term "hospital bed" is used in this guidance to refer to a variety of medical devices which are classified as "beds" and used for adult patients primarily in acute care, long term care or home care settings. Because hospital bed systems primarily intended for one type of care setting can be moved into other care settings during the life of a bed system, beds used in all healthcare settings are included within the scope of this guidance.

~~FDA recognizes that this draft guidance document, when finalized, may be used by healthcare facilities, home health agencies and oversight entities for evaluating legacy equipment. Legacy equipment is defined as hospital bed systems currently in use and purchased prior to the effective date of this guidance.~~ A risk-benefit analysis should also be conducted by healthcare providers to ensure that appropriate steps are taken to mitigate the risk of entrapment without creating different, unintended risks or reducing clinical benefits available to patients using legacy equipment. Refer to the additional three companion documents mentioned above.

Specific Comments

Page 7 – Request for Comments :

1: EXCLUSIONS: *Given the risks and benefits of using 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?*

The Hospital Bed Safety Workgroup recommended exclusion of these products from the dimensional guidance because they will not pass. The tool used for the measurement weighs 15 pounds, which will always deflate the mattress and frequently cause failure of the tests.

These products are used to treat pressure ulcers, which kill approximately 60,000 people per year.

While recommended for inclusion by the HBSW in April 2002, the concept of risk assessment from the perspective of the clinical needs of the patient was not included in this draft document. There is a clinical profile of an individual at risk for bed rail entrapment, including small stature, over 65 years of age, frail, confused, limited mobility, and/or certain medications. In the JCAHO sentinel event database, all 5 reports of hospital entrapments fell within this profile. Therefore, a clinical assessment would be an important step prior to measurement of the bed system, and is the sequence recommended in the JCAHO document.

If the patient using the flotation therapy product or powered air mattress were at risk, then an assessment of the bed using the dimensional guidance would be prudent.

Page 15 – Request for Comments:

2: MORE STRINGENT DIMENSIONAL LIMIT AT ZONE 2: *FDA considered both the HBSW and the IEC recommended dimension of less than 4 ¾ inches (120 mm) as a dimensional limit and at this time recommends a dimensional limit of less than 4 ¾ inches (120 mm). FDA believes, however, that because of mattress compressibility and wear, an additional degree of protection may be needed to reduce entrapment at this zone. Therefore, FDA requests comments and data on whether it should modify its recommendation to recommend a dimensional limit of less than 2 1/3 inches (60 mm).*

The recommended dimension of 4 ¾ inches is based on the head dimension measured across the face from ear to ear, to include all 5th percentile female head breadth references and most 1st percentile international references in the researched data. This is already an extremely small head size and to lower it further seems absurd, particularly in light of the already low probability of entrapment.

The data from the retrospective study cannot be considered representative of the problem in this zone, because, according to the FDA, “The adverse event report information for identification of Zones 2, 3, and 4 was at times not clear. It was difficult to determine the precise location of the entrapment and to determine whether it occurred in Zone 2, 3, or 4. Most reports only stated that

an entrapment occurred ‘between the rail and the mattress.’” Therefore, one cannot determine with certainty that any entrapments occurred in this zone.

Footnote 10 on page 3 acknowledges limitations of the adverse event report data, including the fact that “many reports lack a complete and detailed description of the adverse event or are not verified.” On page 11, it says, “Many of the entrapment event reports FDA received involved entrapment between the rail and the bed’s “frame.” It is unclear from the event descriptions whether this refers to the mattress deck or even the bed frame that supports the deck.”

Footnote 17 on page 12 expands on the lack of a complete and detailed description of the event, adding, “The beds involved in these adverse events may not have had compatible mattresses or bed rails specifically designed for the particular bed model involved in the reported entrapment. Also, information was limited regarding the condition of the beds, bed rails, and mattress at the time of the entrapment. Specific details about the exact location of the entrapment within the beds were sometimes lacking.”

