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December 17, 2004

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

***Re: Docket Number 2004D-0343, CDRH 200423 - Comments on Hospital Bed System  
Dimensional Guidance to Reduce Entrapment***

Dear Sir or Madam:

AdvaMed, the Advanced Medical Technology Association, respectfully submits these comments to the Food and Drug Administration ("FDA") in response to a August 30, 2004 notice requesting comments on the Agency's draft guidance document *Hospital Bed System Dimensional Guidance to Reduce Entrapment*.

AdvaMed represents more than 1,300 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Its members produce nearly 90 percent of the \$75 billion in health technology products consumed yearly in the United States and nearly 50 percent of the \$175 billion purchased around the world annually. AdvaMed members range from the largest to the smallest medical technology innovators and companies. Nearly 70 percent of our members have fewer than \$30 million in sales annually. A significant and growing percentage of our member companies have health care products that incorporate combination technology, the subject of FDA's request for comments.

### **Introduction**

The potential for patient injuries and even death from hospital bed entrapments is a serious public health issue. AdvaMed members have participated in the Hospital Bed Safety Workgroup (HBSW) for several years to help develop ways to mitigate this risk. The problem has proven challenging to address from a technical standpoint. Nonetheless, AdvaMed is hopeful that significant improvements in bed design and clinical guidance can be implemented in the relatively near future to reduce the risk.

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However, AdvaMed is disappointed with FDA's draft Hospital Bed System Dimensional Guidance to Reduce Entrapment ("Guidance"). Our membership believes that it fails to provide meaningful recommendations that can be implemented in the real world to mitigate entrapment risk. Our general concerns about the approach taken in the Guidance are set forth in the General Comments section, below. Our more focused comments are presented section by section in the Specific Comments section, below.

### **GENERAL COMMENTS**

- The HBSW has been working for several years developing workable dimensional guidance for hospital bed systems that would reduce the risk of patient entrapment. The process of developing useful dimensional guidance has two essential steps. First, it is necessary to devise a set of dimensional measurements that, if adopted, are likely to reduce the risk of entrapment. Second, it is necessary to devise a set of validated tools and test methods that can be used to measure compliance with such dimensional guidance. The second step is essential because, as a practical matter, dimensional guidance is only useful if accompanied by a reliable and consistent way to measure whether beds actually comply with the guidance. The HBSW has spent several years developing such validated tools and test methods. The process is nearing completion, but is not yet complete.

The Guidance recommends bed dimensions but fails to specify validated test methods and tools by which to measure compliance. This omission renders the Guidance of little value in the real world, because interested parties will have no way to reliably and consistently measure compliance with the recommendations. This approach will only cause confusion.

The Guidance should not be finally issued until the HBSW completes its validation of appropriate tools and test methods. The Guidance should then be revised in light of the validation results and republished with guidance on dimensions accompanied by appropriate validated test methods and tools for measuring compliance with the recommendations.

- A comprehensive solution to the entrapment problem should address these issues: (1) the design and manufacture of new beds; (2) the potential for dimensional change in all bed systems over time, through wear and tear (e.g., mattress sag) or substitution of new mattresses and other components not contemplated in the original bed system; and "legacy beds" already installed in health care facilities; The Guidance is essentially focused only on issue (1) without truly addressing the other aspects of the problem. (There is a very limited discussion addressed to healthcare facilities in Appendix F.) This omission means that the Guidance does not go much beyond IEC 60601-2-38 (including Amendment 1). The issue (and benefit) that has delayed publication of the Guidance has been the effort to help healthcare facilities assess legacy bed systems. That is why the HBSW has expended a great deal of time and effort validating tools and test methods to allow healthcare facilities to be able to perform the assessment and monitor the potential for entrapment. These tools and test methods are needed for legacy beds and also to

evaluate new purchases. If the Guidance is now solely addressed to Industry, as it appears to be, the issue of legacy bed systems will remain unaddressed. At the same time, manufacturers will have trouble implementing the recommendations in the Guidance in new beds, because there are no validated measurement tools and test methods by which to do so.

