BP - Bed Rails - NPR
The contents of this document will be discussed at the Open Commission Meeting on March 23, 2011

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

This document has been electronically approved & signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: APRIL 6, 2011

March 16, 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Philip L. Chao, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Notice of Proposed Rulemaking: Safety Standard for Portable Bed Rails

The Office of the General Counsel is providing for Commission consideration the attached draft *Federal Register* notice on a proposed rulemaking on a safety standard for portable bed rails.

Please indicate your vote on the following options.

I. Approve publication of the draft notice in the *Federal Register* without change.

_____ _____
(Signature) (Date)

II. Approve publication of the draft notice in the *Federal Register* with changes. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

III. Do not approve publication of the draft notice in the *Federal Register.*

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments:

Draft *Federal Register* Notice–Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking

Staff Briefing Package: Draft Proposed Standard for Portable Bed Rails, from Rohit Khanna, dated March 2011.

[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1224

[CPSC Docket No. CPSC-2011-]

Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: Section 104(b) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires the U.S. Consumer Product Safety Commission ("CPSC," "Commission," or "we") to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a more stringent safety standard for portable bed rails that will further reduce the risk of injury associated with these products.

DATES: Written comments must be received by **[insert date 75 days after publication in *Federal Register*].**

ADDRESSES: Comments related to the Paperwork Reduction Act aspects of the instructional literature and marking requirements of the proposed rule should be directed to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to oira_submission@omb.eop.gov.

Other comments, identified by Docket No. CPSC-2011-____, may be submitted by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail) except through www.regulations.gov.

Written Submissions

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, U.S. Consumer Product Safety Commission, Room 502, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Rohit Khanna, Project Manager, Office of Hazard Identification and Reduction, U.S. Consumer Product Safety

Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7546; rkhanna@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

1. *The Consumer Product Safety Improvement Act*

The Consumer Product Safety Improvement Act of 2008, Pub. Law 110-314 ("CPSIA") was enacted on August 14, 2008. Section 104(b) of the CPSIA requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. This document proposes a safety standard for portable bed rails. The proposed standard is substantially the same as the voluntary standard developed by ASTM International (formerly known as the American Society for Testing and Materials), ASTM F 2085-10a, "Standard Consumer Safety Specification for Portable Bed Rails," but we are proposing some modifications to strengthen the standard because these more stringent requirements would further reduce the risk of injury associated with portable bed rails.

2. *Previous Commission Rulemaking Activity Concerning Portable Bed Rails*

In the Federal Register of October 3, 2000 (65 FR 58968), we published an advance notice of proposed rulemaking ("ANPR") inviting written comments concerning the risks of injury associated with portable bed rails, regulatory alternatives discussed in the ANPR, other possible ways to address the risks of injury associated with portable bed

rails, and the economic impacts of the regulatory alternatives. The ANPR was intended to initiate a rulemaking proceeding that could result in a rule banning portable bed rails that present an unreasonable risk of injury, and we issued the ANPR under our authority in the Federal Hazardous Substances Act ("FHSA"). Elsewhere in this issue of the Federal Register, the Commission has issued a notice that the Commission has terminated the rulemaking proceeding that it began under the FHSA because it has been superseded by the rulemaking required under section 104(b) of the CPSIA.

In May 2001, the ASTM published a standard, ASTM F 2085, "Standard Consumer Safety Specification for Portable Bed Rails." In October 2001, CPSC staff prepared a draft proposed standard, which included performance requirements to address entrapment hazards on portable bed rails. The Commission voted to direct CPSC staff to prepare a notice of proposed rulemaking ("NPR") based on its recommended standard. Thereafter, the ASTM Portable Bed Rail Subcommittee agreed to ballot a revision to ASTM F 2085 that was substantially the same as CPSC staff's recommended standard. Accordingly, we did not issue an NPR at that time. ASTM approved and published the revised standard in June 2003. In 2008, ASTM published another revision to the standard that included a structural integrity test to address fall incidents involving hinge lock mechanism failures. From 2009 to 2010, ASTM made and published minor revisions to the standard. The current edition of the standard is ASTM F 2085-10a, "Standard Consumer Specification for Portable Bed Rails." The standard in this proposed rule would be more stringent in some respects than the voluntary standard ASTM F 2085-10a. The proposed modifications, if finalized, will further reduce the risk of death and injury associated with portable bed rails.

B. The Product

ASTM F 2085-10a defines a "portable bed rail" as a "portable railing installed on the side of an adult bed and/or on the mattress surface which is intended to keep a child from falling out of bed." The scope of the ASTM standard also states that a portable bed rail "is as a device intended to be installed on an adult bed to prevent children from falling out of bed." Portable bed rails are intended for children (typically from 2 to 5 years of age) who can get in and out of an adult bed unassisted. They include bed rails that only have a vertical plane that presses against the side of the mattress but does not extend over it (referred to as "adjacent type bed rails"), as well as bed rails that extend over the sleeping surface of the mattress (called "mattress-top bed rails").

A review of market information shows that there are products that differ from traditional, rigid portable bed rails in that they are constructed of nonrigid materials, such as foam or inflatable materials. Although these foam and inflatable products do not use the term "bed rails" in their packaging or labeling, we believe that the products meet the definition of a portable bed rail and should be included in the scope of the voluntary standard. However, most performance requirements of ASTM F 2085-10a do not apply to these products because the standard was developed to address the hazards from portable bed rails constructed from rigid (wood/metal) materials. Accordingly, the proposed rule would revise ASTM F 2085-10a to include foam and inflatable products, but would require that only certain relevant provisions of the standard apply to such items.

Both portable bed rails made for a specific manufacturer's adult-size beds and "universal" bed rails that can attach to any adult-size bed are included in the scope of

ASTM F 2085-10a. However, guard rails that are used with crib mattresses on toddler beds are not covered under the voluntary standard. They are addressed under the Consumer Safety Standard for Toddler Beds (April 28, 2010, 75 FR 22291). Other products that are not covered by ASTM F 2085-10a include: side rails that connect the headboard to the footboard and may or may not have any barrier purposes; conversion rails intended to convert a crib to a full-size bed; and adult-size beds where the rail is permanently attached to the bed (*i.e.*, bunk beds).

Additionally, the U.S. Food and Drug Administration ("FDA") has several regulations pertaining to hospital beds, including a regulation for pediatric hospital beds (21 CFR 880.5140). The FDA regulations, in general, identify a hospital bed as having (among other things) movable and latchable side rails. If a pediatric hospital bed is subject to regulation by the FDA as a medical device, then the bed rails on that pediatric hospital bed are outside the scope of this proposed rule.

C. ASTM Voluntary Standard

The ASTM standard for portable bed rails was first published in May 2001 (ASTM F 2085-01). This was a minimum standard with requirements for labeling but no performance requirements. The portable bed rails that met the 2001 standard typically were designed with two arms at right angles to the vertical portion of the rail. This type of portable bed rail was installed on a bed by inserting the arms between the mattress foundation and the mattress. These older style portable bed rails relied on friction between the arms and the foundation/mattress to stay in place. However, this type of design allowed the portable bed rail to be moved outward away from the mattress unintentionally if a force was applied in that direction. An outward force may result

from activity by a child in the bed while the child is asleep or awake. Once the bed rail is moved outward, a gap could be created between the vertical portion of the rail and the side of the mattress. The primary hazard scenario would involve a child rolling into a gap between the mattress and portable bed rail and becoming entrapped. Once entrapped, the child could suffocate or strangle.

To address this hazard, the ASTM Subcommittee on Portable Bed Rails revised the standard in June 2003 (ASTM F 2085-03). ASTM F 2085-03 addressed the entrapment hazard by including a new section, "Openings Created by a Displacement," with requirements to deal with displacement of a portable bed rail. In 2008, ASTM published a revised standard (ASTM F 2085-10) that included a structural integrity test to address incidents involving hinge lock mechanism failures. From 2009 to 2010, ASTM made and published minor revisions to the standard. The current edition of the standard is ASTM F 2085-10a.

To assess the adequacy of ASTM F 2085-10a, we tested a variety of portable bed rails currently in the market. Several portable bed rails were certified to ASTM F 2085-10a by the Juvenile Products Manufacturers Association ("JPMA"). JPMA operates a program to certify portable bed rails to the voluntary standard. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current voluntary standard. For portable bed rails that are assembled and installed in accordance with the manufacturer's instructions, we believe that the requirements to address structural integrity and prevent displacement from the mattress are adequate. However, if a portable bed rail is misassembled or

misinstalled on the bed, it could present an entrapment hazard. ASTM F 2085-10a does not address misassemby or misinstallation of foam or inflatable products.

We also reviewed the British Standard Institution ("BSI") standard for bed rails, BS 7972:2001 +A1:2009 Safety Requirements and Test Methods for Children's Bedguards for Domestic Use. The BSI standard primarily addresses entrapment and structural integrity, but also includes some requirements for warning labels. The BSI standard also contains a performance requirement that the bed rail remain attached to the bed after rolling a 30 lb cylinder into the bed rail. The test simulates a child rolling into the bed rail; the ASTM standard does not have an equivalent requirement. We conducted limited testing to compare this requirement with requirements in the ASTM standard that address potential entrapment hazards. Based on staff's review, we find that the ASTM standard is more stringent than the BSI standard because the ASTM test methods provide more stress to the portable bed rail and mattress interface when evaluating entrapment hazards.

D. Incident Data

1. *Incident Reports*

The CPSC Directorate for Epidemiology analyzed incident data related to portable bed rails from January 1, 2000 through March 31, 2010. We received reports of a total of 132 incidents related to portable bed rails. Among the 132 reported incidents, there were 13 fatalities, 40 nonfatal injuries, and 79 noninjury incidents. Of the 13 child fatalities reported involving portable bed rails, most children (9 out of 13) were under 1 year old; two were between 1 and 2 years old; and two children, both physically handicapped, were 6 years old. While all 13 incidents reported some sort of entrapment

of the child between the portable bed rail and the mattress, no additional product- or scenario-specific information was available for five reports. Among the remaining eight incidents, two deaths resulted from portable bed rail displacement, when the portable bed rail partially pushed away from underneath the mattress and allowed the child to fall into the opening and get trapped. There were three cases of portable bed rail misassembly. In the first incident, the middle bar was absent, and the child rolled into the mesh and got wedged between the mattress and the rail. In the second incident, the middle bar was not inserted through the mesh sleeve, and the child's head slipped between the bottom edge of the mesh panel and the top edge of the mattress. In the third incident, the bottom horizontal bar was not attached to the vertical bar, resulting in a hazardous gap. In the remaining three fatality incidents, not enough information was available to determine the contributing factor(s) that led to the hazardous entrapment scenario. The beds used in all eight cases were adult-size.

A total of 40 nonfatal incidents associated with the use of a portable bed rail involved injury to a child. Eighty-three percent of the injured children were 2 years old or older. The majority of the injuries (28 out of 40, or 70 percent) were identified as fractures/contusions resulting from a fall when the portable bed rail became dislodged, or lacerations/scratches on sharp or broken surfaces of the portable bed rail. The remaining injuries resulted from the child getting caught on a torn mesh panel of the rail; the child getting partially entrapped in a portable bed rail that was partly pushed out; and the child nearly choking on small parts (*e.g.*, hardware or labels) that separated from the portable bed rail. While no injuries were reported for the remaining 79 incidents, the incident scenarios indicate that injuries or fatalities potentially could have occurred.

2. *Hazard Patterns*

We considered the 132 incidents together to identify the hazard patterns associated with portable bed rail-related incidents. The hazard patterns can be grouped into the following categories:

- *Displacement of the portable bed rail* - Sixty-nine of the 132 incidents (52 percent) involved the displacement of the portable bed rail, where the portable bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail. In cases where the opening was small, the child became entrapped in the space. In cases where the opening was wide or the rail dislodged completely, the child fell to the floor. There were two fatal incidents, where the portable bed rail had pushed out partially and entrapped the child. There were about 21 nonfatal injuries that resulted from displacement of the rail. A small proportion of the 69 incident reports provided enough information to indicate that, for some "double-rail" configurations (*i.e.*, a design that has two bed rails, one on each side of the mattress), failure of the push-pin or buckle lock mechanism (on the connecting bars/straps underneath the mattress) usually was the main cause of the portable bed rail displacement.
- *Worn or poor quality fabric on mesh panel* - Seventeen of the 132 incidents (13 percent) involved a tear in the mesh, the unraveling of the stitching around the mesh, or simply very loose fabric on the mesh panel. Most nonfatal incident reports in this category involved the child getting caught in the tear/hole (tooth, limb, or even head); loose thread from the stitching getting

tightly wound around the child (finger or neck); and mesh coming completely loose, allowing the child to slide through the panel and fall. Many consumers in the incident reports expressed concern over the potential of the tears/holes in the mesh to become larger and increase the risk of strangulation.

- *Sharp surface* - Fourteen of the 132 incidents (11 percent) involved lacerations or scratches, or the potential thereof, on sharp surfaces of the portable bed rail. Some of the portable bed rails reportedly involved in these incidents had sharp surfaces to begin with, while in other incidents, sharp surfaces were created when parts of the portable bed rail broke away. Occasionally, depending upon the part that broke, the broken components created a potential fall hazard.
- *Hinge lock disengagement* – Eleven of the 132 incidents (8 percent) involved the hinge lock mechanism failing to remain locked to keep the side panel in an upright position. This allowed the child to fall out. Three out of the 11 incidents involving hinge lock mechanism failures resulted in injuries.
- *Misassembly* – Seven of the 132 incidents (5 percent) involved either misassembly or misinstallation of the portable bed rail. Misassembly resulted in three fatalities. In the first case, the middle bar was absent; in the second case, the middle bar was not inserted through the mesh sleeve; and in the third case, the bottom horizontal bar was not attached to the vertical bar. Examples of nonfatal incidents related to misinstallation included the use of a portable bed rail on a toddler bed, as well as the use of a portable bed rail with an extra thick mattress, which prevented the portable bed rail from attaching securely.

- *Miscellaneous Other or Unknown Issues* – Fourteen of the 132 incidents (11 percent) involved other problems not listed above. Six reports—including five fatalities—did not provide any product- or scenario-specific information. Three additional fatality reports provided insufficient information to draw any conclusions about why the portable bed rail was not flush with the mattress. The remaining five nonfatal incidents involved the potential for choking on small parts, such as loose hardware or labels; instability issues resulting from loose hardware; and inadequate design issues, such as extra-wide openings in nonmesh side panels or insufficient rail height.

E. Assessment of Voluntary Standard ASTM F 2085-10a and Description of Proposed Changes and the Proposed Rule

1. Assessment of Voluntary Standard ASTM F 2085-10a

Section 104(b) of the CPSIA requires the Commission to assess the effectiveness of the voluntary standard in consultation with representatives of consumer groups, juvenile product manufacturers, and other experts. CPSC staff has consulted with these groups regarding the ASTM voluntary standard, *Consumer Safety Specification for Portable Bed Rails,* throughout its development. Consultation with members of this subcommittee is ongoing. ASTM F 2085-10a contains several labeling and performance criteria. The standard addresses many of the same hazards associated with other durable nursery products, and includes requirements for lead in paints, sharp edges/sharp points, small parts, wood part splinters, structural integrity, openings, protrusions, and warning labels. For the eight fatal incidents associated with portable bed rails for which investigations by CPSC staff were completed, we identified two major contributing

factors: (1) improper installation, and (2) misassembly. It is also notable that 11 of the 13 deaths involved children under 2 years old. Portable bed rails, which are meant to be installed on an adult bed, are not intended for this age group. Placing a railing on the side of an adult bed does not make the adult bed safe for infants (*i.e*. convert an adult bed into a crib). Despite the current warning label cautioning against the use of this product with children under 2 years old, parents of infants continue to use this product with their infants.

Most portable bed rails currently in the market are difficult for consumers to assemble correctly, due to the number of components and the complexity of the fastening hardware. There were three fatal incidents involving misassembled portable bed rails and, based on our testing of sample portable bed rails, consumers are likely to have difficulty assembling and installing portable bed rails correctly. The proposed rule would contain new performance requirements and associated test methods to address misassembly of portable bed rails.

These proposed performance requirements should reduce the likelihood of portable bed rail misassembly. The proposed misassembly performance requirements would prevent portable bed rail entrapment fatalities that result from assembly of a product without critical assembly components (*i.e.*, any component of the portable bed rail that requires consumer assembly to meet the performance requirements); incorrectly installing the portable bed rail's fabric cover/mesh (if present); or inverting/interchanging parts of the portable bed rail. The addition in the standard of misassembly performance requirements will result in portable bed rail designs that will render the portable bed rail no longer functional if it is not assembled according to the manufacturer-intended final

assembly, or make it obvious to the consumer that the product is misassembled. While current portable bed rail designs do not meet the proposed misassembly requirements, we are aware of the technical feasibility of this requirement because we have developed and demonstrated to ASTM, two prototypes using common portable bed rails designs (adjacent style and mattress top) that meet the proposed requirements.

The proposed rule also would contain a new performance requirement and associated warning label for portable bed rail critical installation components to address issues related to misinstallation of portable bed rails. Although we are not aware of any deaths associated with portable bed rail misinstallation, we are aware of entrapment hazards caused by misinstallation. Furthermore, review and testing of market samples indicate that some consumers may have difficulty installing portable bed rails, which could lead to potentially hazardous conditions. Installation of a portable bed rail onto a bed can require complex or physically demanding adjustments to the portable bed rail, particularly when reaching between the mattress and mattress foundation. A portable bed rail that has been installed improperly could move away from the mattress and form a hazardous gap. Portable bed rail installation components, such as anchor plate and strap combinations, can be misplaced, or not used at all. The proposed performance requirement for critical installation components would increase the likelihood that such components are attached permanently to a structural component of the portable bed rail. In addition, a proposed new warning label for critical installation components would reinforce the importance of using the installation components when installing portable bed rails onto the bed and reduce the likelihood of misinstallation.

2. Proposed Changes to the ASTM Standard's Requirements

Consistent with section 104(b) of the CPSIA, the Commission, through this proposed rule, would establish a new 16 CFR part 1224, *Safety Standard for Portable Bed Rails.* The new part 1224 would incorporate by reference the requirements for portable bed rails in ASTM F 2085-10a with certain changes to specific provisions and additions to the standard. The proposed modifications and additions to the standard would reduce further the risk of injury associated with portable bed rails.

