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Comments on Draft Guidance: Hospital Bed System Dimensional Guidance to Reduce Entrapment.

Docket No. 2004D-0343

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**Comment on Introduction and phrase “hospital bed” used throughout**

Most bed entrapments causing positional asphyxia occur in nursing homes. A lesser number occur in home care and in hospitals. The reference to “hospital beds” is misleading and overly constrained to the title of the workgroup. It should be changed to refer to “adult medical beds with siderails.”

**Comment on the diverse uses of bedrails in relation to this guidance.**

Health care providers, facilities, and home care programs use bedrails for a variety of reasons. They are mostly used to as a “reminder” to prevent inadvertent falls from bed though they have not been validated for this use. They are also used as restraints and as assistive devices to enable a person to position themselves in bed or to have a handhold for getting in and out of bed. I am not commenting on the validity of these uses or whether a rail is the best and safest device for such uses. However, it is important to note that a gap that can cause an entrapment *never* enhances any real or putative therapeutic benefit to the use of rails. Therefore, it should be noted that the guidelines apply to any situation in which rails are used either as a restraint, reminder, or as an assistive device. Furthermore, when rails are used as an assistive device, they are being used as an adaptive aid and should be so addressed, evaluated, and monitored by an occupational or physical therapy plan rather than being left to the evaluation of a nursing plan.

**Comment on the focus on clinicians rather than manufacturers.**

The Draft Guidance unduly focuses on clinicians' responsibility to address the risk of entrapment and neglects manufacturers' responsibilities for these avoidable injuries and deaths. This is inadequate for the following reasons.

?? The FDA defines an injurious "malfunction" as including inadequate labels and warnings. Such malfunctions are immediately remediable by bed, rail, and mattress manufacturers.<sup>1</sup> The Draft Guidance lacks:

- Specifications for required safety labeling and dimension markings on beds, to include indicators on the bed frame for minimum mattress dimensions and other relevant material to decrease gaps.
- Specifications for the content of a "package insert for clinician users" to be provided with each component of a bed system (beds, rails, and mattresses) at sale, resale, and leasing for the life of the product to describe the risk, clinical risk factors, measurement, and specific information to address the practice of combining "interchangeable" "universal" bed frames, mattresses, and rails. This clinicians material should describe the issues of gap creation and closure as it applies to each of these components as they are combined in a bed system. The FDA vigorously supports standards to ensure the compatibility of other combination medical products.<sup>2</sup> Various sized mattresses slide from side to side on bed frames creating gaps large enough to entrap a person between the mattress and the bedrail. Accessory bedrail kits have diverse bed frame attachments that allow the rails to work with frames of nonstandard widths; such variety makes it easy for beds to be assembled with wide gaps between the rail and the mattress.
- Specifications for the content of a "package insert for patients or families" to inform such persons of the evidence of the benefits and risks of rails to address widespread misconceptions and over-estimations of the demonstrated beneficial effects of the routine use of rails.
- A mechanism for assuring that the above package inserts is provided with the bed, or rails, or mattress (whether marketed as a unit or separately) from the manufacturer to the clinician and to leasing or resale redistributors throughout the entire life of the product.
- A mechanism, including a clear label on bed frames, mattresses, and rails for ongoing registration of the product on each manufacturer's website so that updated safety information can be continually provided to health care facilities, resellers, and leasing agents.

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<sup>1</sup> FDA, Medical Device Reporting for Manufacturers. <http://www.fda.gov/cdrh/manual/mdrman.html> (Accessed July 6, 2004).

<sup>2</sup> Food and Drug Administration, Standards Database Search Engine, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> (Accessed July 7, 2004).

?? The FDA defines an injurious “malfunction” as including a failure of the structure, design of bed components, a specific responsibility of bed manufacturers.<sup>3</sup> The Draft Guidance lacks requirements that beds be designed to accept safety accessories, such as positioning alarms or devices to measure force against bedrails, that might indicate an entrapment.

The training cycle for the complex measurement standards proposed by the standards will be long and unevenly implemented. The proposal of these clinician centered responsibilities does not justify further delaying in setting clear standards for the design, labeling and informational material of the components of adult medical bed systems. This deficiency in the draft guidance is highly anomalous given FDA requirements for other medical devices.

**Comment on the exclusion of air mattresses, mattress overlays, air fluidized therapy beds, framed flotation therapy beds.**

The Draft Guidance states that these devices are excluded because “the nature of the therapy does not allow the patient to exit the bed easily,” “the therapeutic benefit is expected to outweigh the risk of entrapment,” and “these products provide high clinical benefit for patients needing pressure reduction services.” The Draft Guidance “encourage[s] manufacturers to make new pressure reduction therapeutic products that meet all of the recommendations in this guidance.” This Guidance should be amended for several reasons.