- HBSW has extensively researched siderail entrapment and published several documents addressing the issue, with an emphasis on providing clinical guidance. The Guidance briefly references the HBSW documents in Appendix F, but otherwise seems to presume that all hospital beds should conform to the dimensional requirements. This approach will be expensive and inefficient considering the small percentage of patients susceptible to entrapment. Furthermore, it may not work, because a one-time measurement approach does not address the possibility of wear and tear or substitution of new components altering the bed dimensions, even for a bed system that is deemed in compliance at a particular point in time. We would prefer a focus on the dimensions as one part of an overall clinical assessment and mitigation strategy. If a bed system is measured at a time remote from the patient need, there is no guarantee that the bed system will meet the recommendation at the time of the need (especially if the measurement tool and/or test method is not validated).
- The Guidance seems to contemplate that the necessary test methods and tools, when validated, will be published as an HBSW document. This unusual venue would not allow for public comment. We believe it is vital to obtain public input on the test methods and tools in conjunction with dimensional recommendations. For instance, hospital personnel need to have the opportunity to comment on the viability of using the tools and measurement processes.
- In addition, we are unaware of any plan for the continuation of the HBSW after its work is complete. It is therefore unclear who would accept long-term responsibility for updating an HBSW document setting forth measurement test methods and tools associated with the dimensional recommendations in FDA's Guidance. The dimensional recommendations and the test methods and tools are inextricably linked and need to be published in a consolidated document for which a known organization has long-term responsibility.
- The entanglement illustrations in the Guidance unnecessarily evoke emotion, detracting from the objectivity of the Guidance. While there is some benefit to the inclusion of illustrations, they should, at a minimum, be reduced to human "outline" drawings, eliminating facial expressions and emotional appeals.
- The Guidance should focus on only the zones with a significant number of reported entrapments. The number of tests should be minimized to encourage compliance. Moreover, the Guidance should focus on addressing the areas with the highest number of reported entrapments rather than burden the public with zones and measurement requirements for entrapment risks that are statistically minimal or nonexistent. This issue is addressed in more detail in the Specific Comments, below.

- As seen in IEC standard, a provision should be added to the Guidance to allow for alternative risk mitigations to the dimensional requirements based risk management that demonstrates equivalent or greater safety for the patient.
- On page 23, the Guidance says that entrapments have occurred in all care settings. The final Guidance should include data and percentages of occurrences in each care setting (*i.e.*, percent of occurrences in home care, acute care, and long term care). Statistically, a large majority of the entrapments occur in long term care settings. This information is imperative to allow risk managers to prioritize hospital risk mitigating activities. The IEC has divided 2-52 into separate care environments (called “Applications”) in order to address this concern.
- Some period of time is needed for manufacturers to prepare tooling, components and testing. Normal product development takes approximately two years after the completion of a specification. It is unreasonable to think new products can be developed overnight to meet the final Guidance; therefore, it should be noted that a reasonable time frame before the Guidance becomes effective is appropriate.
- The Guidance does not discuss the manner in which the entrapment events theoretically occur, but rather relies on extrapolation from dimensions provided by manufacturers. In a number of instances within the document this leads to incorrect dimensions (*see* comments for Zones 2 and 4, below).
- Throughout the Guidance, 60 mm should be calculated as 2 and 3/8 inches.
- On page 2 of the Guidance, the FDA states that it has adopted what it believes to be the “least burdensome way of addressing these issues.” The agency invites comments on whether there is a less burdensome approach. The HBSW, in conjunction with Industry, spent *several years* designing tools and developing test methods that would result in an efficient way to measure beds to reduce the chance of entrapments. The Guidance has not addressed any tool and test method development to date *and* also added back three entrapment zones and articulated positions for which no test methods have been investigated. Moreover, as discussed more specifically below, some of the entrapment zones addressed in the Guidance have few or no reports of actual injury. This approach does not appear to be the least burdensome way to address the issues.

## **SPECIFIC COMMENTS**

### **Section ~ Exclusions**

- As noted, we believe that mitigation of entrapment risk is a very important public health issue. At the same time, the public health may actually suffer if the Guidance were to be applied more broadly than is justified by the risk. For instance, there are many bed products that provide very important health benefits that cannot, as a practical matter, be

made to satisfy the Guidance. In addition, the Guidance will impose a burden on user facilities that should be restricted to cases in which the entrapment risk is real. Thus, we support sensible application of the Guidance in order to enhance the public health. Toward this end, all exclusions from the Guidance should be carefully considered and defined.