Part 1224 would consist of two sections: § 1224.1, *Scope, application, and effective date*, and § 1224.2, *Requirements for portable bed rails.*

To understand the proposed rule, it is helpful to view the current ASTM F 2085-10a standard for portable bed rails and our proposed modifications, along with the explanations provided in part E.2 of this preamble. The ASTM standard is available for viewing for this purpose during the comment period through this link: http://www.astm.org/cpsc.htm. For example, the proposed rule would create several new sections in ASTM F 2085-10a. To distinguish between the requirements that would be published in the Code of Federal Regulations, we describe those requirements as proposed § 1224.1 or proposed § 1224.2, and describe the new sections that the proposed rule would create in ASTM F 2058-10a as a "new section."

a. Scope, application, and effective date (Proposed § 1224.1)

Proposed § 1224.1 would explain that part 1224 establishes a consumer product safety standard for portable bed rails manufactured or imported on or after a specific date. The date would be the effective date of a final rule, which is normally six months after date of publication of a final rule in the Federal Register.

b. Requirements for portable bed rails (Proposed § 1224.2)

(i). Incorporation by Reference (Proposed § 1224.2(a))

Proposed § 1224.2(a) would state that each portable bed rail, as defined in ASTM F 2085-10a, must comply with all applicable provisions of ASTM F 2085-10a, except as provided in proposed § 1224.2(b). Proposed § 1224.2(a) also would incorporate ASTM F 2058-10a by reference, and inform interested parties how they can obtain a copy of the standard or inspect the standard at the CPSC or at the National Archives and Records Administration.

(ii). Foam and Inflatable Products (Proposed § 1224.2(b)(1)).

Proposed § 1224.2(b)(1) would revise the scope section in ASTM F 2058-10a to include foam and inflatable products. A "foam bed rail" is defined as a portable bed rail constructed primarily of nonrigid materials, such as fabric or foam. An "inflatable bed rail" is defined as a portable bed rail constructed primarily of nonrigid material that requires air to be inflated into the product to achieve structure. Our review of market information indicates that there are products that differ from traditional, rigid portable bed rails in that they are constructed of foam or inflatable rubber materials and meet the definition of a portable bed rail under ASTM F 2085-10a. However, most performance requirements of ASTM F 2085-10a do not apply to these products because the standard was developed to address the hazards from portable bed rails that consist of rigid (wood/metal) materials. Accordingly, the proposed rule would state that the foam and inflatable portable bed rails must meet only the General Requirements of section 5; the performance requirement of subsection 6.3, *Enclosed Openings*; and the warning statements of subsection 9.3.1 of ASTM F 2085-10a because those requirements can be applied to foam and inflatable portable bed rail products.

(iii). Terminology (Proposed § 1224.2(b)(2)).

Proposed 1224.2(b)(2) would revise the terminology in section 3 of ASTM F 2085-10a by creating new terms to be numbered as new sections 3.1.10 through 3.1.14 of ASTM F 2085-10a. The new terms would be as follows:

Foam bed rail is a portable bed rail constructed primarily of nonrigid materials, such as fabric or foam;

Inflatable bed rail is a portable bed rail constructed primarily of nonrigid material that requires air to be inflated into the product to achieve structure;

Critical assembly component is any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of sections 6.1, *Structural Integrity*, 6.3 *Enclosed Openings;* 6.4, *Openings Created by Portable Bed Rail Displacement of Adjacent Style Portable Bed Rails;* 6.5, *Openings Created by Displacement of Mattress-Top Portable Bed Rails;* and 6.6, *Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers' Beds* of ASTM F 2085-10a*;*

Critical installation component is any component of the portable bed rail that is used to attach the portable bed rail onto the bed; and

Misassembled/functional portable bed rail is a portable bed rail that has been assembled incorrectly but appears to function as a portable bed rail. Misassembly/functionality is determined by meeting one of the criteria listed in proposed section 6.9, *Determining Misassembled/Functional Portable Bed Rail,* of ASTM F 2085-10a.

The proposed rule would create these new terms because the Commission is proposing new requirements for foam and inflatable products. In addition, the Commission is proposing new requirements to address misassembly and misinstallation of portable bed rails. Accordingly, the addition of the new terms will help testing laboratories understand the new performance requirements and associated test methods to reduce entrapment hazards associated with portable bed rails.

(iv). General Requirements (Proposed § 1224.2(b)(3)).

Proposed section 1224.2(b)(3) would create a new section 5.6 of ASTM F 2085-10a, *Critical Installation Components.* This new section of ASTM F 2085-10a would provide (at a new section 5.6.1) that critical installation components that are also critical assembly components and meet the definition of a misassembled/functional portable bed rail must be permanently affixed to a structural component(s) of the portable bed rail. If a critical installation component(s) is also a critical assembly component and may result in a misassembled/functional portable bed rail, a new section 5.6.2 of ASTM F 2085-10a would require that a portable bed rail not remain upright or that the vertical height must decrease by 6 inches at any point along the top rail when tested to the method for determining the acceptability of the vertical structure of a misassembled/functional portable bed rail. (The requirement regarding a portable bed rail not remaining upright or meeting certain vertical height requirements would be at a new section 6.10.1 of ASTM F 2058-10a, which we discuss later in section v of this document.) The addition of critical installation components would reduce the likelihood of portable bed rail misassembly in that a misassembled bed rail would no longer be functional without the critical installation components.

(v). Determining Misassembled/Functional Portable Bed Rail (Proposed § 1224.2(b)(4)(i) and (ii)).

Proposed § 1224.2(b)(4)(i) would create a new section 6.9 of ASTM F 2085-10a, *Determining Misassmbled/Functional Portable Bed Rail.* It would consider a portable bed rail to be a misassembled/functional portable bed rail if:

- the portable bed rail can be assembled without any critical assembly component (new section 6.9.1 of ASTM F 2085-10a);
- the portable bed rail can be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component like the frame (new section 6.9.2 of ASTM F 2085-10a);
- the portable bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging critical parts of the frame as intended in final assembly (new section 6.9.3 of ASTM F 2058-10a), or
- the portable bed rail can be assembled by improper placement of any critical component, such as an inverted or an interchanged part, without permanent deformation or breakage (new section 6.9.4 of ASTM F 2058-10a).

To determine the acceptability of a misassembled/functional portable bed rail, proposed section 1224.2(b)(4)(ii) would set forth the requirements for a new section 6.10, *Determining Acceptability of Misassmbled/Functional Portable Bed Rail,* of ASTM F 2085-10a. The new section would provide that misassembled/functional portable bed rails must meet sections 6.10.1, 6.10.2, 6.10.3, or 6.10.4 of ASTM F 2085-10a. Under the proposed rule, a new section 6.10.1 of ASTM F 2085-10a would provide that the portable bed rail must not remain upright or the vertical height must decrease by 6 inches

at any point along the top rail when tested to new section 8.7 (*Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail*) of ASTM F 2085-10a. This section would provide criteria to determine whether a misassembled portable bed rail lacks sufficient vertical structure.

A new section 6.10.2 of ASTM F 2085-10a would provide that the fabric cover or mesh attached to the bed rail must have a permanent sag that is a minimum of 3 inches after tested in accordance with new section 8.8 (*Test Method for Determining Fabric Sag Acceptability of a Misassembled/Functional Portable Bed Rail*) of ASTM F 2085-10a. A new section 6.10.3 of ASTM F 2058-10a would provide that a product will not be considered acceptable if the fabric cover will not fit over the frame without tearing. A new section 6.10.4 of ASTM F 2058-10a would provide that mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a ½ inch protrusion out of the plane of the rail**.** These new sections would provide the criteria for testing laboratories to determine the sufficiency of visual cues for fabric mesh misassembly.

(vi). Test Equipment (Proposed § 1224.2(b)(5)(i)).

Proposed section 1224.2(b)(5)(i) would state that a force gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ± 0.25 lb (1.11N), as set forth under a new section 7.6 of ASTM F 2085-10a. The addition of this section will help clarify the manner in which the force will be applied under the proposed test methods discussed in section (vii) below.

(vii). Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail. (Proposed §§ 1224.2(b)(6)(i) and (ii)).

Proposed §§ 1224.2(b)(6)(i) and (ii) would require new test methods to address misassembly of portable bed rails. These proposed requirements would include a test method for determining the acceptability of the vertical structure of a misassembled/functional portable bed rail under a new section 8.7 of ASTM F 2085-10a, as well as a test method for determining fabric sag acceptability of a misassembled/functional portable bed rail under a new section 8.8 of ASTM F 2085-10a. These tests would provide a method for testing laboratories to determine if a misassembled portable bed rail lacks sufficient vertical structure and also determine the sufficiency of visual cues for portable bed misassembly.

Under a new section 8.7 of ASTM F 2058-10a, the proposed test method for determining acceptability of vertical structure of a misassembled/functional bed would require, if possible, an attempt to assemble the portable bed rail in a misassembled configuration(s), as described in new section 6.9 of ASTM F 2085-10a. The proposed test method also would include:

- Firmly securing the misassembled portable bed rail on a table top or other stationary flat surface using clamps (new section 8.7.2 of ASTM F 2058-10a). The clamps should be located 4 to 6 inches from the intersection of the portable bed rail legs to the vertical plane.
- Gradually applying a force of 10 lbs, using a ½ inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component most likely to vertically deform the portable bed rail; and applying the force over a period of 5 seconds, and holding the force for 10 seconds and releasing (new section 8.7.3 of ASTM F 2058-10a); and

- Repeating the steps in new sections 8.7.1 through 8.7.3 for all misassembly configurations (new section 8.7.4 of ASTM F 2058-10a).

The proposed test method for determining fabric sag acceptability of a misassembled/functional portable bed rail (at a new section 8.8 of ASTM F 2058-10a) would require, if possible, an attempt to assemble the portable bed rail in a misassembled configuration(s), as described in new section 6.9 of ASTM F 2085-10a. The proposed test method would include:

- gradually applying a force of 1 lb using a ½ inch disc on the fabric/mesh in any direction or location along the fabric/mesh that is most likely to cause it to come off of the frame; applying the force over a period of 5 seconds; and holding for an additional 10 seconds and releasing (new section 8.8.2 of ASTM F 2058-10a); and
- repeating these steps for all misassembly configurations discovered in new section 6.9 of ASTM F 2085-10a (new section 8.8.3 of ASTM F 2058-10a).

(viii). Marking and Labeling. (Proposed § 1224.2(b)(7), (8), and (9).

Proposed section 1224.2(b)(7) would add a warning symbol "  " and the word "WARNING" prior to "Suffocation and Strangulation Hazard" under section 9.3.1.1 of ASTM F 2085-10a. This proposed addition would give the warning more emphasis.

Proposed section 1224.2(b)(8) would replace the existing marking under section 9.3.1.3 of ASTM F 2085-10a, which states: "Infants who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place infants in adult beds with or without a portable bed rail." The proposed warning would state instead: "Children who cannot get in and out of an adult bed without help can

be trapped between a mattress and a wall and suffocate. NEVER place children younger than 2 years old in adult beds with or without a portable bed rail." Despite the current warning label cautioning against the use of this product with children under 2 years old, parents of infants continue to use this product with their infants. Accordingly, the revised language would emphasize the hazard presented to children younger than 2 years old when placed in adult beds.

Proposed section 1224.2(b)(9) would require critical installation components to be labeled with the entrapment hazard warning for portable bed rail use to warn of issues related to misinstallation of portable bed rails under a new section 9.4 of ASTM F 2085-10a. A new section 9.4 of ASTM F 2058-10a would require the entrapment hazard warning to be in contrasting colors, permanent, conspicuous, and sans serif-style font. The proposed warning would require in the entrapment hazard warning statement the safety alert symbol "  "and the words "WARNING - ENTRAPMENT HAZARD" to be not less than 0.20 in. (5 mm) high. The remainder of the text would consist of characters whose upper case must be at least 0.10 in. (2.5 mm) high. The warning would state: "NEVER use a portable bed rail without installing this part onto bed. Incorrect installation can allow the portable bed rail to move away from mattress, which can lead to entrapment and death." Components such as a locking clamp on a mattress-top portable bed rail or an anchor plate/strap are critical installation components. If these components are not installed properly, the portable bed rail will not be secure and may move away from the mattress and can result in an entrapment hazard. The warning requirement would emphasize the importance of proper installation of key components.

(ix). Instructional Literature (Proposed § 1224.2(b)(10)). This proposed section would revise the language in section 11.1 of ASTM F 2058-10a to add the word "installation" among the topics in instructional literature. This proposed section would read: "Instructions must be provided with the portable bed rail and must be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, must be included." This requirement would add clear instructional literature for installation components to provide consumers easy to understand information for securing portable bed rails on beds.

F. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for portable bed rails. We invite all interested persons to submit comments on any aspect of the proposed rule. Comments should be submitted in accordance with the instructions in the ADDRESSES section at the beginning of this notice.

G. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). To allow time for manufacturers of portable bed rails to bring their products into compliance with the new requirements, the Commission intends that the standard would become effective six months after publication of a final rule. The Commission seeks comment on how long it would take manufacturers of portable bed rails to come into compliance with the rule.

H. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed rules on small entities, including small businesses. Section 603 of the RFA requires that we prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

1. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

2. A description of the reasons why action by the agency is being considered;

3. A succinct statement of the objectives of, and legal basis for, the proposed rule;

4. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and

5. An identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule that would accomplish the stated objectives of the proposed rule and at the same time reduce the economic impact on small entities.

2. The Market

Typically, portable bed rails are produced and/or marketed by juvenile product manufacturers and distributors or by furniture manufacturers and distributors. Currently, there are at least 14 known manufacturers or importers supplying portable bed rails to the U.S. market. Ten are domestic manufacturers (71 percent) and three are domestic importers (21 percent). The remaining firm has an unknown supply source, and there is no publicly available information regarding its size.

Under the U.S. Small Business Administration ("SBA") guidelines, a manufacturer of portable bed rails is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, nine of the domestic manufacturers and all of the domestic importers known to be supplying the U.S. market are small. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

The Juvenile Product Manufacturers Association ("JPMA") runs a voluntary certification program for several juvenile products. Five manufacturers supply portable bed rails to the U.S. market that are compliant with the ASTM standard. Among them, four are JPMA-certified as being compliant with the current ASTM voluntary standard, and one claims compliance with the ASTM standard. Of the importers, one is JPMA-certified, and one claims compliance. JPMA estimates that current annual sales of portable bed rails are approximately 750,000 units, and retail sales are approximately $20 million. This estimate is similar to a 2003 sales estimate provided by JPMA. No information is available about the average product life of portable bed rails; if, for example, portable bed rail sales are assumed to have remained constant and portable bed

rails remain in use for three to five years, there might be 2.25 million to 3.75 million portable bed rails in use. National estimates of portable bed rail product injuries are not available because National Electronic Injury Surveillance System ("NEISS") data does not allow for clear identification of portable bed rail incidents. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

3. Impact of the Proposal on Small Business

Out of the 14 firms currently known to be producing or selling portable bed rails in the United States, one is a large domestic manufacturer, nine are small domestic manufacturers, and three are small domestic importers; and there is insufficient information regarding the size or supply source of the remaining firm. The impact on the 12 small domestic firms could be significant. However, the impact of the proposed standard on small manufacturers could differ, based on whether their products are compliant with the voluntary ASTM F 2085-10a. Of the nine small domestic manufacturers, five produce portable bed rails that are certified as compliant by JPMA or claim to be in compliance with the voluntary standard. The four noncompliant manufacturers may require substantial modifications to meet both the ASTM standard and the proposed requirements. The costs associated with these modifications could include product design, development and marketing staff time, product testing, and focus group expenses. There may be increased costs of production as well, particularly if additional materials are required. The actual cost of such an effort is unknown but could be significant for some firms. However, the impact of these costs may be mitigated if they are treated as new product expenses and amortized.

The impact of the proposed standard on the five compliant firms may be less significant because they already comply with the voluntary standard. However, even ASTM-compliant portable bed rails currently on the market will require modifications to meet the proposed changes. Any product redesign would entail costs similar to those outlined for non-ASTM compliant firms. Some ASTM-compliant firms may opt to preassemble the critical assembly components rather than redesign their product. Preassembled products may require larger shipping boxes, and there may be higher shipping costs associated with shipping larger boxes. To the extent that retailers charge high stocking and inventory fees, firms may face additional costs. Manufacturers may be able to offset these fees if they are able to pass on some of the expense to consumers.

While preassembly may reduce product redesign costs, meeting a requirement that critical installation components be affixed permanently may also require some product redesign. There will be some costs associated with redesign. In addition, all manufacturers will need to modify existing warning labels. A new warning label poses a small burden because it represents a minor modification. Costs associated with the new warning label would be low because no new materials are used. At least one small manufacturer's product line consists entirely or primarily of nonrigid portable bed rails. This firm may need to alter the warning label but otherwise is not likely to be affected significantly by the proposed standard.

Of the three small domestic importers, two import portable bed rails that are certified compliant by JPMA or claim to be in compliance with the voluntary standard. All of these small importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the new requirements of the

proposed standard. The cost to importers may increase, and, in turn, they may pass on some of those increased costs to consumers. Some importers may respond to the rule by discontinuing the import of their portable bed rails. However, the impact of such a decision may be lessened by replacing the noncompliant portable bed rail with a complying product or another juvenile product. Deciding to import an alternative product would be a reasonable and realistic way for most importers to offset any lost revenue, given that most import a variety of products. However, for small importers whose product lines rely largely on portable bed rails, substituting another product may not be realistic. The impact on these small importers likely would be more significant.

4. Alternatives Regarding Impact on Small Business

If the current voluntary standard is adopted without any modifications, the impact on small businesses potentially could be reduced in terms of costs for manufacturers and importers because redesign would not be required. Small manufacturers and importers who are compliant with the voluntary standard would have a reduced burden. However, firms that are not in compliance with the ASTM standard may still need to make substantial product changes to meet ASTM F 2085- 10a. A second alternative to reduce the impact on small businesses would be to set an effective date later than six months. This would allow suppliers additional time to modify or develop compliant portable bed rails and spread the associated costs over a longer period of time.

5. Conclusion of the Initial Regulatory Flexibility Analysis

It is possible that the proposed standard, if finalized, could have a significant impact on some small firms. The extent of these costs is unknown, but because product redevelopment would likely be necessary, it is possible that the costs could be large for

some firms. Additionally, all manufacturers eventually will be subject to third party testing and certification requirements, as discussed in section L below. There will likely be some additional costs associated with third party testing and certification.

However, at least some costs are expected to be passed on to consumers without a reduction in the firms' ability to compete because of the special features associated with these products. We invite comment on what these costs may be, whether they may be passed on to the consumer, and how these costs will impact small businesses. We also seek information on the effect on retailers (*e.g.*, the impact of increased package size on the number of units kept in stock).

I. Environmental Considerations

The Commission's environmental review regulation at 16 CFR part 1021 has established categories of actions that normally have little or no potential to affect the human environment and therefore do not require either an environmental assessment or an environmental impact statement. The proposed rule is within the scope of the Commission's regulation, at 16 CFR 1021.5(c)(1), which provides a categorical exclusion for rules that provide design or performance requirements for products. Thus, no environmental assessment or environmental impact statement for this rule is required.

J. Paperwork Reduction Act

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget ("OMB") under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes the time for reviewing instructions, searching existing data

sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

We particularly invite comments on: (1) whether the collection of information is necessary for the proper performance of the CPSC's functions, including whether the information will have practical utility; (2) the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to reduce the burden of the collection of information on respondents, including the use of automated collection techniques, when appropriate, and other forms of information technology; and (5) estimated burden hours associated with label modification, including any alternative estimates.

