



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

Re: Docket 2004D-0343

Dear Sir/Madam:

The Food and Drug Administration (FDA) has published the *Draft Guidance for Industry and FDA Staff Hospital Bed System Dimensional Guidance to Reduce Entrapment (Draft Guidance)*. In the publication announcement, the FDA has requested comments and suggestions regarding the draft document. Kinetic Concepts, Inc. (KCI), a member of the Hospital Bed Safety Workgroup, has reviewed the draft document and submits the following comments and recommendations to the FDA.

KCI is a manufacturer and major international supplier of specialty therapy bed systems, including low-airloss and air-fluidized therapy bed systems for the purpose of treating or preventing bedsores (decubitus ulcers), treating severe or extensive burns, and to aid circulation. KCI also provides kinetic therapy bed systems to treat or prevent pulmonary complications in critically ill patients as well as a full continuum of risk management and therapy bed systems designed for the obese patient.

Background for KCI's Comments

The FDA issued a Safety Alert in August 1995¹ indicating a potential safety issue with the use of hospital bed siderails, after reviewing several years' data submitted to the FDA by hospital bed manufacturers and others. The Safety Alert indicated that a small identifiable segment of the patient population was at risk for potential entrapment.

Following the issuance of the Safety Alert, the FDA continued to collect data and finally in 1999 invited interested parties to form a group to study the issue and present recommendations. The group first met in April 1999 at FDA offices in Washington, D.C. and consisted of a number of manufacturers, healthcare organizations, FDA representatives and other special interest groups and individuals. Over time, more than seventy individuals directly participated in the meetings of the Hospital Bed Safety Workgroup ("HBSW"), and, in addition, a number of engineers and scientists contributed to the efforts by doing research and performing testing. The group also reviewed available data from FDA databases and other sources, including healthcare industry and manufacturers' data.

KCI joined the effort in 2000 with a team of seven professionals who represented the company at various meetings. In addition, a team of over fifteen scientists and engineers

¹ *Entrapment Hazards with Hospital Bed Siderails*, FDA Safety Alert, August 1995,

2004D-0343

C18

from the company also supported HBSW efforts by performing testing, participating in scientific discussions, and demonstrating specialty beds.

As a group, the HBSW has issued several documents on bed safety, including a brochure on bed safety for the general public and the healthcare industry describing the issue², and a Clinical Guidance document³ describing bed rail assessment and implementation actions for the healthcare provider. Most recently, the Hospital Bed Safety Workgroup submitted to the FDA a proposed draft guidance (“HBSW Guidance”) identifying zones of potential entrapment within a bed system and dimensions of each zone to reduce potential entrapments. At the time of release of the final HBSW guidance, a corrective action guide for existing beds will be released along with a measurement kit to determine if beds meet the dimensional guidance.

The HBSW has spent many thousands of hours researching this issue, with the best possible science, based on data supplied by the FDA and data supplied by manufacturers. The conclusions of this research are stated in the HBSW Guidance. The FDA revised the HBSW Guidance document and published the FDA Draft Guidance. Overall KCI recommends that the FDA Draft Guidance be revised in accordance with the original recommendations of the HBSW Guidance. KCI’s specific comments follow below.

KCI Comments for specific sections of the FDA Draft Guidance:

Standards and Future Harmonization

The FDA has worked with international organizations to develop an international regulatory environment to allow medical device manufacturers to compete in a least burdensome environment. In addition, the FDA has met with the international workgroup (IEC SC 62D/JWG 4: Medical Beds) that is attempting to revise the present international standard for hospital beds and produce a new standard, (Electromedical equipment - Part 2-52: Particular requirements for the safety and essential performance of medical beds,) and has a member in that group. The HBSW carefully worked with the international group to attempt to develop a draft guidance that would be harmonized, yet provide a suitable level of safety for hospital bed systems. The international standard will also address the issue of entrapment, which has also been recognized by other regulators such as the United Kingdom⁴ and Canada⁵.