- ?? Clinician awareness of the hazard of positional asphyxia in these beds is low. This Guidance does not address the obligation of manufacturers to provide instructional material and labeling that warns consumers or clinical users or distributors of the risk of the hazard of entrapment in these beds or of information pertaining to clinical characteristics, behaviors, or events that might adversely change the risk to benefit ratio of these beds.
- ?? The Draft Guidance does not caution against the common clinical practice of combining air mattresses or overlays with bed frames for which they are specifically designed. The widespread use of “universal” and interchangeable air mattresses with diverse bed-bedrail systems increases the incidence of death as it decreases the manufacturer of any one element in a bed-rail-mattress combination’ accountability for the death. It should be noted that the FDA supports standards to promote the compatibility of other combined medical products.<sup>4</sup>
- ?? Short of proposing standards for these types of beds, the FDA might easily make recommendations, requirements, or a timetable to require that the excluded beds
  - be designed to accept or have safety accessories, such as positioning alarms or devices to measure force against bedrails that might indicate an entrapment.
  - contain clear graphic warnings of the risk of positional asphyxiation in these beds including a notation that this risk may change the risk to benefit ratio of these beds in some clinical situations, ie those involving paralyzed, confused, or impulsive patients.

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<sup>3</sup> FDA, Medical Device Reporting for Manufacturers. <http://www.fda.gov/cdrh/manual/mdrman.html> (Accessed July 6, 2004).

<sup>4</sup> Food and Drug Administration, Standards Database Search Engine, <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> (Accessed July 7, 2004).

?? The Draft Guidance overstates and misuses the “high clinical benefit” of air mattress beds as a reason for not addressing the problem of positional asphyxia in these systems. This phrasing implies, contrary to other FDA policy, that the risks posed by such a beneficial therapy need not be addressed by risk reduction information or standards. In fact, the data supporting low air pressure mattresses and viscous overlays for preventing or treating decubitus ulcers is very thin. (I am excluding the data on air-fluidized particulate beds and intra-operative use where the patient is continuously monitored and only on the bed for a very short time.)

- Most studies have found foam mattresses equal to or superior to low air flow mattresses.<sup>5 6 7 8 9 10 11 12 13</sup>
- Two trials, involving a total of 120 persons, have found significant advantages to air mattresses over other mattresses.<sup>14 15</sup> Others studies have found favorable but not statistically significant advantages to air mattresses.<sup>16 17 18</sup>

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<sup>5</sup> Rosenthal MJ, Felton RM et al. Healing of advanced pressure ulcers by a generic total contact seat: 2 randomized comparisons with low air loss bed treatments. *Arch Phys Med & Rehab* 2003;84:1733-42.

<sup>6</sup> Russell L, Reynolds TM, Towns A et al. Randomized comparison trial of the RIK and the Nimbus 3 mattresses. *Brit J Nurs* 2003;12:254, 256-9.

<sup>7</sup> Conine TA, Daechsel D, Lau MS. The role of alternating air and Silicore overlays in preventing decubitus ulcers. *Int J Rehab Research* 1990;13:57-65.

<sup>8</sup> Branom R, Rapp L. Constant force technology" versus low-air-loss therapy in the treatment of pressure ulcers. *Ostomy Wound Manage* 2001;47:6.

<sup>9</sup> Daechsel D, Conine TA. Special mattresses: effectiveness in preventing decubitus ulcers in chronic neurologic patients. *Arch Phys Med & Rehab* 1985;66:246-8.

<sup>10</sup> Evans D, Land L, Geary A. A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system. *J Wound Care* 2000;9:181-6.

<sup>11</sup> Land L, Evans D, Geary A, Taylor C. A clinical evaluation of an alternating-pressure mattress replacement system in hospital and residential care settings. *J Tissue Viability* 2000;10:6-11.

<sup>12</sup> Ooka M, Kemp MG, McMyn R, Shott S. Evaluation of three types of support surfaces for preventing pressure ulcers in patients in a surgical intensive care unit. *J Wound, Ostomy, & Continence Nurs* 1995;22:271-9.

<sup>13</sup> Warner DJ. A clinical comparison of two pressure-reducing surfaces in the management of pressure ulcers. *Decubitus* 1992;5:52-5, 58-60, 62-4.

<sup>14</sup> Ferrell BA, Osterweil D, Christenson P. A randomized trial of low-air-loss beds for treatment of pressure ulcers. *JAMA* 1993;269:494-7.

<sup>15</sup> Sanada H, Sugama J, Matsui Y, et al. Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation. *J Tissue Viability* 2003;13:112-4, 116, 118.

<sup>16</sup> Sanada H, Sugama J, et al. Randomised controlled trial to evaluate a new double-layer air-cell overlay for elderly patients requiring head elevation. *J Tissue Viability* 2003;13:112-4, 116, 118.

<sup>17</sup> Young T, Haughton B, Williams C. Pressure area management in an orthopaedic setting. *Brit J Nurs* 1998;7:702-8.

This research base does not merit the HBSW and FDA's misleading endorsement of "high clinical benefit" for air-pressure beds in the circumstances especially insofar as that endorsement might lead clinicians to move entrapment prone patients from regular beds to air systems for the treatment or prevention of decubitus ulcers in routine day to day care.

On a personal note, I recently leased a medical bed for home care for my father. I contacted 6 rental companies. Siderails were automatically included with all beds. Not one distributor was even aware of the hazard of positional asphyxia in the bed. Four out of six could not tell me what bed, rail, mattress combination would be supplied. As one rental representative put it, "When we get your order, the guys in the back put together a bed and we deliver it to you."

The Draft Guidance optimistically presumes the ability to rapidly and effectively disseminate a complex form of bed assessment while leaving the manufacturers who have built these needless hazardous products unregulated.

Sincerely,

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<sup>18</sup> Gebhardt KS, Bliss MR, Winwright PL, Thomas J. Pressure-relieving supports in an ICU. *J Wound Care* 1996;5:116-21.