Title: Safety Standard for Portable Bed Rails

Description: The proposed rule would require each portable bed rail to comply with ASTM F 2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*. Sections 9, 10, and 11 of ASTM F 2058-10a contain requirements for marking and instructional literature.

Description of Respondents: Persons who manufacture or import portable bed rails.

We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1224.2(a)	7	2	14	1	14

There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following:

Proposed § 1224.2(a) would require each portable bed rail to comply with ASTM F 2085-10a. Sections 9 and 11 of ASTM F 2085-10a contain requirements for marking, labeling, and instructional literature that are disclosure requirements, thus falling within the definition of "collections of information" at 5 CFR 1320.3(c).

Section 9.1.1 of ASTM F 2085-10a requires that the name and the place of business (city, state, mailing address, including zip code, or telephone number) of the manufacturer, importer, distributor, or seller be clearly and legibly marked on each product and its retail package. Section 9.1.2 of ASTM F 2085-10a requires a code mark or other means that identifies the date (month and year as a minimum) of manufacture.

There are 14 known firms supplying portable bed rails to the U.S. market. Seven of the 14 firms are known to produce labels that comply with these sections of the standard, so there would be no additional burden on these firms. The remaining seven firms are assumed to use labels on their products and their packaging but would need to make some modifications to their existing labels. The estimated time required to make these modification is about 1 hour per model. Each firm supplies an average of two different models of portable bed rails; therefore, the estimated burden hours associated with labels is 1 hour x 7 firms x 2 models per firm = 14 annual hours.

We estimate that the hourly compensation for the time required to create and update labels is $28.00 (Bureau of Labor Statistics, September 2010, all workers, goods-producing industries, sales, and office, Table 9). Therefore, the estimated annual cost to industry

associated with the Commission-recommended labeling requirements is $392 ($28.00 per hour x 14 hours = $392).

Section 11.1 of ASTM F 2085-10a requires instructions to be supplied with the product. Portable bed rails are products that generally require assembly, and products sold without such information would not be able to compete successfully with products supplying this information. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because the CPSC is unaware of portable bed rails that: (a) generally require some installation, but (b) lack any instructions to the user about such installation, we estimate tentatively that there are no burden hours associated with the instructions requirement in section 11.1 of ASTM F 2085-10a because any burden associated with supplying instructions with portable bed rails would be "usual and customary" and not within the definition of "burden" under the OMB's regulations. Based on this analysis, the proposed standard for portable bed rails would impose a burden to industry of 14 hours at a cost of $392 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by [**insert date 30 days after date of publication in the FEDERAL REGISTER**], to the Office of Information and Regulatory Affairs, OMB (see ADDRESSES).

K. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a "consumer product safety standard under [the CPSA]" is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as "consumer product safety rules," thus implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

L. Certification

Section 14(a) of the Consumer Product Safety Act ("CPSA") imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard, or regulation under any other act enforced by the Commission, be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Such certification must be based on a test of each product or on a reasonable testing program or, for children's products, on tests on a sufficient number of samples by a third party conformity assessment body accredited by the Commission to test according to the applicable requirements. As discussed in part K of this preamble, section 104(b)(1)(B) of the CPSIA refers to standards issued under that section, such as the rule for portable bed rails proposed in this notice, as "consumer product safety

standards." Furthermore, the designation as "consumer product safety standards" subjects such standards to certain sections of the CPSA, such as section 26(a) of the CPSA, regarding preemption. By the same reasoning, such standards also would be subject to section 14 of the CPSA, regarding testing and certification. Therefore, any such standard would be considered a consumer product safety rule to which products subject to the rule must be certified.

Because portable bed rails are children's products, certifications of compliance must be based on testing conducted by a CPSC-approved third party conformity assessment body. In the future, we will issue a notice of requirements to explain how laboratories can become accredited as third party conformity assessment bodies to test to the new safety standard. We seek comment on the testing requirements of this standard, particularly comment on whether any further specificity is required for the testing procedures and equipment and comment on whether the testing requirements are reliable, replicable, and sufficiently specific to allow laboratories to set pass/fail criteria for compliance determinations.

Portable bed rails also must comply with all other applicable CPSC requirements, such as the lead content and phthalate content requirements in sections 101 and 108 of the CPSIA; the tracking label requirement in section 14(a)(5) of the CPSA; and the consumer registration form requirements in section 104 of the CPSIA.

List of Subjects in 16 CFR Part 1224

Consumer protection, Imports, Incorporation by reference, Infants and Children, Labeling, and Law enforcement

Therefore, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding a new part to read as follows:

PART 1224—SAFETY STANDARD FOR PORTABLE BED RAILS

Sec.

Authority: Sections 3 and 104 of Pub. L. 110-314, 122 Stat. 3016 (August 14, 2008).

§ 1224.1 Scope, application, and effective date.

This part 1224 establishes a consumer product safety standard for portable bed rails manufactured or imported on or after [**insert date 6 months after date of publication in the FEDERAL REGISTER**].

(a) Except as provided in paragraph (b) of this section, each portable bed rail as defined in ASTM F 2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*, approved October 1, 2010, must comply with all applicable provisions of ASTM F 2085-10a. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of this ASTM standard from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959 USA, phone: 610-832-9585; http://www.astm.org/. You may inspect copies at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For

information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal regulations/ibr_locations.html.

(b) Comply with the ASTM F 2085-10a standard with the following additions:

(1) In addition to complying with section 1.4 of ASTM F 2085-10a, comply with the following:

(i) 1.4.1 *Foam and inflatable bed rails* need meet only the General Requirements of section 5, the performance requirement of 6.3 *Enclosed Openings*, and the warning requirement of section 9.3.1.

(ii) [Reserved]

(2) In addition to complying with section 3.1.9.1 of ASTM F 2085-10a, comply with the following:

(i) 3.1.10 *foam bed rail, n* – portable bed rail constructed primarily of nonrigid materials such as fabric or foam.

(ii) 3.1.11 *inflatable bed rail, n* – a portable bed rail constructed primarily of nonrigid material that requires air be inflated into the product to achieve structure.

(iii) 3.1.12 *critical assembly component, n* – any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of 6.1 *Structural Integrity*, 6.3 *Enclosed Openings,* 6.4 *Openings Created by Portable Bed Rail Displacement of Adjacent Style Portable Bed Rails,* 6.5 *Openings Created by Displacement of Mattress-Top Portable Bed Rails and* 6.6 *Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers' Beds*.

(iv) 3.1.13 *critical installation component, n* - any component of the portable bed rail that is used to attach the portable bed rail onto the bed.

(v) 3.1.14 *misassembled/Functional portable bed rail, n-* a portable bed rail that has been assembled incorrectly but appears to function as a portable bed rail. Misassembly/functionality is determined by meeting one of the criteria listed in 6.9.

(3) In addition to complying with section 5.5 of ASTM F F 2085-10a, comply with the following:

(i) 5.6 *Critical Installation Components* that are also *critical assembly* components and that meet the definition of a misassembled/functional portable bed rail must meet 5.6.1 or 5.6.2.

(A) 5.6.1 Critical installation components must be permanently affixed to a structural component(s) of the portable bed rail.

(B) 5.6.2 If a critical installation component(s) is also a critical assembly component and may result in a misassembled/functional portable bed rail, the portable bed rail must meet 6.10.1.

(4) In addition to complying with section 6.8 of ASTM F 2085-10a, comply with the following:

(i) 6.9 *Determining Misassembled/* - a portable bed rail must be considered a misassembled/functional portable bed rail if it meets one of the criteria in 6.9.1, 6.9.2, 6.9.3, or 6.9.4.

(A) 6.9.1 The portable bed rail can be assembled without any critical assembly component.

(B) 6.9.2 The portable bed rail can be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component such as the frame.

(C) 6.9.3 The portable bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging parts of the frame as intended in final assembly.

(D) 6.9.4 The portable bed rail can be assembled by improper placement of any critical assembly component, such as an inverted or an interchanged part, without permanent deformation or breakage.

(ii) 6.10 *Determining Acceptability of Misassembled/Functional Portable Bed Rail- Misassembled/Functional Portable Bed Rails* must meet 6.10.1, 6.10.2, 6.10.3 or 6.10.4.

(A) 6.10.1 The portable bed rail must not remain upright or the vertical height must decrease by 6 inches at any point along the top rail when tested to 8.7.

(B) 6.10.2 The fabric cover or mesh must have a permanent sag a minimum of 3 inches after tested in accordance with 8.8.

(C) 6.10.3 The fabric cover will not fit over the frame without tearing.

(D) 6.10.4 Mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a ½ inch protrusion out of the plane of the rail**.**

(5) In addition to complying with section 7.5 of ASTM F F 2085-10a, comply with the following:

(i) 7.6 *Force Gauge* – gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ± 0.25 lb (1.11N).

(ii) [Reserved]

(6) In addition to complying with section 8.6 of ASTM F 2085-10a, comply with the following:

(i) 8.7 *Test Method for Determining Acceptability of Vertical Structure of a Misassembled/Functional Portable Bed Rail:*

(A) 8.7.1 If possible, attempt to assemble the portable bed rail in a misassembled configuration(s) as defined in 6.9 *Determining Misassembled/Functional Portable Red Rail*

(B) 8.7.2 Firmly secure the misassembled portable bed rail on a table top or other stationary flat surface using clamps. The clamps should be located 4 to 6 inches from the intersection of the portable bed rail legs to the vertical plane (see figure 8).

(C) 8.7.3 Gradually apply a force of 10 lb using a ½ inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component most likely to vertically deform the portable bed rail (see figure 8). Apply the force over a period of 5 seconds, hold the force for 10 seconds, and release.

(D) 8.7.4 Repeat 8.7.1 through 8.7.3 for all misassembly configurations discovered in 6.9.

(ii) 8.8 *Test Method for Determining Fabric Sag Acceptability of a Misassembled/Functional Portable Bed Rail:*

(A) 8.8.1 If possible, attempt to assemble the portable bed rail in a misassembled configuration(s) as defined in 6.9 *Determining Misassembled/Functional Portable Bed Rail.*

(B) 8.8.2 Gradually apply a force of 1 lb using a ½ inch disc on the fabric/mesh in any direction or location along the fabric/mesh that is most likely to cause it to come off of the frame (see figure 8). Apply the force over a period of 5 seconds, hold for an additional 10 seconds, and release.

(C) 8.8.3 Repeat 8.8.1through 8.8.2 for all misassembly configurations discovered in 6.9.

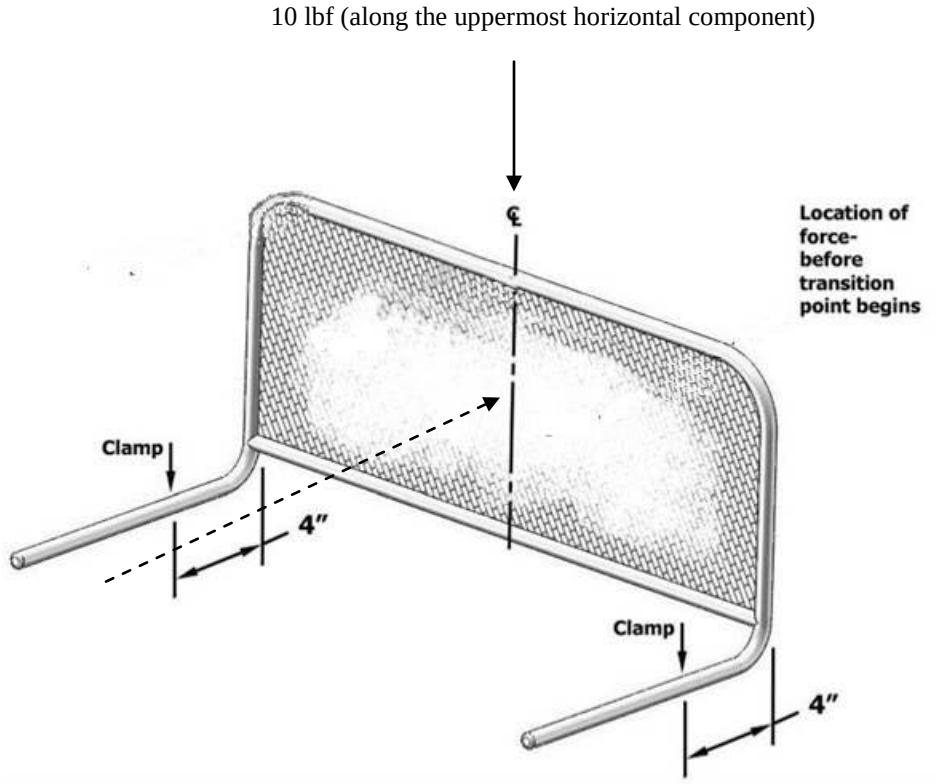

Figure 8: Determining misassembly/functional portable bed rail test setup

(7) Instead of complying with sections 9.3.1.1 of ASTM F 2085-10a comply with the following:

(i) 9.3.1.1 **WARNING**: Suffocation and Strangulation Hazard.

(ii) [Reserved]

(8) Instead of complying with sections 9.3.1.3.of ASTM F 2085-10a, comply with the following:

(i) 9.3.1.3 Children who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place children younger than 2 years old in adult beds with or without a portable bed rail.

(ii) [Reserved]

(9) In addition to complying with section 9.3.2.5 of ASTM F 2085-10a, comply with the following:

(i) 9.4 Critical installation components must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning must be in contrasting colors, permanent, conspicuous, and sans serif-style font. In the entrapment hazard warning statement the safety alert symbol "⚠" and the words "WARNING - ENTRAPMENT HAZARD" must not be less than 0.20 in. (5 mm) high. The remainder of the text must be characters whose upper case must be at least 0.10 in. (2.5 mm) high.

(A) 9.4.1. The warning must including the following, exactly as stated below:

⚠ WARNING - ENTRAPMENT HAZARD

NEVER use a portable bed rail without installing this part onto bed.
Incorrect installation can allow the portable bed rail to move away from mattress, which can lead to entrapment and death.

(B) [Reserved]

(ii) [Reserved]

(10) Instead of complying with sections 11.1 of ASTM F 2085-10a, comply with the following:

(i) 11.1 Instructions must be provided with the portable bed rail and must be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, must be included.

(ii) [Reserved]

Dated:_____

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Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission

Staff Briefing Package

Draft Proposed Rule for Portable Bed Rails
(CPSIA Section 104)
3/16/2011

CPSC Hotline: 1-800-638-CPSC (2772) CPSC's Web Site: http://www.cpsc.gov

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Briefing Memo

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

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Memorandum

March 16, 2011

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: Robert J. Howell, Assistant Executive Director
Office of Hazard Identification and Reduction
Rohit Khanna, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Draft Proposed Standard for Portable Bed Rails

I. INTRODUCTION

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to study and develop safety standards for certain infant and toddler products. The Commission is charged with examining and assessing the effectiveness of relevant voluntary consumer product safety standards and for promulgating mandatory safety standards for these products by either making the existing voluntary safety standards for these products mandatory or developing stricter safety standards. Portable bed rails intended to prevent children from falling out of adult beds are considered to be under the purview of Section 104.

Section 104 of the CPSIA also requires the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the voluntary standards. For portable bed rails, this consultation process commenced in August 2010, during the ASTM International (formerly known as the American Society for Testing and Materials) subcommittee meeting regarding the ASTM portable bed rail voluntary standard, in which CPSC staff participated.

This briefing package assesses the effectiveness of the voluntary standard and presents the staff's draft proposed rule to address potential hazards associated with portable bed rails.

II. BACKGROUND

A. Voluntary and International Standards Overview

A portable bed rail is defined in the ASTM voluntary standard as a device intended to be installed on an adult bed to prevent children from falling out of bed. Bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2 to 5 years of age).

In October 2000, the Commission published an advance notice of proposed rulemaking (ANPR) to address hazards associated with portable bed rails. The most common hazard pattern involving child fatalities was entrapment, which can occur when the bed rail moves outward (away from the mattress) and the child rolls into the gap between the mattress and bed rail. Once entrapped, the child can asphyxiate.

ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails,* is the voluntary standard that was developed to address the identified hazard patterns associated with the use of portable bed rails. The ASTM standard was first published in May 2001. The initial standard included requirements for labeling but had no performance requirements to prevent entrapment hazards.

In October 2001, the Commission voted to direct staff to prepare a notice of proposed rulemaking (NPR) based on staff's draft proposed standard, which included performance requirements to address entrapment hazards. Subsequently, the ASTM Portable Bed Rail Subcommittee agreed to ballot a revision of ASTM F 2085 that was substantially the same as staff's draft proposed standard; accordingly, the NPR was postponed. The revised standard was approved and published in June 2003. In 2008, ASTM published another revision of the standard that included a structural integrity test to address incidents involving hinge lock mechanism failures. From 2009 to 2010, minor revisions of the standard were published. The current edition of the standard is ASTM F 2085-10a (ASTM F 2085).

The ASTM standard contains the following general and performance requirements (the numbers in the parentheses refer to the section of the standard):

- Hazardous Sharp Edges or Points (5.1),
- Small Parts (5.2),
- Exposed Wood Parts Smooth and Free of Splinters (5.3),
- Lead in Paints (5.4),
- Permanency of Warning Labels (5.5),
- Structural Integrity (6.1),
- Openings (6.2),
- Enclosed Openings (6.3),
- Openings Created by Bed Rail Displacement of Adjacent Style Portable Bed Rails (6.4),
- Openings Created by Displacement of Mattress-Top Portable Bed Rails (6.5),
- Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers' Beds (6.6),

- Protrusions (6.7), and
- Openings Between Bedposts (*e.g*., Headboard, Footboards) and Ends of Portable Bed Rail (6.8).

CPSC staff also assessed the British Standard Institution (BSI) standard for bed rails, BS 7972:2001 +A1:2009, *Safety Requirements and Test Methods for Children's Bedguards for Domestic Use*. The BSI standard primarily addresses entrapment and structural integrity, but includes some requirements for warning labels. Staff noted that the BSI standard contains a performance requirement that the bed rail remain attached to the bed after rolling a 30 lb cylinder into the bed rail. The test appears to be a simulation of a child rolling into the bed rail; the ASTM standard does not have an equivalent requirement. CPSC staff conducted limited testing to compare this requirement with requirements in the ASTM standard that address potential entrapment hazards. Staff concluded that the ASTM standard is more stringent than the BSI standard in that its test methods provide more stress to the bed rail and mattress interface, which is important when evaluating the potential for entrapment.

Staff is not aware of any other standards for portable bed rails for children.

B. ***Certification that Products Meet Voluntary Standard***

The Juvenile Products Manufacturers Association (JPMA) has a certification program for a variety of juvenile products, including portable bed rails. To obtain JPMA certification, manufacturers submit their products to an independent test laboratory for conformance testing to the most current ASTM voluntary standard. Currently, there are four manufacturers whose products are certified by JPMA to be compliant with ASTM F 2085; and a fifth manufacturer claims that its bed rails meet the requirements of the ASTM standard.