It is important for U.S. manufacturers to remain competitive in the medical device arena and to have international standards for these products. If the FDA were to produce a

² *A Guide to Bed Safety*, Hospital Bed Safety Workgroup, 2000

³ *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings*, Hospital Bed Safety Work Group, 2003

⁴ Medicines and Healthcare Products Regulatory FDA Medical Device Alert MDA/2004/007, and MDA DB2001(04), *Advice on the Safe Use of Bedrails*

⁵ Medical Devices Alert No. 107, *Hazards with Hospital Bed Split Side Rails*, Health and Welfare Canada, Health Protection Branch.

dimensional guidance that conflicted with the international standard being developed, manufacturers would be forced to raise costs by producing different products for different markets, with no increased level of safety.

Scope

KCI recommends that the FDA publish a final guidance using the dimensions developed by the many person-years of engineering and scientific effort represented in the HBSW Guidance. In addition, KCI recommends that the basis for the dimensional changes proposed by FDA be presented in the Draft Guidance.

FDA Request for Comments: 1. Exclusions

KCI concurs with the recommended exclusions presented in the Draft Guidance as further supported by the discussion below.

In 2002, HBSW formed a study group on Specialty Beds during a meeting in Chicago. This group examined various specialty beds and determined the following categories should be excluded from the HBSW Guidance:

- A. Air-Fluidized Bed Systems
- B. Bariatric Bed Systems
- C. Treatment Tables and stretchers
- D. Rotation Bed Systems
- E. Air Flotation Bed Systems (partial exemption*)
- F. Pediatric beds and cribs
- G. Labor Delivery Recovery and Postpartum and/or maternity beds

* Inside the rail dimensions apply (Zone 1)

The framed flotation therapy products are widely utilized to treat serious wounds or prevent skin breakdown in patients at risk. The safety and effectiveness of these types of products has been widely documented in clinical literature for over 10 years.

The FDA Draft Guidance referred to an article by Stephen Miles⁶ in questioning the exclusion of framed flotation-therapy products and bed systems using powered air mattress replacements. In the article, Dr. Miles stated: "Healthcare managers should manage this risk rather than abandoning the use of pressurized mattresses for treating or preventing decubitus ulcers." Dr. Miles recognized that decubitus ulcers, which are acquired by 1.5 million patients per year⁷, and result in 60,000 deaths per year⁸, are a

⁶ *Death Between Bedrails and Air Pressure Mattresses*, JAGS, June 2002, Vol. 50 No. 6, pp 1124-1125

⁷ *The WOC Nurse: Economic, Quality of Life, and Legal Benefits; wound, ostomy, and continence nurse*, Dermatology Nursing, no. 3, Vol. 13; pg 215.

much greater threat to the health of patients than potential entrapments. Using the principles of risk management, it would be more dangerous to withhold the treatment provided by air pressurized mattresses to the much larger population of patients with these life-threatening wounds than to eliminate the small number of exposures to the hazard of entrapment that might occur.

The FDA Draft Guidance also referred to the Joint Commission on Accreditation of Healthcare Organizations' ("JCAHO") Sentinel Event Alert⁹ ("Alert") with regard to the recommended exclusion. The Alert points to the same article in its discussion of air pressure mattresses and quotes the same conclusion from Dr. Miles. In other words, the JCAHO also concludes that the use of these valuable medical devices should continue. The JCAHO Alert, while making no specific recommendations for air-pressure mattresses, makes six general recommendations for all bed systems to reduce entrapment:

1. Provide orientation and training to staff about entrapment dangers with bed rails and assessment of patients/residents for entrapment risk, as appropriate to the patient population and the care environment.
2. Assess patients/residents for risk of entrapment, including physical, mental, behavioral or medication impairment.
3. Re-evaluate beds for entrapment potential, including "gap" measurement and appropriate sizing of mattresses for bed frames.
4. For individual patients/residents at risk for entrapment, implement appropriate changes to beds (for example, the use of retrofit kits, bed rail netting, clear padding, Velcro or anti-skid mats) to reduce the risk of entrapment.
5. When possible, keep patients/residents with risk factors for entrapment under more frequent observation.
6. Educate the patient/resident and/or his or her family about the purpose and potential dangers of bed rails.

Engineering and science are being utilized by manufacturers to produce the safest possible product. But at this time, a solution that continues to maximize the treatment of these wounds while meeting the dimensional requirements of the Draft Guidance has not been found. Because these engineering solutions are currently unavailable, failure to exclude specialty beds would mean these clinical tools would become unavailable. However, when a solution is found, manufacturers will apply it, using the principles of risk management required by the FDA continually applied to all products.