Footnote 18 on the same page states, “Mattresses involved in reporting entrapment events may have been different from the manufacturers recommended mattresses, which means actual gap sizes in entrapments involving the mattresses may have been different from those identified by the manufacturers in the retrospective study.”

This does not constitute justification for an even more restrictive dimension.

Page 16 – Request for Comments:

3: MORE STRINGENT DIMENSIONAL LIMIT AT ZONE 3: *Consistent with HBSW’s and IEC’s recommendation, FDA is recommending a dimensional limit of less than 4 ¾ inches (120 mm) for the area between the inside surface of the rail and the top edge of the compressed mattress. FDA requests comments and data, however, on whether it should modify its recommendation for this zone to recommend a dimensional limit of less than 2 1/3 inches (60 mm).*

The recommended dimension of 4 ¾ inches is based on the head dimension measured across the face from ear to ear, to include all 5th percentile female head breadth references and most 1st percentile international references in the researched data. This is already an extremely small head size and to lower it further seems absurd, particularly in light of the already low probability of entrapment.

The data from the retrospective study cannot be considered representative of the problem in this zone, because, according to the FDA, “It could not be determined from the description of entrapment events whether entrapments occurred at Zones 2, 3, or 4.” Therefore, one cannot determine with certainty that any entrapments occurred in this zone.

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This does not constitute justification for an even more restrictive dimension.

Page 20 – Request for Comments:

4: RECOMMENDATION FOR A DIMENSIONAL LIMIT FOR ZONE 5: *Even though entrapments in split rail configured beds can be eliminated by lowering the foot rail, the FDA believes that dimensional limits of either less than 2 1/3 inches (60 mm) or greater than 12 1/2 inches (318 mm) and an angle of greater than 60 degrees in the V-shaped spaces between the rails, would reduce entrapments in this zone. Adding the recommendation regarding angles greater than 60 degrees to V-shaped spaces is believed to provide an additional margin or safety to reduce entrapment by wedging of the neck. Thus, FDA is requesting comments and data on whether its final guidance should include the recommendation for Zone 5 of a dimensional limit of either less than 2 1/3 inches (60 mm) or greater than 12 1/2 inches (318 mm) and an angle of greater than 60 degrees in the V-shaped spaces between the rails.*

The 1st percentile female neck diameter is 3 1/8 inches, but to allow for compressibility of the neck, the dimension has been reduced to only 2 1/3 inches. The data cited on a wedging effect is based on swimming pool equipment and expandable baby gates, and recommends angles at 55, 60, or 75 degrees, with 75 degrees recommended for the baby gates. Given the already low probability of entrapment, regulating the angle size places further unnecessary restrictions on the manufacture of new beds and the continued use of legacy beds.

Zone 5 was recommended for exclusion from the dimensional guidance by the Hospital Bed Safety Workgroup, since Zones 5 and 6 collectively represent only about 20% of the entrapment reports.

Page 21 – Request for Comments:

5: RECOMMENDATION FOR DIMENSIONAL LIMITS FOR ZONE 6: *FDA requests comments and data on whether the final guidance should include the recommendation for Zone 6*

of a dimensional limit at the head end of less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees between the end of the upper (head) side rail and the side edge of the headboard. Further, FDA is requesting comments and data on whether it should include a dimensional limit at the foot end of either less than 2 1/3 inches (60 mm) and an angle of greater than 60 degrees or greater than 12 1/2 inches (318 mm) between the end of the lower (foot) side rail and the side edge of the footboard.

The 1st percentile female neck diameter is 3 1/8 inches, but to allow for compressibility of the neck, the dimension has been reduced to only 2 1/3 inches. The data cited on a wedging effect is based on swimming pool equipment and expandable baby gates, and recommends angles at 55, 60, or 75 degrees, with 75 degrees recommended for the baby gates. Given the already low probability of entrapment, regulating the angle size places further unnecessary restrictions on the manufacture of new beds and the continued use of legacy beds.