III. DISCUSSION

A. Incident Data (Tab A)

CPSC staff from the Directorate for Epidemiology, Division of Hazard Analysis, analyzed incident and death data related to portable bed rails from January 1, 2000, through March 31, 2010. Staff is aware of 13 fatalities and 119 nonfatal incidents (with and without injuries) related to portable bed rails. All 13 fatal incidents reported entrapment of the child between the bed rail and mattress.

In-Depth Investigations (IDIs) were conducted for 8 of the 13 fatal incidents and provided additional product- and scenario-specific information about these incidents:

- Two of the deaths resulted from bed rail displacement, where the bed rail pushed away from the mattress, and the child rolled into the gap between the bed rail and the mattress, resulting in an entrapment.

- Three of the deaths resulted from misassembly of the bed rail.

- In the first incident, the bed rail's middle bar[1] was not present, which created a hazardous gap when the child rolled against the bed rail's mesh/cover.
- In the second incident, the bed rail's middle bar was not inserted through the mesh sleeve, which resulted in the child's head slipping between the bottom edge of the mesh panel and the top edge of the mattress.
- In the third incident, the bed rail's bottom horizontal bar was not attached to the vertical bar, resulting in a hazardous gap.

- In the remaining three fatalities, not enough information was available to determine the contributing factor(s) that caused the hazardous entrapment scenario:

  - In the first incident, the bed rail was not flush against the mattress, for unknown reasons. A pillow was used to cover the gap between the bed rail and the mattress. The child was found entrapped between the bed rail and mattress, with her face on the pillow that was used to cover the gap.
  - In the second incident, the consumer was aware of a gap between the bed rail and the mattress and used a blanket to cover the gap.
  - In the third incident, a female child with extreme cerebral palsy was found on her back lying across the head of the bed with her neck twisted and her head wedged between the bed rail's mesh railing and the mattress.

It is notable that 11 of the 13 reported fatalities involved victims under the manufacturer-recommended age of 24 months. The other two victims were physically handicapped 6-year-olds, one with Rett syndrome (a neurological and developmental disorder) and the other with cerebral palsy.

Forty of the 119 nonfatal incidents (34 percent) involved an injury to a child. The majority of the injuries were fractures/contusions—resulting from a fall when the bed rail moved outward (away from the mattress)—or lacerations/scratches from sharp or broken surfaces of the bed rail.

Listed below are classifications of the hazard patterns identified among the 132 total fatal and nonfatal incident reports:

- **Bed rail displacement:** Sixty-nine incidents (52 percent) involved displacement of the bed rail, where the bed rail moved outward from underneath the mattress, and resulted in an opening between the mattress and bed rail. In cases where the opening was small, the child was entrapped. In cases where the opening was wide, or where the bed rail was dislodged completely, the child fell to the floor. Bed rail displacement resulted in two fatalities and 21 nonfatal injuries.

- **Worn or poor quality fabric and mesh panel:** Seventeen incidents (13 percent) involved problems with the bed rail's mesh cover resulting from tearing, unraveling of the stitching, or loose fabric. Most of the nonfatal incidents associated with this hazard pattern involved a

[1] The bed rail is made with three horizontal bars, and the assembly is covered with a mesh fabric cover. In this incident, the middle bar was missing, which resulted in formation of a hazardous gap.

child's tooth, limb, or head getting caught in the tear or opening in the mesh panel. In cases where there was loose mesh stitching, it became tightly wound around the child's neck or finger. When the mesh came loose completely, the child fell to the floor.

- **Sharp surface:** Fourteen incidents (11 percent) involved lacerations or the potential for lacerations on sharp surfaces of the bed rail. Some of these incidents involved sharp surfaces to begin with, or incidents that arose when sharp surfaces were created by parts of the bed rail that broke away during use.

- **Hinge lock disengagement:** Eleven incidents (8 percent) involved the bed rail's hinge lock mechanism failing to remain in the locked position, causing the side panel to collapse, and resulting in the child falling to the floor. Three injuries resulted from this scenario.

- **Misassembly:** Seven incidents (5 percent) reportedly were due to misassembly or misinstallation of the bed rail. It is important to note that three fatalities resulted from misassembly.

- **Miscellaneous other or unknown issues:** There were 14 incidents (11 percent) involving a range of additional problems. Six reports, including five fatalities, did not provide any information on the cause of the incident. Three additional fatality reports did not provide sufficient information to determine the cause of the entrapment hazard. The remaining five nonfatal incidents involved potential choking on small parts; instability resulting from loose hardware; bed rail openings that were too large; and insufficient bed rail height.

B. Analysis of Portable Bed Rail-Related Deaths and Injuries (Tab B)

For the eight fatal incidents associated with portable bed rails for which IDIs were completed, CPSC staff identified two major contributing factors: (1) improper installation and (2) misassembly. It is also notable that 11 of the 13 deaths involved children under 2 years old. Bed rails, which are meant to be installed on an adult bed, are not intended for this age group. Adult beds are not a safe sleeping environment for very young children. Placing babies to sleep in adult beds puts them at risk for hazards such as: (1) suffocation; (2) strangulation; (3) entrapment in the bed frame, headboard, footboard, bed railings, or adjacent furniture; and (4) possible overlay from bed sharing. Placing a railing on the side of an adult bed does not make the adult bed safe for infants (*i.e.*, convert an adult bed into a crib). Despite the current warning label cautioning against the use of this product with children under 2 years of age, parents of infants continue to use this product with their infants.

C. Assessment of the Current Voluntary Standard, ASTM F 2085 (Tab C)

CPSC staff conducted an assessment of the current voluntary standard by reviewing the incident data for the performance requirements and conducting testing and evaluation of current products in the market. Based on staff's review, the requirements in the voluntary standard are not adequate to address some of the known hazards associated with portable bed rails. Therefore, staff recommends four changes to ASTM F 2085 in its draft proposed rule. These changes have been discussed and developed in collaboration with the ASTM task group, and a ballot to include these changes was sent for subcommittee approval on February 24, 2011.

1. Scope–Addition of Foam and Inflatable Products

Staff's review of market information showed that there are products that differ from traditional, rigid, portable bed rails in that they are constructed of foam or inflatable rubber materials. Although these foam and inflatable products did not use the term "bed rail" in their packaging or labeling, staff maintains that these products meet the definition of a portable bed rail and should be included in the scope of the voluntary standard. Therefore, staff recommends that the scope section of the voluntary standard be revised to include foam and inflatable products.

Because ASTM F 2085 was developed to address the hazards associated with bed rails made of rigid (wood/metal) materials, most of the performance requirements of the standard do not apply to foam and inflatable products. Staff recommends that the foam and inflatable bed rails be required to meet only the General Requirements of section 5; the performance requirement of subsection 6.3, Enclosed Openings; and the warning requirement of subsection 9.3.1 of section 9, Marking and Labeling.

2. Misassembly

Most bed rails currently in the market are difficult for consumers to assemble correctly, due to the number of components and the complexity of the fastening hardware. There were three fatal incidents involving misassembled bed rails; and based on staff's testing of sample bed rails, staff asserts that consumers are likely to have difficulty assembling and installing portable bed rails correctly. Staff recommends new performance requirements and associated test methods to address misassembly of portable bed rails. These new performance requirements should reduce the likelihood of portable bed rail misassembly because a misassembled bed rail should no longer be functional, or it should be obvious to the consumer that the product is misassembled.

The aim of the misassembly performance requirements is to prevent bed rail entrapment fatalities that result from assembly of a product without critical assembly components[2]; incorrectly installing the bed rail's fabric cover/mesh (if present); or inverting/interchanging parts of the bed rail. The addition of misassembly performance requirements will lead to bed rail designs in which the bed rail will no longer be functional if it is not assembled according to the manufacturer-intended final assembly. While current bed rail designs do not meet staff's proposed misassembly requirements, staff has established the technical feasibility of this

[2] A critical assembly component refers to any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of the staff-recommended proposed standard.

requirement by developing two prototypes using common bed rails designs (adjacent style and mattress top) that meet staff's proposed requirements.

3. Misinstallation

Staff recommends a new performance requirement and associated warning label for portable bed rail critical installation components.[3] Although staff is not aware of any deaths associated with bed rail misinstallation, review and testing of market samples indicate that some consumers are likely to have difficulty installing portable bed rails, which could lead to potentially hazardous conditions. Installation of a bed rail onto a bed can require complex or physically demanding adjustments to the bed rail, particularly when reaching between the mattress and mattress foundation. A bedrail that has been installed improperly potentially could move away from the mattress and form a hazardous gap.

Bed rail installation components, such as anchor plate and strap combinations can be misplaced or not used at all. Staff's performance requirement for critical installation components will ensure that they are permanently attached to a structural component of the bed rail. Also, staff recommends the addition of a new warning label for critical installation components as stated below:

⚠WARNING – ENTRAPMENT HAZARD

NEVER use bed rail without installing this part onto bed.
Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death.

This warning label will reinforce the importance of using the installation components when installing bed rails onto the bed and reduce the likelihood of misinstallation.

4. Revised Warning Label

Staff recommends a revised label to clarify warning language to address product use. The staff-recommended language adds a warning symbol and specifies that bed rails should not be used for children under the age of 2 years.

⚠ **WARNING**: Suffocation and Strangulation Hazard.
9.3.1.3 Children who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place children younger than 2 years old in adult beds with or without a bed rail.

[3] A critical installation component is any component of the bed rail that is used to attach the bed rail onto the bed.

D. Potential Small Business Impact (Tab D)

Generally, portable bed rails are manufactured and/or sold by juvenile product or furniture manufacturers and distributors. There are 14 firms known to be producing or importing portable bed rails to the U.S. market (all domestic). Ten are manufacturers and three are importers. The remaining firm has an unknown supply source, and there is no publicly available information regarding its size. Based on U.S. Small Business Administration definitions, there are 12 small firms—9 small manufacturers and all known (three) small importers—likely to be affected by the draft proposed standard, as described in the Directorate for Economic Analysis memo (Tab D).

It is possible that the draft proposed standard may have a significant impact on some small entities. The Juvenile Product Manufacturers Association (JPMA) runs a voluntary certification program for several juvenile products. Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard. Among them, four are JPMA-certified as compliant with the current ASTM voluntary standard, and one claims compliance with the ASTM standard. Of the importers, one is JPMA-certified, and one claims compliance.

The impact of the staff-recommended standard on small manufacturers could vary, based upon whether they are compliant with the voluntary ASTM standard. The firms that are not in compliance with the current ASTM standard, may require substantial modifications to meet the ASTM standard and the staff-recommended revisions. The costs associated with these modifications include: staff time for design, development, marketing, and product/market testing. The actual costs are unknown but could be significant for some firms. The impact of the staff-recommended standard on firms in compliance with the current ASTM standard may be less significant; however, all firms will require some product modifications to meet the new performance and labeling requirements detailed in staff's draft proposed standard to address entrapment hazards posed by portable bed rail misassembly and misinstallation.

IV. ENVIRONMENTAL IMPACT

The Commission's environmental review regulation at 16 CFR part 1021 has established categories of actions that normally have little or no potential to affect the human environment and therefore, do not require either an environmental assessment or an environmental impact statement. The draft proposed rule is within the scope of the Commission's regulation at 16 CFR §1021.5(c)(1), which provides a categorical exclusion for rules to provide design or performance requirements for products. Thus, no environmental assessment or environmental impact statement is required for this rule.

V. STAFF RECOMMENDATION

CPSC staff recommends that the Commission adopt as mandatory ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails*, with the following modifications:

1. revisions to scope to include inflatable and foam-type bed rail products;

2. new performance requirements and associated test methods to address fatal entrapment incidents related to misassembly of portable bed rails;
3. new performance requirement and warning label to address the potential for fatal entrapment incidents related to misinstallation of portable bed rails; and
4. revised warning label to specify intended user age for portable bed rails.

CPSC staff recommends that the Commission publish the Notice of Proposed Rulemaking as drafted by the Office of the General Counsel and submitted separately from this briefing package. CPSC staff also recommends an effective date of six months after publication of the final rule.

TAB A: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: 2000–Present

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: February 16, 2011

TO : Rohit Khanna
Portable Bed Rails Project Manager
Office of Hazard Identification and Reduction

THROUGH: Gregory B. Rodgers, PhD
Acting Associate Executive Director
Directorate for Epidemiology

Kathleen Stralka
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis

SUBJECT : Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries; 2000–Present

Introduction

This memorandum reports the number of deaths and injuries and characterizes the types of hazard patterns related to portable bed rails (a subset of products coded as 4075 in the U.S. Consumer Product Safety Commission (CPSC) epidemiological databases) for a period of more than 10 years, beginning in 2000.[4] These characterizations are based on reports received by CPSC staff. The data from before 2000 has been reviewed extensively for regulatory/standard development activities.[5] Therefore, this memo focuses on the data reported to CPSC staff from 2000 forward.

The ASTM International (ASTM) voluntary standard for portable bed rails is ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails*. According to the ASTM definition, a portable bed rail is a device intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted, typically ranging in age from two to five years old.

[4] Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff.
[5] http://www.cpsc.gov/library/foia/foia00/brief/bedrail1.pdf.

I. Incident Data[6] on Portable Bed Rails

From January 1, 2000, through March 31, 2010, CPSC staff received reports of a total of 132 incidents related to youth portable bed rails. The reports from emergency department-treated injuries (none of which were fatal) were ambiguous in the product descriptions and, hence, are excluded from this analysis. Among the 132 reported incidents, there were 13 fatalities, 40 nonfatal injuries, and 79 noninjury incidents. The number of reported fatalities, nonfatal injuries, and noninjury incidents for this period may change in the future because reporting is ongoing.

Table 1: Distribution of Portable Youth Bed Rail-Related Incident Reports Severity of Incident by Year 01/01/00–03/31/10

Year of Incident	Reported Fatalities	Reported Injuries	Reported Noninjury Incidents	Total
2000	1	9	18	**28**
2001	0	8	19	**27**
2002	1	8	7	**16**
2003	2	2	8	**12**
2004	6*	2	6	**14**
2005	0	2	8	**10**
2006	0	2	2	**4**
2007	3*	2	6	**11**
2008	*0*	*3*	*3*	***6***
2009	*0*	*2*	*1*	***3***
2010	*0*	*0*	*1*	***1***
Total	**13**	**40**	**79**	**132**

Source: CPSC epidemiological databases IPII, INDP, and DTHS.
*** : Very limited information available for three deaths in 2004 and two deaths in 2007.**
Note : Data in italics indicates reporting is ongoing, especially for 2008–2010.

Fatalities and Nonfatal Injuries

A. Fatalities

From the year 2000 forward, there were 13 child fatalities reported to the CPSC that were coded as involving bed rails. Most of the decedents (9 out of 13) were under 1year old; two were between 1 and 2 years old; and two decedents, both physically handicapped, were 6years old.

[6] The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to portable bed rails.

Date of extraction for reported incident data on portable bed rails was April 1, 2010. All data coded with product code 4075 and age as 6 years old or younger (to accommodate any physically handicapped children) was extracted. Upon careful joint review with the CPSC's Directorate for Engineering Sciences staff, some cases were considered out of scope for the purposes of this memo. See Appendix A for a complete listing of data records included in the analysis.

While all 13 incidents reported some sort of entrapment of the child between the bed rail and the mattress, no additional product- or scenario-specific information was available for five of the reports (task numbers 0406130408, 0427019066, 0442078182, 0717000449, and 090903HCC1056). Among the remaining eight incidents, two of the deaths resulted from bed rail displacement, when the bed rail partially pushed away from underneath the mattress and allowed the child to fall into the opening and get trapped (task numbers 000913HWE6005 and 040727HCC2657). There were three cases of bed rail misassembly. In the first case (task number 050324HCC1605), the middle bar was absent, and the child rolled into the mesh and got wedged between the mattress and the rail. In the second case (task number 030730HCC1771), the middle bar was not inserted through the mesh sleeve, and the child's head slipped between the bottom edge of the mesh panel and the top edge of the mattress. In the third case (task number 080925HCC2061), the bottom horizontal bar was not attached to the vertical bar. In the remaining three fatalities, not enough information was available to determine the failure mode that led to the hazardous entrapment scenario. In the first (task number 031201HCC2146), for unknown reasons, the bed rail was not flush against the mattress. Instead, a pillow was placed to close the gap between the mattress and the rail; the decedent ended up trapped between the rail and mattress with her face on the pillow. In the second case (task number 05721HBB1979), the consumer was aware of a gap between the mattress and the bed rail and placed a blanket in that gap. In the third case (task number 070518HCC1504), a 6-year-old female, who had extreme cerebral palsy, was found on her back lying across the head of the bed with her neck twisted and her head wedged between the mesh railing on the bed and the mattress. The beds used in all eight cases were adult-size.

B. Nonfatal Incidents

A total of 40 incidents associated with the use of a portable bed rail involved an injury to a child. Eighty-three percent of the injured were 2 years old or older. The majority of the injuries (28 out of 40, or 70 percent) were identified as fractures/contusions, resulting from a fall when the bed rail became dislodged, or lacerations/scratches caused by sharp or broken surfaces of the bed rail. The remaining injuries resulted from the child getting caught on the torn mesh panel of the rail; the child getting partially entrapped in the bed rail, which was partly pushed out; and the child nearly choking on small parts (*e.g.*, hardware or labels) that separated from the bed rail.

While no injuries were reported for the remaining 79 incidents, the incident scenarios that were reported indicated that they potentially could have resulted in injuries or fatalities.

Hazard Pattern Identification

CPSC staff considered all 132 incidents together to identify the hazard patterns associated with portable youth bed rail-related incidents. The hazard patterns can be grouped into the following categories:

- displacement of bed rail,
- worn or poor quality fabric on mesh panel,

- sharp surfaces,
- hinge lock disengagement,
- misassembly, and
- miscellaneous other or unknown issues.

A. *Displacement of bed rail:* Sixty-nine of the 132 incidents (52 percent) involved the displacement of the bed rail, where the bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail. In cases where the opening was small, the child became entrapped in the space. In cases where the opening was wide or the rail dislodged completely, the child fell to the floor. There were two fatal incidents where the bed rail had pushed out partially and entrapped the child. There were about 21 nonfatal injuries, resulting from displacement of the rail. A small proportion of these 69 incident reports provided enough information to indicate that for some double-rail configurations, failure of the push-pin or buckle lock mechanism (on the connecting bars/straps underneath the mattress) usually was the main cause of the bed rail displacement.

B. *Worn or poor quality fabric on mesh panel:* Seventeen of the 132 incidents (13 percent) involved a tear in the mesh, the unraveling of the stitching around the mesh, or simply very loose fabric on the mesh panel. Most of the nonfatal incident reports in this category involved the child getting caught in the tear/hole (tooth, limb, or even head); loose thread from the stitching getting tightly wound around the child (finger or neck); and mesh coming completely loose, allowing the child to slide through the panel and fall. Many consumers expressed concern about the potential of the tears/holes in the mesh to become larger and increase the risk of strangulation.