As with all medical devices, the risk management process is applied to hospital bed systems by manufacturers, and in cases where risks are greater than the acceptable level, manufacturers are required to demonstrate that the medical benefits of the product outweigh the risks. Dr. Miles and JCAHO have recognized this to be the case with air

⁸ *A new perspective on pressure sore prevention*, P.M. Kynes, Journal of Enterostomal Therapy, 1986, 13(2), pp.42-43.

⁹ Issue 17 Sentinel Event Alert: *Bed-related Entrapment Deaths* (September 6, 2002), Joint Commission on Accreditation of Healthcare Organizations.

pressure mattresses by recommending their use be continued, but also recommending that medical personnel should use the general recommendations in the JCAHO document listed above to mitigate the risks present with the use of the device. Further, KCI agrees that the medical benefits of the air fluidized bed systems, bariatric bed systems and rotation bed systems clearly outweigh any risk associated with entrapment.

Organization of this Guidance

KCI agrees with the “Organization of this Guidance” section.

Key Body Parts at Risk

KCI agrees with the Draft Guidance position on “Head” and “Neck” data to determine dimensions. However, under its discussion of “Chest”, the FDA refers to “This space...” in the second sentence, which apparently refers to an entrapment zone identified as “Zone 5” on page 11. The FDA should better identify the space that is discussed in this section.

Potential Zones for Entrapment

KCI generally agrees with this discussion, but recommends that the FDA present information in this section that describes the varying probabilities for entrapment shown by its data in each of the zones. For example, Zone 7 entrapments were not identified in any FDA data, nor have any manufacturers or others indicated entrapments in this zone. Conversely, FDA data show that Zones 1 and 3 have higher probabilities of entrapment than the other zones. The description of the rates would be helpful to the healthcare professional in assessing the use of specific products for a patient.

Entrapment at the Bed Deck or Frame

This discussion is helpful in describing the problems in analysis of the FDA data.

A Retrospective Study of Entrapment Reports to FDA

This discussion is helpful in describing the process HBSW used, the data sources, and the problems encountered with the data.

However, in footnote 18, the FDA questions the manufacturers’ data as “best case” without providing any evidence to the contrary. The manufacturers’ best interest is to provide the safest possible product to the public, and have strived to develop the best feasible solutions to the problem of entrapment. In addition, footnote 18 goes on to suggest that testing should be performed with beds in articulated positions. KCI feels

strongly that this would create a near impossible situation for healthcare providers as described later in this document.

Recommended Dimensional Limits for the Identified Entrapment Zones

Zone 1-Within the Rail

KCI agrees with the dimensions proposed by the Draft Guidance.

Zone 2-Between the Top of the Compressed Mattress and the Bottom of the Rail, Between the Rail Supports

KCI agrees with the dimensions recommended by IEC SC 62D/JWG 4: Medical Beds and HBSW, rather than the dimensions proposed by the Draft Guidance. To the best of KCI's knowledge, FDA has not conducted any scientific or engineering studies of the dimensions proposed as alternatives and has not produced any data to show that these recommendations would lessen the risk of entrapment below the dimensions proposed by the IEC and HBSW. The FDA has proposed that mattress wear and compressibility increase the risk of entrapment without providing the data to support this theory. The engineering problem of creating a design that would meet this added requirement also adds significant cost to hospital bed systems without a demonstrated benefit.

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

FDA again proposes that mattress compressibility and wear could cause the recommended dimension to not provide enough protection. In contrast, KCI supports the HBSW Guidance position and the dimensions recommended therein. KCI believes that the work by the HBSW (in which FDA was an active participant) was sufficiently rigorous to produce dimensions that provide effective protection from entrapments and to consider the variability of the mattress over time in the entrapment equation.

Zone 3-Between the Rail and the Mattress

KCI supports the HBSW engineering and scientific work and the dimension the HBSW recommends rather than that proposed by the FDA.

Data from Retrospective Study

The FDA states that "If the incidents identified as possibly occurring in Zone 2, 3, or 4 actually occurred in Zone 3, many of them still might have occurred despite the HBSW recommended dimensional limit for that Zone, greater than 4 ¾ in. (120 mm)." The FDA

does not provide any supporting data for this theory. The FDA should provide engineering evidence to support this position.