The footnoted commentary on the data is very telling, “Many of the reports of entrapment between the rail and end board did not specify which end (head or foot) was involved. In those cases, manufacturers were asked to report the minimum and maximum gaps over both ends. Thus, the gap data may not relate directly to the entrapment location. For example, if the measured minimum gap distance occurred at the foot end, but the entrapment actually occurred at the head end, then the measured gap has no relation to the gap involved in the entrapment.” Therefore, the data from the retrospective study is unreliable.

Zone 6 was recommended for exclusion from the dimensional guidance by the Hospital Bed Safety Workgroup, since Zones 5 and 6 collectively represent only about 20% of the entrapment reports.

Page 22 – Request for Comments:

6: RECOMMENDATION FOR A DIMENSIONAL LIMIT FOR ZONE 7: *FDA requests comments and data on whether its guidance should include a dimensional limit of less than 2 1/3 inches (60 mm) for this zone. Specifically, FDA is requesting data on entrapment reports or near-miss entrapment events that may have occurred in Zone 7, including any details on these events and their frequency.*

This recommendation is based purely on speculation. There are no adverse event reports that identify any Zone 7 entrapments. Given the lack of data, there is no reason to include any dimensional limits on this zone.

Zone 7 was recommended for exclusion from the dimensional guidance by the Hospital Bed Safety Workgroup for lack of data.

Page 23 – Request for Comments:

7: ARTICULATED BED POSITIONS: *This guidance generally addresses entrapment in the flat deck position. FDA’s adverse events reports of entrapment do not specify that entrapments are occurring only in a flat deck position. FDA believes that patient care occurs in many*

different deck positions. Some entrapment areas change in size when the bed is articulated and may pose additional entrapment risks. FDA is seeking comment on the need to apply dimensional limits to articulated positions.

- *Are you aware of entrapment events or near-entrapment events occurring when the bed is articulated? Please provide information on these events and their frequency.*
- *Do you believe entrapments only occur in the flat deck position?*

The last bulleted question in this recommendation is loaded. If one accepts the fact that entrapments occur in bed systems, it is unreasonable to think that they would only occur in the flat deck position.

But it is also unreasonable to suggest that measurement limits can be applied to articulated positions. Given the nature of the bed articulations, each bed can have an infinite number of positions, each with a slightly varied dimension in one or more zones. Not only would it be impossible to define the exact articulated position to which the dimensional limit applies, it would be impossible to measure the bed at each articulated position.

Including a requirement to measure the dimensions at multiple articulated positions causes the cost of measuring legacy beds to rise exponentially. Given the low probability of entrapment events to begin with, this addition to the guidance is an attempt to engineer out virtually all risk, which is impossible.

Page 23 – 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: acute care, long-term care, and at home?*

Entrapment statistics for the 19 years from January 1, 1985 to January 1, 2004 are presented on page 3 of the draft document as follows:

- | | |
|----------------------|-----|
| • Entrapment reports | 575 |
| • Deaths | 358 |
| • Injuries | 111 |

At the April 2002 meeting of the HBSW, it was determined that approximately 20% of the reported entrapments occurred in acute care hospitals. Therefore acute care hospitals experienced an average of 6 entrapments per year over the 19 years of collected data. Based on an estimate of 34 million hospital admissions annually, this equates to one entrapment per every 5.7 million admissions.

While recommended for inclusion by the HBSW in April 2002, the concept of risk assessment from the perspective of the clinical needs of the patient was not included in this draft document. There is a clinical profile of an individual at risk for bed rail entrapment, including small stature, over 65 years of age, frail, confused, limited mobility, and/or certain medications. In the JCAHO sentinel event database, all 5 reports of hospital entrapments fell within this profile. Therefore, a

clinical assessment would be an important step prior to measurement of the bed system, and is the sequence recommended in the JCAHO document.

This approach would have acute care hospitals assessing the dimensions of legacy beds only as appropriate for an at-risk patient.