C. *Sharp surface:* Fourteen of the 132 incidents (11 percent) involved lacerations or scratches, or the potential thereof, on sharp surfaces of the bed rail. Some of these bed rails reportedly had sharp surfaces to begin with, while other sharp surfaces were created when parts of the bed rail broke away. Occasionally, depending upon the part that broke, the broken components created a potential fall hazard.

D. *Hinge lock disengagement:* There were 11 reports (eight percent) of the hinge lock mechanism failing to remain locked to keep the side panel in an upright position. This allowed the child to fall out. Three of these incidents resulted in an injury.

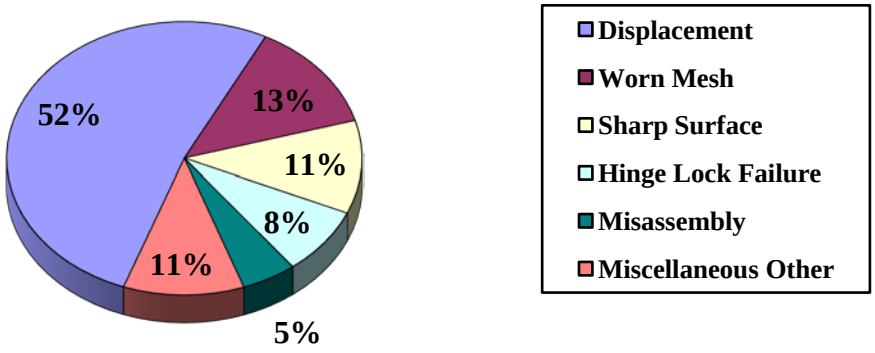
E. *Misassembly:* Misassembly or misinstallation of the bed rail was identified in seven of the 132 incidents (five percent). Misassembly resulted in three fatalities. In the first case, the middle bar was absent; in the second case, the middle bar was not inserted through the mesh sleeve; and in the third case, the bottom horizontal bar was not attached to the vertical bar. Examples of nonfatal incident reports included the use of a bed rail on a toddler bed, as well as the use of a bed rail with an extra thick mattress, which prevented the bed rail from attaching securely.

F. *Miscellaneous Other or Unknown Issues:* There were 14 incident reports (11 percent), which involved a host of other problems, not listed above. Six of the reports—including

five fatalities—did not provide any product- or scenario-specific information. Three additional fatality reports provided insufficient information to draw any conclusions about why the bed rail was not flush with the mattress. The remaining five nonfatal incidents involved the potential for choking on small parts, such as loose hardware or labels; instability issues resulting from loose hardware; and inadequate design issues, such as extra wide openings in non-mesh side panels or insufficient rail height.

The distribution by hazard pattern of the 132 reported incidents described in Sections A through F above are shown in Fig 1 below.

Fig 1: Distribution of Incident Reports Associated with Portable Bedrails by Hazard Pattern Characterizations 01/01/00-03/31/10



Source: CPSC epidemiological databases IPII, INDP, and DTHS.

Appendix A

Portable Youth Bedrail Incidents*

Age: 0 - 6 yrs

CPSC Databases: IPII/INDP/DTHS

Fatalities are shown in bold font

*This spreadsheet was prepared by CPSC staff, has not been reviewed or approved by, and may not necessarily reflect the views of the Commission

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
1	000317CCC0500	H0030091A		3/8/2000	MA	DEDHAM	1	M	3	A 3 YEAR OLD MALE SUSTAINED A PARTIAL AMPUTATION AND FRACTURE OF THE TOP SECTION OF HIS MIDDLE RIGHT FINGER, AFTER IT BECAME CAUGHT IN AN OPENING IN A PLASTIC HINGE OF A PORTABLE BED SAFETY RAIL.
2		H0040332A		4/1/2000	MO	NIXA	0	M	2	A 2-1/2 OLD BOY WAS FOUND STUCK IN A LARGE HOLE IN THE BED RAIL'S NYLON MESH FOR A TWIN SIZE BED. HIS FEET WERE FOUND HANGING OFF OF THE BED AND CONSUMER HAD TO USE FORCE TO PULL HIM THROUGH THE HOLE. HE WAS NOT INJURED.
3		I0040102A		4/9/2000	UT	LAYTON	1	M	4	A 4 YEAR OLD MALE SUFFERED A SEVERE LACERATION ON HIS FOOT FROM EXPOSED SHARP EDGES OF TUBING FROM A YOUTH BED GUARD RAIL. REPEATED LOCKING / UNLOCKING OF RAIL EXPOSED EDGES. INJURY REQUIRED 2 STITCHES TO CLOSE ARTERY, 7 STITCHES TO CLOSE WOUND.
4-5		H0260018A		4/30/2000	MA	MEDFIELD	0	M	2	A BOY, AGE 2, WAS NOT INJURED IN A FALL FROM HIS BED WHEN THE BEDRAIL FAILED & ALLOWED HIM TO FALL ONTO THE FLOOR. ON ANOTHER OCCASION, THE BOY'S LOWER BODY WAS ENTRAPPED IN BETWEEN THE MATTRESS & THE BED RAIL DURING USE. POSES AN ENTRAPMENT HAZARD.
6		I0050228A		5/1/2000	IL	FORT WAYNE	0	M	2	CONSUMER CONCERNED ABOUT STITCHING ON A NET PANEL OF A TODDLER SAFETY RAIL THAT IS COMING UNDONE. CONSUMER CONCERNED 2 YEAR OLD SON COULD FALL OUT OF HIS BED.
7	**000913HWE6005**	**H0090103A**	**X0072883A**	**5/21/2000**	**CA**	**SACRAMENTO**	**8**	**F**	**206**	**6-MONTH-OLD FEMALE VICTIM HAD BEEN SLEEPING IN BED WITH HER PARENTS WITH A BED RAIL POSITIONED ON ONE SIDE OF THE BED, WHEN SHE WAS DISCOVERED UNRESPONSIVE AND WEDGED BETWEEN THE BED RAIL AND THE MATTRESS. THE VICTIM WAS TRANSPORTED TO THE HOSPITAL VIA AMBULANCE WHERE SHE WAS PRONOUNCED DEAD. THE BED RAIL IS BEING RETAINED BY THE FAMILY'S ATTORNEY.**
8-11		H0050334**B**		5/24/2000	NJ	STEWARTSVILLE	1	F	2	A 2 YEAR OLD GIRL RECEIVED BRUISES TO HER LEFT EAR, FOREHEAD, AND LEFT SIDE OF FACE AFTER FELL ONTO THE CARPETED FLOOR WHEN A CHILD'S SAFETY RAIL USED TO A BED SLID OUT OF PLACED.
12	010412CCC2398	Retailer rpt		6/1/2000	MN	OAKDALE	0	M	3	A THREE-YEAR-OLD OAKDALE, MN MALE WAS SLEEPING IN HIS FAMILY'S RESIDENCE IN A TWIN BED EQUIPPED WITH TWO BED RAILS, ONE ON EACH SIDE. THE BOY'S MOTHER FOUND THE CHILD THE NEXT MORNING STILL ASLEEP, LYING ACROSS THE BED WITH HIS HEAD PUSHED THROUGH A HOLE IN THE BED RAIL'S POLYESTER NETTING. THE BOY WAS REMOVED UNINJURED.

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13	010412CCC3260	Retailer rpt		6/29/2000	CA	LONG BEACH	0	M	3	A CONSUMER COMPLAINED THAT HER 5-YEAR-OLD SON SOMEHOW MADE A 5-IN DIAMETER HOLE IN THE MIDDLE OF THE MESH PANEL OF A BED RAIL ATTACHED TO HIS TWIN BED. THERE WAS NO INCIDENT, BUT THE MOTHER WAS CONCERNED THAT THE SON MIGHT GET HIS HEAD CAUGHT IN THE HOLE AND STRANGLE.
14		I0090083A		7/1/2000	MI	EAST LANSING	0	F	2	A GIRL, AGE 2, BECAME TRAPPED BETWEEN HER BED YOUTH RAIL AND TWIN MATTRESS DURING SLEEP OVERNIGHT. NO INJURY.
15		I0090333A		7/1/2000	CA	SANTA CRUZ	0	M	219	A MALE, AGE 19 MONTHS, WHILE CLIMBING OUT OF BED GOT HIS HEAD STUCK BETWEEN BED RAILING AND THE BED. NO INJURY. CONSUMER FREED HIM.
16	010412CCC2400	Retailer rpt		7/15/2000	WI	RACINE	0	F	2	THE PARENTS OF A TWO AND A HALF YEAR OLD FEMALE PURCHASED A NEW MESH BED RAIL FOR THEIR DAUGHTER WHEN SHE MOVED FROM HER CRIB TO A TWIN BED. WITHIN TWO MONTHS THE MESH BEGAN TO RIP ALONG THE BOTTOM SEAM LEAVING TWO AND FOUR INCH HOLES. THE PARENTS RETURNED THE BED RAIL TO THE MANUFACTURER AND OBTAINED A REFUND. NO INJURIES WERE REPORTED.
17	010412CCC0493	Retailer rpt		7/18/2000	NY	HOWARD BEACH	1	M	3	A THREE YEAR OLD AUTISTIC MALE SUSTAINED MINOR INJURIES AROUND HIS NECK WHEN THE MESH NETTING FROM HIS MESH BED RAIL GOT TANGLED AROUND HIS NECK WHILE HE WAS ASLEEP.
18	000801CCN0388	H0070202A		7/19/2000	MN	WOODBURY	0	M	2	ON JULY 19, 2000, A TWO-YEAR-OLD MALE WAS SLEEPING IN A TWIN BED EQUIPPED WITH A BED RAIL IN HIS WOODBURY, MN HOME. THE CHILD ROLLED AGAINST THE BED RAIL AND THE MATTRESS. THE BED RAIL'S FABRIC RIPPED AND THE BOY FELL BETWEEN THE METAL BED RAIL FRAME AND THE MATERIAL. THE CHILD WAS REMOVED BY THE PARENTS WITHOUT INJURY.
19	010412CCC0490	Retailer rpt		8/1/2000	PA	NORRISTOWN	0	M	211	WHILE EXAMINING THE MESH PANEL OF A BED RAIL BEING USED ON A QUEEN SIZE BED BY HER 11 MONTHS OLD SON, THE COMPLAINANT DISCOVERED A TEAR IN THE MESH PANEL. THE RAIL WAS LESS THAN A YEAR OLD. NO INJURIES OCCURRED.
20		I0080308A		8/20/2000	PA	PENN VALLEY	0	F	217	A 17 MONTH OLD GIRL COULD HAVE INJURED WHEN SHE FELL BETWEEN THE GUARDRAIL AND THE BED AND WAS CAUGHT BY THE NECK AT THE LOWER PART OF THE GUARDRAIL.
21	010412CCC2401	Retailer rpt		9/1/2000	OH	NEWARK	0	M	2	A 29-YEAR-OLD FEMALE PURCHASED A YOUTH BED RAIL FOR HER 28-MONTH-OLD, 28 POUND SON'S BED. WITHIN TWO WEEKS OF THE PURCHASE DATE THE MESH MATERIAL BEGAN TO RIP AWAY FROM THE NYLON OUTER LINER AT THE SEAMS. THE DAMAGE WAS CONFINED TO THE MESH MATERIAL OF THE BED RAIL AND THERE WAS NO ACCIDENT OR INJURIES.

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22		I0090340A		9/12/2000	MA	BURLINGTON	1	F	6	A FEMALE, AGE 6, SLIPPED OUT OF HER BED CAUSING THE METAL BEDRAIL TO FALL OUT FROM UNDER THE MATTRESS. SHE RECEIVED SEVERE CUTS TO HER FACE WHEN THE METAL BEDRAIL POLE SNAPPED IN HALF.
23		I0110300A		10/1/2000	PA	PITTSBURGH	0	F	218	AN 18 MONTH OLD FEMALE FELL BETWEEN THE MATTRESS AND BED RAIL AFTER THE BED RAIL PUSHED AWAY FROM THE MATTRESS. NO INJURY
24	001004CCN0010	G00A0033A		10/1/2000	MN	WOODBURY	0	M	3	A THREE-YEAR-OLD, 34 LB. MALE WAS SLEEPING IN A TWIN BED EQUIPPED WITH TWO BED RAILS IN HIS WOODBURY, MN HOME. DURING THE NIGHT, THE CHILD APPARENTLY LAID OR PUSHED AGAINST ONE OF THE BED RAILS. THE NEXT MORNING, THE BED RAIL'S FABRIC WAS FOUND RIPPED AWAY FROM ALONG THE BOTTOM OF THE RAIL'S METAL FRAME. NO INJURIES.
25	010412CCC0491	Retailer rpt		11/1/2000	PA	GEIGERTOWN	0	M	218	A CONSUMER RECEIVED AS A BABY SHOWER GIFT, A BED SAFETY RAIL, WITH A MESH TYPE FABRIC SIDING FOR USE ON A TWIN SIZED BED FOR HER 18 MONTH OLD CHILD. THREE WEEKS AFTER BEING PUT INTO USE, THE MESH FABRIC DEVELOPED THUMB-SIZE HOLES. CONCERNED THAT HER CHILD MIGHT BECOME ENTRAPPED IN THE HOLES, THE CONSUMER RETURNED THE ITEM TO THE MANUFACTURER FOR A REFUND. NO INJURY OR ENTRAPMENT WAS INVOLVED. THE CONSUMER COULD NOT REMEMBER ANY INFORMATION AS TO THE BRAND, MODEL, NOR MANUFACTURER.
26	010412CCC2397	Retailer rpt		11/7/2000	MO	LEE'S SUMMIT	0	M	218	AN OPENING DEVELOPED WHERE THE MESH ATTACHES TO THE NYLON/PLASTIC PART OF A MESH BED RAIL EXTENDER BEING USED ON A TODDLER BED. INITIALLY, THE OPENING WAS THE SIZE OF A NICKEL COIN, BUT EXPANDED TO GRAPEFRUIT SIZE. NO INJURY OCCURRED. THE PRODUCT WAS RETURNED FOR A REFUND.
27	010816CCN0829	G0180125A		12/4/2000	WI	FOND DU LAC	1	M	3	A THREE YEAR OLD MALE FELL FROM HIS BED WHEN THE BED GATE RELEASED FROM ITS LOCKING POSITION DURING THE NIGHT. AS A RESULT OF THE FALL, THE BOY SUFFERED A FRACTURE TO HIS RIGHT CLAVICLE.
28		I00C0197A		12/15/2000	MA	BILLERICA	0	M	2	THE FOLDABLE BEDRAIL USED FOR A BOY, AGE 2, ON A TWIN SIZE BED FALLS OUT. NO INJURY.
29	011016HAA1048	I0110381A		1/21/2001	FL	PEMBROKE PINE	1	F	3	A 3-YEAR OLD FEMALE CHILD SUFFERED A HAIRLINE FRACTURE TO THE BIG TOE OF HER LEFT FOOT WHEN SHE WEDGED THE FOOT BETWEEN THE BED RAIL AND HER BED WHILE SLEEPING ALONE IN THE BEDROOM AT HER HOME. THE VICTIM WAS TREATED AND RELEASED AT A HOSPITAL AND CONSULTED AN ORTHOPEDIC PEDIATRICIAN AND RECEIVED A CAST ON HER FOOT.
30		I0150457A		1/27/2001	WI	STOUGHTON	1	F	209	A 9-1/2 MONTH OLD GIRL WAS ABLE TO PUSH THE GUARD RAIL AWAY FROM THE BED AND FALL THROUGH THE GAP TO THE FLOOR. SHE SUFFERED BUMPS AND BRUISES TO HER SIDE AND HER HEAD.

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31		I0150200A		3/1/2001	MO	RAYTOWN	1	F	2	A 2 YEAR OLD FEMALE HAS BECOME STUCK AFTER PUSHING HER YOUTH BED RAIL LOOSE FROM HER TWIN SIZE BED. SHE HAS ALSO FALLEN THROUGH HITTING HER CHIN ON THE BED FRAME LEAVING A RED MARK.
32		H0130266A		3/10/2001	PA	CLARKS SUMMIT	0	F	3	A GIRL, AGE 3, FELL TO THE CARPETED FLOOR WHEN SHE ROLLED OVER INTO BED RAIL CAUSING ITS PLASTIC GRIPPERS TO SLIDE FROM UNDER THE MATTRESS. CONSUMER FEELS BED RAIL DOES NOT SECURE ONTO MATTRESS PROPERLY, POSING A STRANGULATION HAZARD. NO INJURY.
33		H0140166A		3/31/2001	ID	BOISE	1	F	2	A GIRL, AGE 2, BIT BED RAILING MESH WHEN HER TOOTH BECAME WEDGED IN THE MESH. SHE PULLED HER HEAD BACKWARDS CAUSING HER TOOTH TO BE PULLED FROM GUMS. CONSUMER FEELS THAT THE SIZE OF THE MESH HOLES CAN POSE AN ENTRAPMENT HAZED FOR CHILDREN TEETH.
34		H0140013A		4/1/2001	AZ	CAVE CREEK	1	M	219	A 19 MONTH OLD MALE RECEIVED RED MARKS AROUND HIS NECK AFTER HE GOT IT STUCK SPACE BETWEEN THE MATTRESS AND THE MESH PROTECTIVE YOUTH GUARD RAIL ON HIS BED.
35		I0140260A		4/13/2001	WA	OAK HARBOR	0	F	222	A 22 MONTH OLD FEMALE WAS NEARLY INJURED WHEN SHE MANAGED TO GET CAUGHT BETWEEN THE CRIB EXTENDER BEDRAIL AND THE MATTRESS ON HER BED. NO INJURY.
36		H0150260A		5/11/2001	RI	CUMBEMRLAND	0	M	204	A 4 MONTH OLD BOY COULD HAVE INJURED HIMSELF WHEN HE WAS FOUND FACE DOWN IN A SPACE BETWEEN THE INFANT BED RAIL AND THE MATTRESS OF HIS TWIN SIZE BED. NO INJURY.
37		I0150377A		5/23/2001	MN	HAM LAKE	0	F	2	A GIRL, AGE 2, WAS NEARLY INJURED AFTER SHE SLIPPED BETWEEN THE SIDE OF HER BED AND THE BED RAIL. NO INJURY.
38	010928CNE6753	I0190281A		6/1/2001	MD	BEL AIR	0	F	2	A PORTABLE BED RAIL USED ON A TWIN BED, TRAPPED A TWO YEAR OLD CHILD WHILE SHE SLEPT IN THE BED. THE CHILD WAS APPARENTLY "WIGGLING" IN HER SLEEP AND BECAME CAUGHT BETWEEN THE MESH SIDING AND THE MATTRESS. NO INJURY WAS SUSTAINED BY THE CHILD.
39		H0170010A		7/2/2001	KS	WICHITA	0	M	222	A 22 MONTH OLD MALE BECAME TRAPPED IN BETWEEN HIS PORTABLE YOUTH BED RAIL WITH MESH AND HIS TWIN SIZE BED. NO INJURY.
40		H0180049A		7/8/2001	MI	CHARLOTTE	0	M	3	A BOY WAS NOT INJURED WHEN HIS LEFT LEG WAS ENTRAPPED IN THE SPACE CREATED BY THE BED AND ITS BED RAIL WHILE SLEEPING IN THE TODDLE BED WITH A METAL BED RAIL.
41		H0170444A		7/24/2001	MA	WATERTOWN	0	M	3	A 3 YEAR OLD MALE FELL THROUGH THE METAL BED RAIL AND MATTRESS ONTO THE FLOOR WHILE HE WAS SLEEPING. NO INJURY. CONSUMER FEELS THAT THE BED RAIL POSES A FALL HAZARD.
42		I0170426A		7/26/2001	NC	GREENSBORO	1	M	212	A 12 MONTH OLD BOY SUFFERED MINOR INJURIES IN A FALL FROM HIS BED WHEN THE BEDRAIL FAILED AND ALLOWED HIM TO FALL ONTO THE FLOOR.