- We support excluding pressure reduction therapeutic products from the Guidance. There are estimates of 1.5 million patients per year<sup>1</sup> acquiring decubitus ulcers resulting in 60,000 deaths per year.<sup>2</sup> This risk greatly exceeds the risk of entrapment. Given the nature of the benefit provided to patients requiring pressure reduction surfaces, and the inherently compressible nature of pressure reduction surfaces, the Guidance should not be extended to all entrapment areas for these products.
- On pages 5-7, the Guidance sets forth a number of proposed product exclusions, with Comment 1 specifically requesting feedback. This includes total exclusion for air fluidized therapy beds, bariatric / pediatric / infant cribs, and non-extended stay stretchers, and partial exclusion for rotation, maternity and pressure reducing therapy products. The Guidance states that the intent is to reduce “life-threatening entrapments.” The proposed product exclusions all deal with patients: a) who are continually monitored during use of the product (i.e. pediatric and infant) b) who are not in the age/mental capacity demographics for which a vast majority of entrapments occur, (i.e. bariatric) or; c) for whom the time occupying the product is limited (i.e. non-extended stay stretchers). Moreover, the benefit provided to patients in all of these proposed exclusions *far* outweighs the risk of entrapment. The goal of the Guidance must be to minimize patient entrapments while maintaining a perspective that not all products can, or should, be included.

### Section ~ A Retrospective Study of Entrapment Reports to FDA

The Guidance relies heavily upon a retrospective study conducted by the HBSW which compared manufacturer supplied information on bed spacing where entrapment occurred to recommended gap sizes. The Guidance states: “If the size of the openings in the reported bed models did not meet the HBSW recommended limits, i.e., the openings in the reported beds were outside the limits of the recommended gap sizes, then the HBSW dimensional limits were considered to be an appropriate limit to reduce entrapments at that area.” (Emphasis added.) It is clear, however, from footnotes 17 and 18, that there were significant limitations on the HBSW study. In note 17, for example, it is noted that the reports often do not indicate whether compatible mattresses or bed rails specifically designed for the bed were in use at the time of entrapment. In note 18, it is noted that actual gap sizes may be different than reported by manufacturers for a variety of reasons. It is a mistake, therefore, to rely so exclusively on the retrospective study to determine whether HBSW’s dimensional limits are appropriate.

<sup>1</sup> *The WOC Nurse: Economic, Quality of Life, and Legal Benefits; wound, ostomy, and continence nurse, Dermatology Nursing*, no. 3, Vol. 13; pg 215.

<sup>2</sup> *A new perspective on pressure sore prevention*, P.M. Kynes, *Journal of Enterostomal Therapy*, 1986, 13(2), pp.42-43

## **Section ~ Recommended Dimensional Limits for the Identified Entrapment Zones**

### **Zone 1 – Within the Rail**

- The discussion of dimensional selection should include the discussion of how entrapment theoretically occurs. In this case, the theory is that the patient's movements move the patient's head through the openings in the rail, allowing the compression of the neck between the surface of the mattress and the inner edge of the rail. Therefore, by preventing the head from going through the opening in the rail, the possibility of this form of entrapment can be substantially reduced, in theory.
- The last sentence of the second paragraph states: "Nearly all of these entrapment events may have been prevented if the spaces within the rails had been less than 4¾ inches (120 mm)." This statement is speculative and not substantiated by the data.

### **Zone 2 – Between the Top of the Compressed Mattress and the Bottom of the Rail, Between Rail Supports**

- Again, the manner in which the entrapment theoretically occurs should be discussed. In this case, the theory is that the movement of the patient pushes their head under the rail, between the rail supports, which would create a compression to the patient's neck between the compressed mattress and the bottom of the rail between the rail supports.
- On the basis of how the entrapment theoretically occurs, and the anthropometric data, the measurement indicated in the Guidance is incorrect. It states: "This is the diagonal distance from the top of the compressed mattress to the bottom of the rail between rail supports." It is not that particular measurement that allows entrapment, but rather a space that would allow a 120 mm object to pass under the bottom edge of the rail between the rail supports from the top of the compressed mattress. To illustrate the flaw in FDA's guidance, consider the following hypothetical: If the bottom edge of the siderail were 30 mm from the mattress support deck and the top of the compressed mattress were 180 mm from the support deck, an entrapment here could not occur, because the patient could not get their head under the bottom edge of the rail between the rail supports. Nonetheless, the bed system would fail FDA's proposed dimensional guidance, because the diagonal measurement from the bottom edge of the rail between the rail supports and the top of the compressed mattress would be greater than 120 mm.
- The IEC dimension is based on the distance between the support platform and the bottom edge of the rail because if this dimension is less than the anthropometric head size (120 mm), the entrapment as described cannot occur within the anthropometric range of patients, regardless of mattress or mattress compressibility.