Zone 4-Between the Top of the Compressed Mattress and the Bottom of the Rail at the end of the Rail

KCI agrees with the dimension proposed by HBSW and supported by the FDA.

Data from Retrospective Study

KCI has no comments for this section.

Zone 5-Between the Split Rails

KCI supports the position that zone 5 requirements are not required, since the number of entrapment instances reported is very few. In addition, the cost of changing the rail dimensions would greatly exceed the benefit. Other solutions such as side rail pads are as effective and more economically feasible.

If the FDA determines it is necessary to include this dimensional requirement, KCI would support the dimension suggested by the international standard workgroup that is supported by HBSW work.

Data from Retrospective Study

KCI has no comments for this section.

Request for Comments: 4. Recommendations for a dimensional limit for Zone 5.

The recommendation for a dimensional limit for this zone may be acceptable. However, the FDA should note that JCAHO is citing healthcare facilities that leave all 4 rails in the “up” position, and that the practice of rails remaining in the “up” position is decreasing.

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

While the FDA’s position in this case is commendable, KCI supports the HBSW, whose data show that the incidence of entrapment in this area is very low (the lowest incidence identified). Further, as described in the FDA’s discussion, FDA data were unclear as to the actual area in which the patient is entrapped.

Data from Retrospective Study

KCI has no comments for this section.

Request for Comments: 5. Recommendations for dimensional limits for Zone 6

KCI supports the HBSW position that no dimension be identified until the problem can be clearly described and a solution identified.

Zone 7-Between the Head or Foot Board and the End of the Mattress

Although this zone could possibly allow entrapment, in nearly 20 years of FDA data, no incidents have been identified.

Data from Retrospective Study

Again, no entrapments have occurred in this zone according to FDA data.

Request for Comments: c. Recommendations for a dimensional limit for Zone 7.

KCI supports the HBSW position that if no entrapments have occurred in 19 years of FDA data, it seems that no solution is necessary. KCI supports the position that Zone 7 dimensional limits are not required.

Additional Request for Comments: 7. Articulated bed positions

The only possible method of completing this testing is with the use of engineering computer systems that work in three-dimensions. The human is not capable of completing these tests for the infinite number of positions of articulation. It would take hundreds of person-hours of effort to test one bed in the infinite number of bed and rail positions that the bed and the rails could reach in a normal bed system.

Additional Request for Comments: 8. Application of this guidance to all health care settings

According to the Draft Guidance, the FDA has identified 575 entrapments over 19 years of collecting data.¹⁰ In the Draft Guidance the hazard of entrapment should be placed in perspective. That is, manufacturers using the techniques of risk management recommended by the FDA would evaluate the hazard in the terms of severity of hazard and probability of occurrence. The FDA has described a severity of hazard, death or serious injury, but has not identified a probability of occurrence. The FDA has identified how many incidents took place but has not compared this to the total number of opportunities. This comparison is necessary to apply risk management techniques to assess the hazard and to apply control measures properly to the hazard.

The FDA representatives attended the presentation to the HBSW by the American Society for Healthcare Engineering of the American Hospital Association (“ASHE”)¹¹ in April 2002 in Chicago. The data presented showed, for hospitals, a probability of 3.1×10^{-7} entrapment incidents per hospital admission, or 1 death per hospital per 1000 years. The data were based on 2,000,000 hospital beds in the United States. Additionally, the presentation by ASHE indicated that a far greater problem for hospitals was nosocomial infections, at a rate of 16 deaths per hospital per year or $.002 (2 \times 10^{-3})$ per hospital admission.

Sections of the Draft Guidance¹² suggest that healthcare facilities should expend their limited resources to measure all hospital bed and mattress combinations in a facility to determine if the hazard exists in the facility. But in fact, the HBSW has identified a more practical method of reducing the risk in HBSW’s Clinical Guidance. The estimates are that in hospitals alone, over \$17,000,000¹³ would be expended to measure bed systems, with no assurance the problem would be solved, because important contributors to the issue are the mattress and the “at risk” characteristics of the individual patient when that patient is placed on a “mattress/frame” system. As the mattress wears over time, it could easily open the gaps the FDA has identified as important, and if the mattress is moved from one bed to another – a common practice in healthcare facilities – the gaps could be different. Thus, the solution proposed by the FDA might not significantly reduce the probability of entrapment.