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43	010913CCC1868	I0180370A		8/1/2001	MD	OCEAN CITY	1	M	3	A 3 YEAR OLD MALE WAS ASLEEP ON A FULL SIZE MATTRESS WITH A METAL AND FABRIC BED RAIL. HE SOMEHOW MANAGED TO SLIDE DOWN BETWEEN THE BED RAIL AND THE MATTRESS AND BECAME ENTRAPPED WITH HIS NECK ON THE LOWER BAR AND HIS FACE IN THE MESH. HE CRIED AND AWAKENED HIS MOTHER WHO DISCOVERED HIM AND EXTRICATED HIM. NO MEDICAL ATTENTION WAS SOUGHT.
44		H0180072A		8/2/2001	TX	SANTA FE	1	F	2	A GIRL, AGE 2, WHILE SLEEPING, LEANED AGAINST THE BED RAIL WHEN IT FELL OFF ALONG WITH HER. SHE SUSTAINED A BROKEN COLLAR BONE AND MINOR INJURY TO FOREHEAD , NOSE & CHEEK.
45		I0180120A		8/6/2001	CT	STONGINGTON	0	F	3	A GIRL, AGE 3, FELL FROM HER BED WHEN THE PORTABLE BEDRAIL PULLED OUT FROM BETWEEN THE BOX SPRING AND MATTRESS DURING USE. NO INJURY. NO SECURING CABLE COMES WITH THE BEDRAILS.
46-47		H0180534A		8/13/2001	VA	VIRGINIA BEACH	0	M	2	A 2 YEAR OLD BOY WAS NOT INJURED WHEN HE WAS CAUGHT IN A SPACE BETWEEN TWIN BED AND METAL GUARD RAIL DURING USE. POSES AN ENTRAPMENT HAZARD.
48-49		I0180231A		8/15/2001	NV	LAS VEGAS	0	M	2	A BOY, AGE 2, WAS CAUGHT UP BETWEEN THE BED RAIL AND THE BED, HANGING ABOVE THE FLOOR TWICE. NO INJURY. CHOKING HAZARD.
50-52		I0180410A		8/24/2001	NY	ENDWELL	0	M	2	A BOY, AGE 2, SLID BETWEEN THE BED RAIL AND THE BED ON 3 DIFFERENT OCCASIONS. THE BED RAIL SLIDES AWAY FROM THE BED VERY EASILY WITH VERY LITTLE PRESSURE. NO INJURY.
53	010907CNE6697	I0190076A		9/1/2001	GA	NORCROSS	0	M	4	A 4-YEAR OLD MALE FELL OUT OF A FULL SIZE ADULT BED AFTER A PLASTIC COMPONENT BROKE FROM THE BED RAIL. THE VICTIM WAS NOT INJURED AND NO MEDICAL TREATMENT WAS ADMINISTERED. THE INCIDENT OCCURRED IN THE VICTIM'S BEDROOM AT APPROXIMATELY 0100 HOURS.
54		H0190339A		9/27/2001	TN	HERMITAGE	0	M	2	A BOY, AGE 2, HEAD BECAME ENTRAPPED BETWEEN THE GUARDRAIL AND THE MATTRESS OF A TWIN BED DURING TWIN BED USE. NO INJURY. ENTRAPMENT HAZARD.
55		I01B0334A		11/22/2001	FL	MIAMI	0	M	212	A BOY, AGE 1, FELL TO THE FLOOR WHEN HE ROLLED AGAINST THE BED RAIL & IT MOVED AWAY FROM THE BED. NO INJURY. OWNER NOTICED THAT THE BED RAIL DOES NOT STAY IN PLACE WHEN PRESSURE IS APPLIED TO IT.
56		I03C0048A		1/1/2002	IL	BOLINGBROOK	0	F	218	OWNER WHILE SLEEPING WITH DAUGHTER, AGE 18 MONTH, IN A TWIN BED, FOUND HER HEAD HANGING THROUGH THE SIDE RAILING. NO INJURY.
57		I04C0519A		1/1/2002	MD	all	0	F	4	A GIRL, AGE 4, WAS NOT INJURED WHEN SHE WAS FOUND TRAPPED BETWEEN THE GATE (THAT PREVENTS CHILDREN FROM FALLING OUT OF BED) & HER BED. THE GATE HAD SLIGHTLY SLIDE FROM UNDER THE BED, CAUSING HER BODY TO FALL BETWEEN THE GATE & THE BED. ENTRAPMENT HAZARD.

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58		I0210251A		1/13/2002	AA	0	1	M	2	A BOY, AGE 2, RAISED THE SIDE BED RAIL & LET IT DOWN. HIS FINGER GOT PINCHED & CUT BETWEEN THE BRACKET & THE METAL WASHER THAT LOCKS IT IN UPRIGHT POSITION.
59		H0220115A		2/7/2002	IA	CEDAR RAPIDS	1	M	218	A PORTION OF THE BED RAIL DETACHED ITSELF FROM THE HEAD END WHILE AN 18 MONTH OLD BOY WAS GETTING OUT OF THE BED. HE SCRATCHED HIS FACE ON THE BROKEN PIECE THAT WAS ATTACHED TO THE HEAD END OF THE BED RAIL.
60		G0240260A		4/1/2002	MI	TROY	0	M	2	A 2-1/2 YEAR OLD BOY WAS NOT INJURED WHEN HE WAS FOUND WEDGED BETWEEN THE MATTRESS AND THE YOUTH BED RAIL WHILE SLEEPING ON HIS BED.
61		I0260173A		6/6/2002	TN	OCOEE	0	M	209	A 9 MONTH OLD MALE FELL AGAINST A BED RAIL DURING THE NIGHT AND THEN BECAME TRAPPED BETWEEN THE RAIL AND THE BED. NO INJURY.
62		H0270272A		7/21/2002	MO	KIRKWOOD	1	M	3	BED RAILS WERE ASSEMBLED AND A 3 YEAR OLD BOY WAS SLEEP IN THE BED WHEN CONSUMER HEARD A LOUD CRASH. SHE NOTICED THAT HER SON HAD FALLEN ONTO THE FLOOR & WAS LAYING ON TOP OF THE GAURD RAIL WHICH HAD ALSO COLLAPSED ONTO THE FLOOR. 3 INCH SCRAPE ON BACK (SEE AMENDMENT).
63		H0280417A		8/21/2002	CA	EL CERRITO	1	F	2	A GIRL, AGE 2, FELL OUT OF HER BED, OVER THE BED RAIL DURING USE. SHE RECEIVED A BUMP TO HER FOREHEAD. THE BED RAIL IS ONLY 3" ABOVE THE MATTRESS.
64		H0290241A		9/17/2002	IL	DES PLAINS	0	M	3	A BOY, AGE 3, GOT CAUGHT BETWEEN THE MATTRESS & BED RAIL OF A TWIN BED & HUNG STRAIGHT UP. HIS FEET WERE NOT TOUCHING THE GROUND. NO INJURY.
65	**030730HCC1771**	**0237050424**		**9/21/2002**	**NC**	**MOUNT PLEASANT**	**8**	**M**	**205**	**A 5-MONTH OLD MALE WAS PRONOUNCED DEAD FROM ASPHYXIA WHEN HE BECAME ENTRAPPED BY A PORTABLE BED RAIL. THE BED RAIL HAD BEEN IMPROPERLY ASSEMBLED. THE CHILD ROLLED-OVER AND HIS HEAD SLIPPED BETWEEN THE FABRIC MESH PANEL AND THE TOP EDGE OF THE TWIN-SIZE MATTRESS, CUTTING-OFF HIS CIRCULATION.**
66	020927CWE6006	I0290426A		9/25/2002	AZ	CHANDLER	0	F	2	A 2-YEAR OLD GIRL BECAME TRAPPED BETWEEN A SOFT BED RAIL AND THE SIDE OF HER BED. SHE WAS NOT INJURED DURING THIS INCIDENT.
67-69		I02A0047A		10/4/2002	IL	LOCKPORT	1	M	2	TWO BOYS, AGES 2 & 3, WERE INJURED IN A FALL FROM THEIR BEDS WHEN THE BED RAIL FELL OUT DURING USE. THEY HIT THEIR HEADS ON THE FLOOR. OWNER NOTICED THAT THE RUBBER STOPPERS AT THE END COME OFF WHILE UNDER THE MATTRESS.

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70	021022CWE5022	H02A0099A		10/8/2002	OR	WEST LINN	0	M	2	A TWO YEAR OLD MALE BECAME ENTRAPPED BETWEEN THE SIDE OF A MATTRESS AND A PORTABLE BED RAIL WHILE SLEEPING IN A FULL SIZE ADULT BED. THE VICTIM'S FAMILY MOVED HIM FROM A CRIB TO THE BED AND INSTALLED THE BED RAIL ONE WEEK BEFORE THE EVENT. THE VICTIM APPARENTLY PUSHED AGAINST THE BED RAIL AND SLIPPED FEET FIRST INTO A GAP BETWEEN THE RAIL AND THE MATTRESS. THE FATHER DISCOVERED THE VICTIM BEFORE HIS BREATHING WAS IMPAIRED AND NO INJURY OCCURRED.
71		H02C0313A		12/30/2002	AK	HARTMAN	1	F	206	A 6 MONTH OLD FEMALE RECEIVED A BUMP ON HER HEAD THEN THE SIDE BED RAILS ON A FULL SIZE BED FAILED (CAME LOOSE) AS SHE WAS SLEEPING AND SHE FELL ONTO THE FLOOR.
72		H0310309A		1/25/2003	NY	CROTON ON HUI	0	F	2	A GIRL, AGE 2 1/2, LOWER BODY BECAME TRAPPED BETWEEN THE TWIN BED RAILS & THE MATTRESS DURING RAILS 1ST TIME USE. THE BED RAILS, INSTALLED PER INSTRUCTIONS HAD SLIPPED OUT EASILY AFTER INSTALLATION. NO INJURY.
73	031230CCC1295	I03C0512A		12/26/2003	PA	EXTON	1	F	222	A 22 MONTH OLD FEMALE PUT A SCREW THAT DETACHED FROM A BUNKBED BEDRAIL AND PUT IT IN HER MOUTH. SHE ALMOST CHOKED. THE RAILS WERE ASSEMBLED INCORRECTLY AND A BOY FELL OUT.
74	030428HCC2418	I0340290A	I0340448A	4/24/2003	MI	ROCHESTER	1	F	212	A CONSUMER CHECKED ON HER DAUGHTER AFTER HEARING HER CRY OUT. SHE FOUND HER ONE-YEAR-OLD DAUGHTER WEDGED BETWEEN THE MATTRESS AND A BED RAIL. THE CHILD'S PARENTS WERE ABLE TO REMOVE THE BED RAIL FROM THE MATTRESS AND FREE THE CHILD. THE CHILD SUSTAINED A BRUISE ON HER RIGHT ARM AND A WELT ON HER NECK. THE CHILD WAS NOT HOSPITALIZED AND NO OTHER INJURIES WERE SUSTAINED.
75	030604HCC1596	I0350243A		5/16/2003	SC	HILTON HEAD ISLAND	0	F	209	A MOTHER HAD BEEN FEEDING HER 9-MONTH-OLD FEMALE WHEN THEY BOTH FELL ASLEEP ON A QUEEN SIZE BED AT THE CONDOMINIUM WHERE THEY WERE STAYING WHILE ON VACATION. THE MOTHER HAD ATTACHED A PORTABLE SAFETY BED RAIL TO THE SIDE OF THE BED. SHE HEARD A NOISE WHEN HER 9-MONTH-OLD DAUGHTER FELL BETWEEN THE SAFETY BED RAIL AND THE MATTRESS. SHE IMMEDIATELY PICKED HER UP AND SHE WAS NOT INJURED.
76-77		I0360194A		6/12/2003	OH	MEDINA	0	F	2	OWNER INSTALLED TWO PORTABLE BED RAILS ON 2 BEDS AT A HOTEL PER DIRECTION. A GIRL, AGE 5, ROLLED AGAINST THE RAIL WHEN SHE & THE RAIL FELL ONTO THE FLOOR. A GIRL, AGE 2 1/2, ALSO SLIPPED BETWEEN THE BED & THE RAIL & GOT HER HEAD STUCK. NO INJURY.

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78	030728HCC2587	H0370241A		7/24/2003	MN	RAMSEY	0	M	3	A MALE CHILD WAS TRANSITIONING INTO AN ADULT SIZED TWIN BED EQUIPPED WITH A MATTRESS, BOX SPRING, AND TWO BED RAILS. APPROX. THREE HOURS AFTER GOING TO BED, THE CHILD'S MOTHER FOUND HIM ON THE CARPETED FLOOR BENEATH HIS MATTRESS, WHICH HAD PARTIALLY COME OFF THE BED. THE CHILD WAS WEDGED IN AN APPROX. NINE INCH OPENING BETWEEN THE BED RAIL AND MATTRESS. A STRAP SECURING THE TWO BED RAILS HAD BENT. NO INJURES.
79		H0370264A		7/28/2003	PA	NEWTOWN	0	F	2	A GIRL, AGE 2, GOT HER BODY TRAPPED BETWEEN THE METAL BED RAIL AND MATTRESS ON HER BED. NO INJURY.
80		H0380239A		8/1/2003	NJ	LAKE HOPATCH(	0	F	2	A GIRL, AGE 2, FELL OUT OF BED WHEN THE BEDRAIL DETACHED. THE BED GATE WAS STILL LOCATED UNDERNEATH THE MATTRESS HOWEVER THE HINGE MECHANISM HAD COMPLETELY DETACHED. THE HINGE HAD DISASSSEMBLED. NO INJURY.
81	**031201HCC2146**	**0326052794**		**8/2/2003**	**MI**	**ROYAL OAK**	**8**	**F**	**205**	**A 5-MONTH-OLD FEMALE WAS PLACED IN A QUEEN SIZE BED TO SLEEP. AFTER APPROXIMATELY 20 MINUTES THE CHILD'S FATHER WENT TO CHECK ON HER AND FOUND HER UNRESPONSIVE WITH HER HEAD TRAPPED BETWEEN THE MATTRESS AND A PLASTIC BED RAIL WITH A PILLOW ON HER FACE. THE VICTIM WAS TAKEN TO THE HOSPITAL WHERE SHE DIED THREE DAYS LATER. AN AUTOPSY WAS PERFORMED WHICH CONFIRMED THE CAUSE OF DEATH AS HYPOXIA DUE TO BEING TRAPPED BETWEEN BED RAIL, MATTRESS AND PILLOW.**
82	031022HCC1070	I0390434A		9/15/2003	PA	BEAVER	0	M	2	A 2 YEAR, 9 MONTH OLD MALE WAS ASLEEP IN A TWIN SIZE BED WITH BEDRAILS ON THE EACH SIDE. HE ROLLED IN HIS SLEEP. HIS MOTHER HEARD A NOISE AND INVESTIGATED. SHE FOUND THE VICTIM LYING ON THE BEDROOM FLOOR ON TOP OF THE BEDRAIL WITH THE MATTRESS PARTIALLY OFF THE BOX SPRING AND PINNING HIM TO THE FLOOR. THE BEDRAIL SOMEHOW COLLAPSED AND ALLOWED THE VICTIM TO FALL TO THE FLOOR. THE VICTIM WAS NOT INJURED IN THE INCIDENT.
83	**040727HCC2657**	**X0473556A**		**12/30/2003**	**KY**	**FRANKLIN**	**8**	**F**	**204**	**THE CONSUMER'S 4 MONTH OLD DAUGHTER WAS CO-SLEEPING IN AN ADULT SIZED BED WITH HER 2 YEAR OLD SISTER WHEN SHE UNEXPECTEDLY ROLLED OVER AND BECAME WEDGED BETWEEN THE MATTRESS AND A PORTABLE BED RAIL. THE INFANT CHILD DIED AS A RESULT OF POSITIONAL ASPHYXIA.**
84	040317CNE1402	I0430234A		3/15/2004	VA	LANSDOWNE	0	M	3	DURING THE MIDDLE OF THE NIGHT, A 3-YEAR-OLD MALE BECAME TRAPPED BETWEEN THE EDGE OF HIS MATTRESS AND THE MESH PORTION OF HIS BED RAIL. THE CHILD YELLED FOR HELP AND HIS MOTHER PULLED HIM OUT OF THE GAP. THERE WERE NO INJURIES ASSOCIATED WITH THIS INCIDENT.