**Request for Comments: More stringent dimensional limit at Zone 2**

- The decision should be based on how the entrapment event occurs and the anthropometric data. Extrapolation from the manufacturer's data is unsupported in this case, because of the potential that surfaces, siderails, and other components used by a healthcare facility were not recommended or are not original issue from the manufacturer of the bed system.
- The event theoretically occurs because the patient gets their head under the bottom of the siderail between the rail supports from the top of the compressed surface. If that space is less than 120 mm, the population of patients within the anthropometric range will not be able to get their heads under the bottom edge of the rail.
- This dimension is meaningless as guidance without a measure of what represents a "compressed" mattress, and how the space will be measured from the compressed mattress. The diagonal measurement will not work in this case, as addressed above.

**Section ~ Recommended Dimensional Limits for the Identified Entrapment Zones****Zone 3 – Between the Rail and the Mattress**

- Again, the manner in which the entrapment theoretically occurs should be discussed. In this case, the theory is that the patient's movement results in their head being between the outer edge of the compressed mattress and the inner surface of the rail. The compression of the mattress then could wedge the patient's head in that space. The fatal result theorized from this entrapment would be from suffocation against the surface and bedding.
- The event theoretically occurs while the patient is in the bed, and is an event related to head entrapment and not to neck entrapment. Therefore, the dimension should be based upon the anthropometric head size and the manner in which the entrapment occurs.
- Again, because of the potential for replacement mattresses and rail, and the wear associated with their use, it is not possible to extrapolate from the manufacturers dimensional data to all similar bed systems.

**Request for Comments: More stringent dimensional limit at Zone 3.**

- The dimension itself is meaningless without a method to measure it. There also is no definition of various terms, such as compressed, rail condition, articulation, or lateral shift of the mattress.
- The final statement is that a patient may enlarge the space by compressing the mattress beyond the specified dimensional limit. This statement assumes that a specified dimensional limit for compression has been established, although none is provided here.

**Section ~ Recommended Dimensional Limits for the Identified Entrapment Zones**  
**Zone 4 – Between the Top of the Compressed Mattress and the Bottom of the Rail, at the End of the Rail**

- Again, the manner in which the entrapment theoretically occurs should be discussed. In this case, the theory is that the patient's movement causes them to exit the bed feet first, either in a large gap between the rails, or at the end of a single raised rail. In sliding out of the bed, the patient's neck could become trapped under the rail at the end of the rail, with both the weight of the patient and the compressed mattress forcing the patient's neck against the underside of the rail, at the end of the rail.
- On the basis of how the entrapment theoretically occurs, and the anthropometric data, the measurement indicated in the Guidance is incorrect. It states: "This space is the diagonal space between the top of the compressed mattress and the bottom of the rail at the end of the rail." It is not that measurement, but rather a space that would allow a 60 mm object to pass under the bottom edge of the rail at the end of the rail from the top of the compressed mattress.

As an illustration, if the dimension presented were used: If the bottom edge of the siderail were 30 mm from the mattress support deck and the top of the compressed mattress were 180 mm from the support deck, an entrapment here could not occur, because the patient could not get their neck under the bottom edge of the rail at the end of the rail. However, the system would fail the dimensional guidance, because the diagonal measurement from the bottom edge of the rail at the end of the rail and the top of the compressed mattress would be greater than 60 mm.

- Currently proposed and accepted measurement techniques for this area (HBSW) start with a baseline acceptable measurement of 60°, and the current proposal for the IEC standard is 60° or greater. The FDA guidance should match the 60° or greater measurement proposed by IEC.
- Once again, the dimension is not meaningful without a method for measuring it, because of the factors of compressibility and other variables.

**Section ~ Zones 5-7**

Dimensional criteria cannot be meaningfully evaluated without a validated measurement system. The Guidance states that the HBSW will issue measurement techniques and tools for The Guidance, but no measurement system has been proposed, developed or tested for Zones 5-7.

**Zone 5 – Between the Split Bed Rails**

- Again, the manner in which the entrapment theoretically occurs should be discussed. In this case, there are two possible theories:

- The movement of the patient could result in their neck being placed between side rails large enough to allow the neck access from above, but small enough to trap the patient's neck.
- The patient attempts to exit the bed (intentionally or not) between raised side rails, and in the attempt, their chest could be compressed between the rails.

**Request for Comments: Recommendation for a dimensional limit for Zone 5.**

- There is no measurement technique for the greater than 60° angle between the siderails, which would only come into play for the <60 mm condition.
- These dimensions are covered for new manufacture in the IEC standard.
- On page 9, 19 and 20, the Guidance says that the FDA continues to receive entrapment reports for Zones 5 and 6. For the public to make informed risk assessments at their hospital, these reports should be made available to the public so that a reasonable risk/benefit assessment can be made. The HBSW decided not to expend resources validating tools and test methods for measuring recommended dimensions in Zones 5 and 6, because there have been so few reports of entrapment in those areas. The Guidance should affirm acceptance of IEC 60601-2-38 for dimensional criteria, state the theoretical risk scenario, and refer to the HBSW clinical guidance for mitigation strategies in legacy equipment.