¹⁰ *Draft Guidance for Industry and FDA Staff Hospital Bed System Dimensional Guidance to Reduce Entrapment*, page 3

¹¹ *Bed Rail Entrapments in Acute Care Hospitals-Examining the Data*, American Society for Healthcare Engineering of the American Hospital Association, Susan McLaughlin, Slide 6.

¹² *Ibid.*, Appendix F

¹³ ASHE

Recommendations

The FDA indicated initially in its Safety Alert of 1995¹⁴ that the patient at risk typically had loss of muscle control, or was confused or restless. The HBSW Clinical Guidance recommended that the patient first be assessed to determine if he/she is susceptible to entrapment and then recommended measures be addressed for the patients at risk. This is a much more cost-effective and overall more effective method to reduce the probability of entrapment. The individual patient needs are addressed in this methodology at the time the risk is determined, and the individual bed would be assessed as to its ability to meet the individual patient needs at the time of use.

In the FDA methodology, the bed would be assessed once, at a time remote from the patient use. In fact, there could be a change in the risk level before the patient use, thus exposing the patient to the hazard. KCI strongly recommends elimination of the requirement for healthcare facilities to measure all bed systems at one time. Rather, KCI recommends this one-time measurement be replaced with the recommendations developed by the HBSW Clinical Guidance for assuring the patient receives the treatment needed.

KCI also recommends that the FDA and the HBSW commence a vast outreach effort to educate healthcare professionals as to the implications of the final guidance. If, as stated by the FDA, they do not "...intend to take enforcement actions that involve 'corrections and removals' under 21 C.F.R. 806 for actions taken in response to this guidance that correct or improve hospital beds currently in use..."¹⁵, and continue the position of the FDA as stated by Dr. Larry Kessler in the April, 1999 meeting of the HBSW¹⁶, then the FDA must make its position clear to the healthcare community so that healthcare facilities do not think they face the prospect of replacing all existing beds.

Additionally, if the FDA expects facilities to measure existing beds, then methods and tools to measure must be immediately available at the time the final guidance is released. A final guidance is incomplete and ineffective without available, usable and validated test methods and tools. The FDA should also publicize at the time of release, the HBSW Clinical Guidance and HBSW's Corrective Action Guide, describing ways to use existing beds in the healthcare inventory. The final guidance document should not be released as a stand-alone document.

KCI believes that a better process for existing beds in a healthcare facility would be to first assess the patient. If the patient is not susceptible to entrapment, no further action would be required. However, if the patient is susceptible to entrapment, as identified in the HBSW Clinical Guidance document, then the bed should be assessed to determine if there is a low risk of entrapment, or if it has the dimensions identified in the FDA Dimensional Guidance. If the bed does not meet the requirements of the Draft Guidance,

¹⁴ Ibid.

¹⁵ Dimensional Guidance p. 5

¹⁶ Namely, the FDA will not cause the recall of hospital beds for entrapment.

then the facility personnel would use the HBSW Corrective Action Guide to correct the deficiencies in the bed so that the patient is placed on a bed with the lowest possible risk of entrapment. This process would ensure that the bed is assessed at the time the patient is placed on the bed, and not at some time remote from the patient need. This process would also address changes that occur, such as wear to the bed, mattress, and rails, that could render the initial measurements invalid and waste the large expenditure of resources by the healthcare facility.

Conclusion

KCI commends the FDA for its long-term effort to find solutions for the entrapment issue and hopes the FDA will expend similar efforts for more frequently occurring issues such as patient falls. KCI also thanks the FDA for allowing KCI to participate in the HBSW joint effort and requests that the FDA adopt the recommendations of HBSW Guidance in full. HBSW participated in good faith to develop the best possible solution for this issue. KCI hopes the FDA recognizes the openness of the participants in working together with FDA and other agencies in a collegial and non-competitive environment in developing practical and affordable solutions.

Very truly yours,


Kay Mary Harrell
Director, Regulatory Affairs