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
85	040415HCC1622	I0430448A		3/24/2004	MA	DEDHAM	0	M	2	APPROXIMATELY FIVE HOURS AFTER PLACING A 2-YEAR-OLD MALE TO BED ON A TWIN-SIZE MATTRESS EQUIPPED WITH A PORTABLE BED RAIL, THE TODDLER'S MOTHER WAS AWAKENED BY HIS SCREAMS AND CRYING. THE MOTHER RESPONDED TO FIND THE 2-YEAR-OLD MALE ENTRAPPED BETWEEN THE BEDRAIL AND MATTRESS WITH HIS HEAD LAYING UPON THE BED RAIL LOWER HORIZONTAL BEAM AND AGAINST THE MATTRESS. THE MOTHER SIMULTANEOUSLY SLID THE BEDRAIL AWAY AND PICKED UP HER SON. THE 2-YEAR-OLD MALE RECEIVED NO MEDICAL ATTENTION AND SUSTAINED NO INJURIES DUE TO THE INCIDENT.
86		**0406130408**		**5/5/2004**	**CA**	**VAN NUYS**	**8**	**F**	**208**	**HEAD CAUGHT IN GUARD RAILING OF BED - ANOXIC ENCEPHALOPATHY; ASPHYXIA FROM HANGING - AUTOPSY YES.**
87		**0427019066**		**7/4/2004**	**MN**	**SAINT CLOUD**	**8**	**F**	**6**	**CHILD ACCIDENTALLY BECAME WEDGED BETWEEN BEDRAIL AND MATTRESS. PROBABLE POSITIONAL ASPHYXIA. AUTOPSY-YES.**
88	040728CWE6020	I0470575A		7/28/2004	CA	SAN JOSE	1	M	3	A 3-YEAR-OLD MALE FELL OUT OF HIS TWIN-SIZE BED, KNOCKING THE BED RAIL LOOSE. HE FELL THROUGH THE OPEN GAP BETWEEN THE MATTRESS AND BED RAIL. HE STRUCK HIS HEAD ON A WOODEN WASTE PAPER CONTAINER AND SUFFERED A CUT LIP, TONGUE, AND A BRUISED CHEEK. HE WAS TREATED AT HOME.
89		**0442078182**		**8/6/2004**	**PA**	**PHILADELPHIA**	**8**	**M**	**201**	**TRAPPED BETWEEN CUSHION AND BEDRAIL. CO-SLEEPING WITH ADULT. ASPHYXIA. AUTOSPSY-YES.**
90	040902HCC1983	I0480462A		8/7/2004	NY	GARDEN CITY	0	M	2	NO INJURIES OCCURRED WHEN A TWO-YEAR OLD MALE WAS SLEEPING IN HIS QUEEN-SIZE BED DURING THE EARLY MORNING HOURS AND HE WAS ABLE PUSH HIS BED RAIL COMPLETELY OUT CAUSING HIM TO FALL ONTO THE CARPETED FLOOR.
91	040817HWE5010	I0480249A		8/12/2004	CA	SACRAMENTO	0	M	212	SEVERAL HOURS AFTER PLACING HER ONE-YEAR-OLD SON ON HER ADULT-SIZE BED WITH A BED RAIL IN PLACE, COMPLAINANT FOUND HIM CRYING IN A FACE-DOWN POSITION STUCK IN A GAP BETWEEN THE BED RAIL AND THE MATTRESS. HE WAS NOT INJURED.
92	041019CCN0070	I04A0290A		8/15/2004	IL	VERNON HILLS	0	F	3	COMPLAINANT PURCHASED BED RAILS FOR HER DAUGHTER'S BED WHEN SHE GREW OUT OF THE CRIB. THE RAILS GO UNDER THE MATTRESS AND AND CAN EASILY BE DETACHED AND USE ON OTHER BEDS. AFTER ABOUT 2 WEEKS OF USE, THE RAILS BEGAN TO SEPARATE NIGHTLY AND THE CHILD FELL OUT THE BED AS A RESULT. COMPLAISANT RETURNED THE RAILS AND RECEIVED ANOTHER SET. THESE DID THE SAME THING AFTER THE FIRST NIGHT OF USE. COMPLAIANT FEELS THESE RAILS ARE UNSAFE FOR CHILDREN.

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
93	**050721HBB1979**	**X0570139A**		**8/28/2004**	**GA**	**LAWRENCEVILLE**	**8**	**F**	**208**	**AN EIGHT MONTH OLD FEMALE WAS PLACED ON AN ADULT TWIN SIZE BED WHILE SLEEPING. THE BED WAS EQUIPPED WITH A PORTABLE BED RAIL. THE VICTIM'S GRANDMOTHER CHECKED ON THE VICTIM AFTER SHE HAS BEEN SLEEPING FOR APPROXIMATELY 30 MINUTES. EVERYTHING WAS NORMAL. AFTER THE VICTIM HAD BEEN SLEEPING FOR AN ADDITIONAL 90 MINUTES, THE VICTIM'S GRANDMOTHER CHECK IN THE VICTIM AND FOUND HER FACE DOWN, WEDGED BETWEEN THE MATTRESS AND THE BED RAIL. THE VICTIM WAS TAKEN TO THE HOSPITAL WHERE SHE WAS PRONOUNCED DEAD FROM POSITIONAL ASPHYXIA.**
94	**050324HCC1605**	**0451042101**	**X0510727A**	**10/9/2004**	**VA**	**NORFOLK**	**8**	**F**	**202**	**A TWO MONTH OLD FEMALE DIED OF MECHANICAL ASPHYXIA AFTER SLIPPING BETWEEN THE MATTRESS AND A REMOVABLE BED RAIL WHILE SLEEPING IN AN ADULT BED WITH HER MOTHER.**
95	041021HCC3034	I04A0226A		10/14/2004	AZ	TUCSON	0	F	2	A 2-YEAR OLD GIRL WAS SLEEPING ON HER BED WHEN SHE ROLLED OVER TO THE SIDE AND SLIPPED DOWN BETWEEN THE MATTRESS AND A BEDRAIL THAT WAS ON THE SIDE OF THE BED. THE CHILD WAS BETWEEN THE BEDRAIL AND THE MATTRESS AND CRIED OUT FOR HER PARENTS. THE CHILD WAS FACING THE MATTRESS & HER FEET WERE TOUCHING THE FLOOR. SHE WAS PULLED UP OUT OF THIS POSITION BY HER MOTHER. THE CHILD WAS NOT INJURED.
96	041026CNE1840	I04A0379A		10/19/2004	FL	OLD TOWNE	1	F	3	THE CONSUMER STATES THAT HER 3-YEAR-OLD DAUGHTER FELL TO THE FLOOR AND BECAME ENTRAPPED BETWEEN A BEDRAIL AND THE SIDE OF HER MATTRESS WHILE SLEEPING. SHE STATES THAT THE CHILD STRUCK HER HEAD ON THE FLOOR DURING THE INCIDENT AND SUFFERED FROM DIZZINESS AFTERWARD. SHE REPORTS DISCOVERING THAT THE BEDRAIL HAD PULLED AWAY FROM THE SIDE OF THE MATTRESS DURING THE NIGHT ON TWO PRIOR OCCASIONS. SHE STATES THAT THE CHILD LATER BECAME DIZZY AND FELL FROM A BENCH WHILE SITTING AT THE KITCHEN TABLE, STRIKING HER HEAD ON THE FLOOR AGAIN. SEEN BY PHYSICIAN.
97	**070518HCC1504**	**0434054322**		**11/6/2004**	**NJ**	**CEDAR BROOK**	**8**	**F**	**6**	**A 6 YEAR OLD FEMALE WHO HAD EXTREME CEREBRAL PALSY WAS FOUND ON HER BACK LAYING ACROSS THE HEAD OF THE BED WITH HER NECK TWISTED AND HER HEAD WEDGED BETWEEN THE MESH RAILING ON THE BED AND THE MATTRESS. SHE WAS NOT BREATHING. CPR WAS ADMINISTERED UNTIL EMERGENCY PERSONNEL ARRIVED. SHE WAS CHECKED FOR VITAL SIGNS AND PRONOUNCED AT THE SCENE.**

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
98		I0510654A		1/21/2005	IN	EVANSVILLE	1	F	3	A 25 LB, 3 YEAR OLD FEMALE WAS CLIMBING INTO BED WHEN THE BEDRAIL SNAPPED UNDER HER WEIGHT CAUSING THE RAIL TO POP IN HER FACE. SHE THEN FELL TO THE HARDWOOD FLOOR - SHE WAS TREATED FOR HER INJURIES AND RELEASED.
99-100		I0510660A		1/27/2005	NY	TAPPAN	0	F	4	SIX MONTH OLD PORTABLE BED RAIL'S HINGE BROKE 2 TIMES. FIRST TIME CHILDREN WERE PLAYING ON IT & THE 2ND TIME IT JUST CRACKED WHEN OWNER PUT IT IN DOWN POSITION. THE RAIL IS USED ON A BED BY A GIRL, AGE 4. NO INJURY. FALL HAZARD.
101	050215CCN0442	I0520279A		2/12/2005	MI	BIRMINGHAM	0	F	3	THE CONSUMER'S THREE YEAR OLD DAUGHTER WOKE UP DURING THE NIGHT SCREAMING. WHEN THE CONSUMER WENT INTO HER ROOM SHE FOUND THE DAUGHTER WITH HER FEET DANGLING TOWARD THE FLOOR BUT HER CHEST AND HEAD STILL CAUGHT BETWEEN THE BED AND BED RAIL. NO INJURIES OCCURRED.
102	050613CNE2506	I0560135A		5/15/2005	FL	NEW PORT RICHEY	0	M	3	A THREE-YEAR-OLD MALE WAS WEDGED IN BETWEEN THE SIDE OF HIS TODDLER BED AND THE BED RAIL AT HOME WHEN THE ELBOW OF THE BEDRAIL BROKE IN TWO PIECES. HE WAS NOT INJURED.
103		J05C0002A		7/1/2005	FL	MIAMI	1	M	2	A BOY, AGE 2, WAS INJURED WHEN A STRAND OF HIS FRAYED, BEDRAIL'S MESH, ENCIRCLED HIS NECK & CUT HIS SKIN DURING BED USE. ALSO HE IS ABLE TO REMOVE THE KNOBS ON THE SCREW WHICH POSES CUTTING & CHOKING HAZARD. THE BEDRAIL WAS INSTALLED PER DIRECTION.
104-106		I0570494A		7/18/2005	FL	FT. MYERS	0	M	2	THE BEDRAILS ON CHILDS BED ARE BROKEN. THE FOLD DOWN SIDE RAIL DOES NOT LATCH PROPERLY THE CONSUMER'S 2 YEAR OLD SON HAS FALLEN OUT OF BED THREE TIMES. NO INJURY.
107		I05C0411A		12/23/2005	MA	SHERBORN	0	F	3	A 3 YEAR OLD GIRL HEAD BECAME CAUGHT BETWEEN THE SOFT BED RAIL & MATTRESS. THE GIRL'S WEIGHT HAD DISLODGED THE RAIL. ALSO THE THICKNESS OF THE MATTRESS MAY HAVE CONTRIBUTED TO THE INCIDENT. NO INJURY.
108		H0630201A		3/19/2006	IN	KENDALLVILLE	0	M	215	A BOY, AGE 15 MONTHS, WAS FOUND HANGING OFF OF A TODDLER BED & ENTRAPPED BETWEEN THE MATTRESS & THE BED RAIL WHILE SLEEPING. THE HORIZONTAL BAR IN THE MIDDLE OF THE BED RAIL BECAME DETACHED & CAUSED HIM TO SLID THROUGH THE BED RAIL. NO INJURY.
109	060725HCC2713	H0660319A		6/29/2006	OH	ELYRIA	1	F	3	A 3-YEAR-OLD FEMALE WAS IN HER TWIN SIZE BED WITH A BED RAIL ATTACHED. WHEN HER MOTHER WENT TO CHECK ON HER SHE BRUSHED AGAINST BROKEN IN HALF AND SCRATCHED HER LEG. THE MOTHER OF THE 3-YEAR-OLD RECEIVED A SCRATCH AND DID NOT SEEK MEDICAL ATTENTION. THE 3-YEAR-OLD FEMALE WAS NOT INJURED.

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
110	061128CNE1673	I06B0369A		7/23/2006	MA	DOUGLAS	0	F	2	WHILE STANDING AND HOLDING ONTO THE BED RAIL INSTALLED ON HER TWIN SIZE BED, A 2-YEAR-OLD FEMALE LOST HER GRIP ON THE FABRIC COVERED TOP BAR AND FELL HEAD-FIRST OVER THE TOP TO THE CARPETED FLOOR BELOW. THERE WERE NO INJURIES RESULTING FROM THIS INCIDENT.
111	070117HCC1252	C0710002A		12/18/2006	PA	SOUTHHAMPTON	1	F	2	A 2-YEAR-OLD FEMALE FELL OUT A TWIN-SIZE BED, KNOCKING THE BED RAIL LOOSE. SHE REPORTEDLY FELL THROUGH THE OPEN GAP BETWEEN THE MATTRESS AND THE BED RAIL AND BRUISED HER BACK. SHE WAS TREATED AT HOME.
112		**0717000449**		**1/10/2007**	**IL**	**DEKALB TWP**	**8**	**F**	**201**	**POSITIONAL ASPHYXIA. ENTRAPMENT BETWEEN MATTRESS AND BED RAILING. AUTOPSY-YES.**
113	070320CNE2118	I0730328A		3/19/2007	PA	PITTSBURGH	0	M	2	A 2 YEAR OLD MALE WAS ATTEMPTING TO CLIMB ON HIS BED WHICH HAD A BEDRAIL ATTACHED TO IT. AS HE PLACED HIS LEG OVER THE BEDRAIL AND PULL HIMSELF ONTO THE TOP OF THE BED, THE HINGES BROKE AND HE FELL ONTO THE WOOD LAMINATE FLOOR. NO ONE WAS INJURED IN THE INCIDENT.
114		I0740161A		4/6/2007	NJ	UPPER MONTCL	0		3	SAFETY WARNING LABEL ON GUARDRAIL FOR CHILDREN'S BED HAD TRANSPARENT FILM OVER IT. A CHILD, AGE 3, WAS ABLE TO REMOVE IT IN THE MIDDLE OF THE NIGHT & WAS EATING IT. NO INJURY.
115	070509CNE2316	I0750045A		4/28/2007	MA	DEDHAM	0	M	2	THERE WERE NO RESULTANT INJURIES WHEN A LOCKING MECHANISM ON A BED RAIL FAILED. THE FAILURE OCCURRED WHILE A TWO-YEAR-OLD MALE WAS ASLEEP ON A TWIN-SIZE BED WITH THE BED RAIL ATTACHED. THE 28-YEAR-OLD FATHER BELIEVED THAT THE PRODUCT POSED A SAFETY HAZARD TO YOUNG CHILDREN.
116	**080925HCC2061**	**X0820071A**	**0717039761**	**6/7/2007**	**IL**	**STEGER**	**8**	**F**	**221**	**A 21-MONTH-OLD FEMALE DIED WHILE SLEEPING WITH HER 3-YEAR-OLD BROTHER ON HIS TWIN SIZE MATTRESS WITH BED RAILS. VICTIM WAS DISCOVERED AFTER APPROXIMATELY EIGHT HOURS WITH HER HEAD CAUGHT BETWEEN THE MATTRESS AND THE BED RAIL. THE CAUSE OF DEATH WAS ASPHYXIA DUE TO BEING TRAPPED BETWEEN MATTRESS AND BED RAIL. EVIDENCE WAS RETAINED BY POLICE AND RETURNED TO FAMILY FOR LEGAL REASONS AFTER CONCLUSION OF INVESTIGATION.**
117	071017HCC2032	I0790044A		8/10/2007	OH	BELLEVUE	0	M	201	A 1 1/2-YEAR-OLD MALE FELL OUT OF HIS TWIN BED SEVERAL TIMES AFTER THE DETENTS WHICH ARE SUPPOSED TO HOLD THE BEDRAIL IN AN UPRIGHT POSITION DID NOT DO SO. THE 1 1/2-YEAR-OLD MALE WAS NOT INJURED.

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
118	071004CNE2807	I07A0071A		9/26/2007	GA	NORCROSS	1	F	2	A TWO YEAR OLD FEMALE WAS SLEEPING IN A STANDARD TWIN SIZED BED EQUIPPED WITH A BED RAIL. DURING THE NIGHT SHE WAS ABLE TO EXPAND, WHAT WAS A SMALL FINGER SIZED HOLE, TO A SIZE THAT WOULD ALLOW HER HEAD TO FIT THROUGH. WHEN THE VICTIM CRIED OUT, THE COMPLAINANT WENT TO CHECK ON HER AND FOUND THE VICTIM WITH HER HEAD COMPLETELY THROUGH THE MESH IN THE BED RAIL. AFTER RIPPING THE MESH TO EXTRICATED THE VICTIM, A BRIEF PERIOD OF HYPERVENTILATING OCCURRED. THE VICTIM SUSTAINED MINOR REDNESS AND IRRITATION ON HER NECK.
119	071010CNE2831	I07A0183A		9/26/2007	MD	PORT REPUBLIC	1	M	3	THE 3YO VICTIM WAS ASLEEP IN HIS BED ONE NIGHT WHEN HE ROLLED OVER AND THE PLASTIC HINGES HOLDING THE BED RAIL UP BROKE CAUSING THE VICTIM TO FALL OUT OF BED AND ONTO THE FLOOR. THERE WERE MINOR BRUISES IN THIS INCIDENT.
120-121	080123HCC2387	I07B0569A		11/18/2007	MN	KASSON	0	F	222	A 22-MONTH-OLD FEMALE WAS SLEEPING IN A TWIN SIZE BED THAT WAS EQUIPPED WITH A PORTABLE BED RAIL. DURING THE NIGHT, THE CHILD'S PARENTS HEARD THEIR DAUGHTER CRY OUT. THE YOUNG CHILD WAS FOUND WEDGED BETWEEN THE MATTRESS AND BED RAIL IN A VERTICAL POSITION. THE CHILD'S FEET HAD PASSED THROUGH AN OPENING THAT HAD FORMED BETWEEN THE BED RAIL AND MATTRESS. THE CHILD WAS UNHURT. A SIMILAR NON-INJURY INCIDENT HAD OCCURRED ONE MONTH PRIOR WITH THE SAME BED RAIL.
122	**090903HCC1056**	**X08A0368A**		**12/18/2007**	**NJ**	**TRENTON**	**8**	**M**	**2**	**A 2 YEAR OLD BOY DIED OF ASPHYXIA WHEN HIS HEAD & NECK WERE CAUGHT BETWEEN A BED RAIL AND THE MATTRESS IN WHICH HE WAS SLEEPING.**
123		I0830257A		3/10/2008	MN	SPRING PARK	1	M	3	3 YEAR OLD BOY PINCHED THE SOFT FLESHY PART OF HIS RIGHT PALM BETWEEN THE BED SAFETY RAIL FOR HIS TWIN MATTRESS & THE CORNER PIECE BECAUSE OF THE MOVEMENT OF THE RAIL & THE DESIGN OF THE CORNERS. THE PINCH CAUSED ACUT ON HIS HAND.
124		I0830400A		3/16/2008	CA	WEST HILLS	0	F	4	A 4 YEAR OLD GIRL FELL FROM HER BED AFTER HER MOTHER PUSHED AGAINST ONE OF THE BED RAILS OF THE THE BED & RAIL FAILED & FELL TO THE FLOOR. CONSUMER STATED THE BED RAILS ARE DESIGNED TO PROTECT CHILDREN FROM FALLING FROM THEIR BEDS. NO INJURY.
125		I0850376A		5/21/2008	VA	MIDLOTHIAN	1	M	3	A CONSUMER REPORTED THAT HER 3 YEAR-OLD SON WAS HOLDING ONTO THE BED RAIL WHEN IT SNAPPED AND HE FELL TO THE FLOOR, SUFFERING A FRACTURED CLAVICLE.
126	080611CNE3488	I0860155A		5/31/2008	CT	WESTBROOK	0		0	A BED RAIL'S NETTING HAD BEGUN TEARING AWAY FROM THE FRAME. A RETAIL STORE STATED THAT THIS PRODUCT APPEARED TO BE DEFECTIVE. NO INJURY.

inc_num	tkno	docno	other docs	dt_inj	state	city	disp	sex	age	narrative
127	080821HCC3793	I0880183A		8/8/2008	NJ	HARVEY CEDARS	1	M	3	A 3 Y/O MALE WAS SLEEPING IN A TWIN BED WITH A BOX SPRING AND INNERSPRING MATTRESS. THE BED HAD BEEN TEMPORARILY FITTED WITH A SET OF PORTABLE BED RAILS BECAUSE THE CHILD HAD A RECORD AS A RESTLESS SLEEPER. AROUND 1 OR 2 AM THE CHILD'S PARENTS WERE AWAKENED BY CRIES OF DISTRESS. THEY FOUND THE CHILD WITH HIS FEET ON THE GROUND BETWEEN THE SIDE OF THE BED AND ONE OF THE RAILS. THE CHILD SUSTAINED BRUISES AND ABRASIONS TO HIS INNER THIGHS. A BREAK IN ONE OF THE CONNECTORS THAT JOIN THE STRAPS WHICH HOLD THE RAILS TOGETHER WAS NOTED DURING THE INVESTIGATION.
128		I0930279A		3/11/2009	NY	VALLEY COTTAG	0	F	3	THE DOUBLE BED RAIL ON A THREE YEAR OLD GIRL'S BED BROKE CAUSING HER TO FALL FROM HER BED. NO INJURY.
129		Retailer rpt		6/26/2009	NY	AMITY HARBOR	1	M	2	INFLATABLE BED RAIL DID NOT HELP KEEP TWO YEAR OLD STAY IN THE BED BECAUSE THE ELASTIC THAT HOLDS IT TO THE BED EASILY SLIDES OFF. HE FELL OUT OF BED DURING THE NIGHT AND GOT TANGELED IN IT.
130		I09C0262A		12/1/2009	IN	TERRE HAUTE	1	M	3	CONSUMER HAS A BED RAIL ON HER BED AND HER 3-YEAR-OLD NEPHEW JUST PUT HIS HAND ON IT AND IT COLLAPSED. HE FELL AND RECEIVED CUTS ON HIS EYE, NOSE, SCRAPED THE TOP OF HIS EYE AND HAS A CUT ON HIS EYELID.
131		I1020915A		2/19/2010	IN	BLOOMINGTON	0	M	3	THE BOLT CONNECTING THE BOTTOM RAIL TO THE SIDE RAIL SHEARED OFF, MAKING THE RAIL UNSTABLE.
132		I0880405A		unknown	PA	GREENCASTLE	0	M	218	18 MONTH OLD BOY HAS BEEN USING A TWIN BED WITH DOUBLE BEDRAILS. THE FOOT OF THE BEDRAIL THAT SLIDES UNDER THE BED IS BROKEN AND UNUSABLE. NO INJURY.