**Section ~ Zones 5-7**

**Zone 6– Between the End of the Rail and the Side Edge of the Head or Foot Board**

- Again, the manner in which the entrapment theoretically occurs should be discussed. In this case, there are two theoretical entrapment events:
  - The movement of the patient could result in their neck being placed between the edge of the side rails and the head or foot board in a space large enough to allow the neck access from above, but small enough to trap the patient's neck.
  - The patient attempts to exit the bed (intentionally or not) between the edge of the side rails and the head or foot board, and in the attempt, their chest could be compressed between the edge of the side rails and the head or foot board.

**Request for Comments: Recommendation for dimensional limits for Zone 6**

- There is no measurement technique for the greater than 60° angle between the edge of the side rails and the head or foot board.
- No rationale is presented as to why there are different dimensional requirements for the head and foot board measurements. Both should present essentially the same risk, and therefore both should be <60 mm or >318 mm.

- Instead of including recommendations in the guidance, FDA should affirm the acceptance of IEC 60601-2-38 for dimensional criteria, state the risk scenario, and refer to the clinical guidance for mitigation strategies in legacy equipment.

**Request for Comments: Recommendation for a dimensional limit for Zone 7**

- For more than 19 years of data collection, there has never been an entrapment reported in zone 7. On page 22, the Guidance admits that there are no reports of entrapments in Zone 7. There is no logical reason to include a Zone 7 dimension, and this Zone should be eliminated from any further consideration.

**Request for Comments: Articulated bed positions**

- We are unaware of any entrapments reported in an articulated bed. If the head of the bed is articulated, it is unlikely that the frail, weakened, at risk patient's movement would take them uphill to an entrapment event at the head end of the bed. Similarly, if the knee section is elevated, a weakened patient may have greater difficulty egressing from the bed. Mitigations for articulated positions should be based on specific risk assessments performed by the caregiver with each individual patient, rather than by the Guidance.

**Request for Comments: Application of this guidance to all health care settings.**

- There is no reason to exclude any health care setting from this guidance.

**Appendix F**

- Appendix F suggests that healthcare facilities should measure all beds to assure compliance with the recommended dimensions of the guidance. The recommended one-time measurement of existing bed systems does not guarantee that bed systems will continue to meet the dimensional recommendations. As already noted, the Guidance does not provide usable test methods and tools. If FDA expects facilities to measure the beds, then such methods and tools must be included in the Guidance.
- Healthcare facilities replace mattresses from time-to-time with mattresses from other beds, or with replacements for worn mattresses. There is no assurance the replacement mattress will have the same dimension as the mattress it replaced, thereby invalidating the earlier measurements done by the facilities. Thus the recommended practice will be an expensive exercise without a guaranteed result of a safe bed system. It has been estimated that the cost to measure the two million beds in hospitals alone will, conservatively, be about \$17.5 million<sup>3</sup>. The same presentation estimated the incidence of entrapment in hospitals at approximately 3 in 10 million hospital admissions. It seems

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<sup>3</sup> *Bed Rail Entrapments in Acute Care Hospitals-Examining the Data*, American Society for Healthcare Engineering of the American Hospital Association, Susan McLaughlin, Slide 6.

that a better approach to entrapment would be the approach listed in the HBSW clinical guidance documents, that is, assuring the bed system meets the patient need at the time the patient is admitted, rather than requiring a burdensome measurement of all beds in a facility at one time, without a guaranteed result.

Appendix F states: "Healthcare facilities should check with their bed system manufacturers to ensure that their hospital beds, mattresses, rails, and accessories are compatible." This statement may be interpreted by the end user to suggest that the *manufacturer* has the responsibility to evaluate bed systems in the field. This expectation is not reasonable. Products often change dramatically from the specifications as they existed when ordered (*i.e.*, mattresses change, new accessories are ordered). The only thing Industry can reasonably comment on is the compliance of new bed systems at the time of order. This statement in Appendix F should be modified to read: "Healthcare facilities should assess their bed systems to assure that their beds, mattresses, rails and accessories are compatible."

We appreciate the opportunity to share our concerns with FDA and look forward to working with the Agency to address issues related to this important guidance.

Respectfully submitted,



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