TAB B: Portable Bed Rail-Related Deaths and Injuries

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: January 27, 2011

TO : Rohit Khanna
Portable Bed Rails Project Manager
Office of Hazard Identification and Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director,
Directorate for Health Sciences
Lori E. Saltzman, M.S., Division Director, Division of Health Sciences

FROM : Suad Wanna-Nakamura, Ph.D., Physiologist

SUBJECT : Portable Bed Rail-Related Deaths and Injuries

Introduction

A portable bed rail is defined by ASTM as a device intended to be installed on the side and/or on the mattress surface of an adult bed, which is intended to keep a child from falling out of bed (ASTM F2085-10). Manufacturers intend the product to be used for young children who can get in and out of an adult bed unassisted (typically for children from 2- to 5-years-old).

This memorandum provides information on deaths associated with the use of portable bed rails. Three CPSC data files were searched for incidents occurring during the period from January 1, 2000 through March 31, 2010. The databases used for this purpose were: Injury and Potential Injury Incidents, In-Depth Investigations, Death Certificates, and NEISS data (Chowdhury, 2011, Tab B "Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries; 2000–Present"). The search revealed a total of the 132 incidents related to youth portable bed rails. Of these 132 reported incidents, there were 13 fatalities, 40 nonfatal injuries, and 79 noninjury incidents and/or consumer complaints.

Fatalities: There were 13 reported fatalities associated with portable bed rails. In 12 of the 13 incidents, the manner of death, as determined by the medical examiner, was asphyxia due to entrapment in gaps generated between the bed side rail and the bed mattress. The gaps occurred due to misassembly of the bed rail or improper installation, or a shift in position (displacement) during use of the bed rail. The remaining incident was classified as asphyxia by hanging, when an infant's head was caught in the guard rail. Most deaths involved children under 1-year-old (9 out of 13); two children were between the ages of 1- and 2-years-old; the remaining two victims

were both physically handicapped 6-year-olds, one with Rett syndrome (a neurological and developmental disorder) and one with cerebral palsy. In five of the 13 incidents, it was reported that the victim was sharing a bed with a parent or sibling. Four of the five were infants under 1-year-old sleeping with their parents on an adult-size bed, and the fifth victim was a 21-month-old child sharing a bed with a sibling.

Eight of the thirteen fatal incidents were investigated by CPSC staff. Two of the eight deaths were due to product displacement; three deaths involved misassembly of the product. In one incident, the consumer did not install the middle bar, and the child rolled into the space between the missing bar and the mesh and ended up wedged between the mattress and the rail with their face pressed against the mattress. In another incident the consumer failed to pull the mesh over the lower metal bar. The child became entrapped at the neck when their body slipped through the opening created between the bottom edge of the mesh panel and the lower rail bar.

Based on the limited information available in the In-Depth Investigations, in the three remaining deaths, it was not clear whether the space between the bed rail and mattress was due to improper installation or a shift in position (displacement) during use (*i.e*., being moved away from underneath the mattress). It is important to note that in two of the five incidents, the consumers probably were aware of the space and had inserted bedding to close the gaps. In one incident, a pillow was used to fill the gap; and in the second incident, a rolled blanket was used to fill the gap.

Health Sciences Staff Conclusion: In 8 of the 13 fatal incidents associated with portable bed rails that were investigated by CPSC staff, improper installation and misassembly were the two major contributing factors. In addition, portable bed rails pose the most significant risk to infants and young children under 2-years-old. This product is not intended for this age group. Placing babies to sleep in adult beds puts them at risk of suffocation, strangulation, and entrapment. Adult beds are not a safe sleeping environment for very young children. Despite the current warning label cautioning against product use with children under 2-years-old, parents of infants continue to use this product with their infants. Placing a railing on the side of an adult bed does not make the adult bed effectively safe for infants (*i.e*. convert an adult bed into a crib). Many parents and caregivers are probably not aware that placing babies in adult beds puts them at risk for hazards such as: (1) suffocation; (2) strangulation; (3) entrapment in the bed frame, headboard, footboard, bed railings, or adjacent furniture; and (4) possible overlay from bed sharing. The safest place for an infant under age two is a crib, play yard, or bassinet that meets federal safety standards.

TAB C: Evaluation of ASTM F 2085-10a, *Standard Consumer Specification for Portable Bed Rails*

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

DATE: February 22, 2011

To: Rohit Khanna
Project Manager, Portable Bed Rails

Through: Erlinda M. Edwards
Acting Associate Executive Director
Directorate for Engineering Sciences

From: Mark E. Kumagai, P.E.
Division Director, Mechanical Engineering

SUBJECT: Evaluation of ASTM F 2085-10a, *Standard Consumer Specification for Portable Bed Rails*

I Background/Overview

Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*, requires the U.S. Consumer Product Safety Commission (CPSC) to assess the effectiveness of voluntary consumer product safety standards for durable infant and toddler products and to promulgate mandatory safety standards. Section 104 (b)(1)(B) states: "The Commission shall … promulgate consumer product safety standards that—(i) are substantially the same as voluntary standards; or (ii) are more stringent than such voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products."

CPSC Division of Mechanical Engineering (ESME) staff conducted an assessment of the voluntary standard, ASTM F 2085-10a, *Standard Consumer Specification for Portable Bed Rails.* ESME staff concluded that additional requirements to address potential hazards associated with misassembly and misinstallation of portable bed rails are needed. CPSC staff is aware of three fatal incidents involving misassembled bed rails. CPSC staff is not aware of deaths associated with misinstallation; however, based on analysis of sample bed rails, staff believes that some consumers are likely to have difficulty assembling and installing portable bed rails properly, which could lead to potentially hazardous conditions.

II. ASTM/Bed Rail History

The ASTM standard for bed rails, F 2085, was first published in May 2001. This was a minimum standard with requirements for labeling but no performance requirements. The bed rails that met the 2001 standard typically were designed with two arms at right angles to the

vertical portion of the rail, as shown in Figure 1. This type of bed rail is installed on a bed by inserting the arms between the mattress foundation and the mattress.

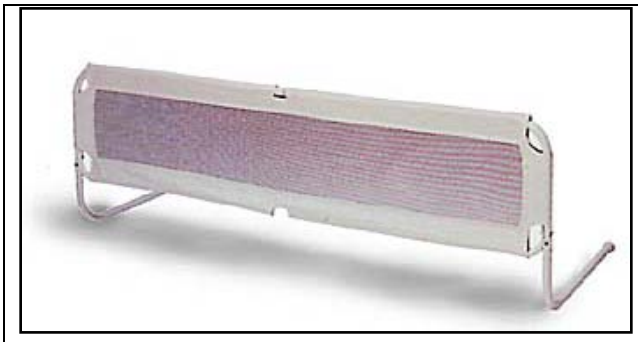


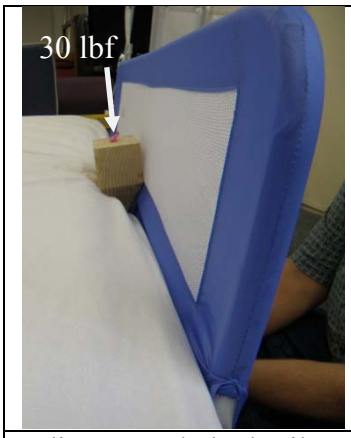
Figure 1. Older Style Portable Bed Rail

These older style bed rails relied on friction between the arms and the foundation/ mattress to stay in place. However, this type of design allowed the bed rail to be moved outward unintentionally, away from the mattress, if a force was applied in that direction. An outward force may originate from activity of a child in the bed, while the child is asleep, or awake. Once moved outward, a gap could be created between the vertical portion of the rail and the side of the mattress. The primary hazard scenario involves a child rolling into a gap between the mattress and the bed rail and becoming entrapped. Once entrapped, the child can asphyxiate or strangle.

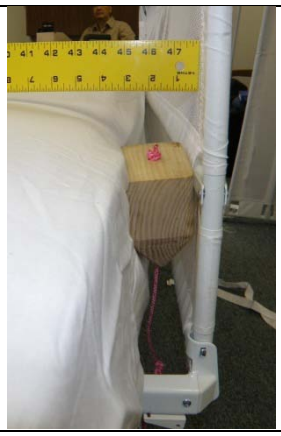
On October 3, 2000, the Commission initiated a rulemaking proceeding on portable bed rails by publishing an advance notice of proposed rulemaking (ANPR) in the *Federal Register* (65 FR Reg 58968).[7] Approximately one year later, on October 30, 2001, the Commission voted 3–0 to continue rulemaking and directed the Office of the General Counsel (OGC) to prepare a notice of proposed rulemaking (NPR) for Commission consideration based on a proposed standard developed by staff.[8] During the same time period, the ASTM Subcommittee on Portable Bed Rails agreed to ballot a revision of the standard that was substantially the same as staff's proposed standard; accordingly, the NPR was postponed. The voluntary standard revision was approved and published in June 2003.

The 2003 version of the standard (ASTM F 2085-03) significantly revised ASTM F 2085-01 to address the entrapment hazard, by including a new section in the standard, *Openings Created by a Displacement,* with requirements to address displacement of a bed rail." ASTM F 2085-03 required that the bed rail resist movement away from the mattress when subjected to a given outward 30 lb force. The requirements were intended to simulate the weight of a 95th percentile 19-month-old boy. The 30 lb force is applied using a specially designed probe, as shown in Figure 2.

[7]Patricia Hackett, OPTIONS TO ADDRESS PORTABLE BED RAIL HAZARDS June 2000 http://www.cpsc.gov/library/foia/foia00/brief/bedrail1.pdf.
[8] Patricia Hackett, OPTIONS TO ADDRESS PORTABLE BED RAIL HAZARDS October 2001 http://www.cpsc.gov/library/foia/foia02/brief/Bedrails1.pdf.



Adjacent style bed rail (pass)



Adjacent style bed rail (fail)

Mattress-top style bed rail (pass)

Figure 2. Displacement Test–30 Lbf Applied Using Torso Probe

To meet the new requirements, manufacturers of adjacent style bed rails designed bed rails to include one or two rigid cross bars, as shown in Figure 3, that help prevent the formation of an entrapment gap, and an anchor system that extends to the other side of the mattress, as shown in Figure 4.

Figure 3. Rigid Cross Bar at Arrow

Figure 4. Anchor

Some manufacturers designed bed rails with two rails—one on each side of the mattress, which were tethered together under the mattress—as shown in Figure 5. For bed rails designed to sit on the top surface of the mattress, a clamping mechanism secured the bed rail to the mattress, as shown in Figure 6.

Figure 5. Double-Sided Bed Rail

Figure 6. Mattress-Top Bed Rail

The standard requires that the displacement tests be conducted on two different mattresses that have the following specifications:

- Mattress Platform 1: a 4- to 5-inch thick, twin-size mattress, representative of a low-cost mattress on a typical box foundation and metal frame.

- Mattress Platform 2: a 10- to 11-inch thick, twin-size mattress, representative of a moderate to higher cost mattress on a typical box foundation and metal frame.

The rationale for picking two widely different mattresses is to ensure that a bed rail will function safely and as intended on a variety of mattresses.

In 2008, ASTM published a revised standard that included a structural integrity test. In this test, ASTM F 2085-08 required that a 40 lb force be applied to the bed rail at three points on the top rail, as shown in Figure 7 to test the structural integrity of the hinges.

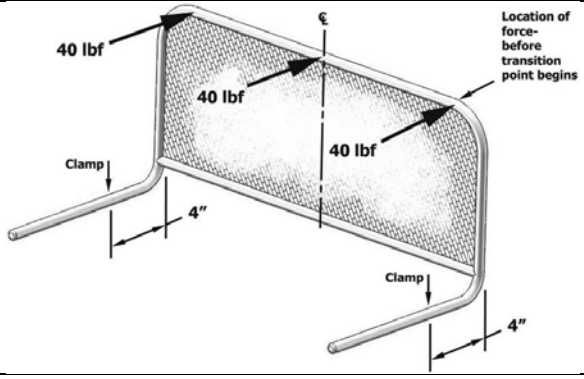


Figure 7. ASTM F 2085-08, Structural Integrity Test

In 2009 and 2010, minor revisions were made to the standard. The current standard is ASTM F 2085-10a.

III. International Standards

CPSC staff reviewed the British Standard Institution's (BSI) standard for bed rails, BS 7972:2001 +A1:2009 *Safety requirements and test methods for children's bedguards for domestic use*. Bedguards are similar to bed rails as defined in the ASTM standard. The BSI standard primarily addresses entrapment and structural integrity, and includes requirements for warning labels. It does not address missassembly or misinstallation. The BSI standard has a test requirement for the bed rail to remain attached to the bed after rolling a 30 lb cylinder into the bed rail. The test appears to be a simulation of a child rolling into the bed rail.

CPSC staff conducted limited testing to compare the requirements of the BSI standard to requirements in the ASTM standard that address potential entrapment hazards. Staff concluded that the ASTM requirement for mattress gaps is more stringent than the BSI requirements. The ASTM tests consist of forcing a wedge block probe between the mattress and bed rail. CPSC staff observed that the wedge block probe in the ASTM test will compress the mattress and deform the horizontal bar on some bedrails. The BSI test did not compress the mattress nor did the bedrail deform. This indicates that the ASTM tests impart a larger force on the bed rail components at the mattress interface than the BSI tests. Stressing the mattress and bedrail interface is critical in determining if the bedrail is adequately designed to prevent a hazardous gap from forming between the mattress and bed rail. For this reason, CPSC staff believes that ASTM F2085-10a *Standard Consumer Safety Specification for Portable Bed Rails* is more stringent than the BSI standard, BS 7972:2001 +A1:2009 *Safety requirements and test methods for children's bedguards for domestic use*. Staff is not aware of any other standards for portable bed rails for children.

IV. Engineering Assessment

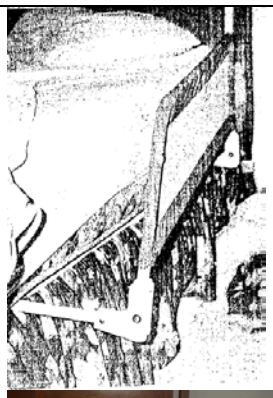
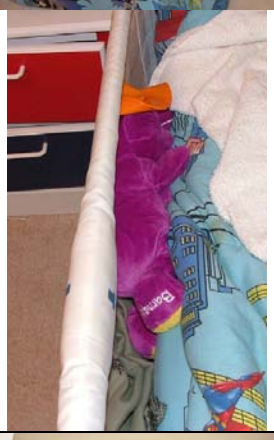
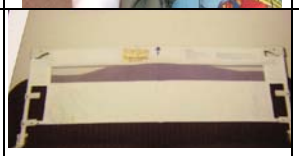
To assess the adequacy of ASTM F 2085-10a, CPSC staff tested a variety of bed rails currently in the market. Most of the bed rails were certified to ASTM F 2085-10a by the Juvenile Products Manufacturers Association (JPMA). Staff also purchased products made of foam and inflatable materials that are intended to prevent children from falling out of beds. Although these foam and inflatable products did not use the term "bed rail" in their packaging or labeling, staff believes they meet the definition of a portable bed rail and should be included in the scope of voluntary standard. Because ASTM F 2085 was developed to address the hazards associated with bed rails made of rigid (wood/metal) materials, most of the performance requirements of the standard do not apply to these products. However, the General Requirements of section 5; the performance requirement of subsection 6.3, Enclosed Openings; and the warning requirement of subsection 9.3.1 of section 9, Marking and Labeling would apply to foam and inflatable portable bed rails products.

For bed rails that are assembled and installed in accordance with the manufacturer's instructions, staff believes that the requirements to address structural integrity and to prevent displacement from the mattress are adequate. However, if the bed rail is misassembled or misinstalled on the bed, it could present an entrapment hazard. ASTM F 2085-10a does not address misassemby or misinstallation.

CPSC staff analysis of the incident data and evaluation of sample bed rails indicate that misassembly and/or misinstallation could present a potential hazard. CPSC staff reviewed the eight In-depth Investigation (IDI) reports of fatal incidents associated with bed rails that are reported to have occurred from 2000 to 2010. Staff determined that two of the eight incidents involved bed rails that were manufactured prior to the 2003 version of the ASTM standard, and found that neither bed probably had a mechanism to secure the rail to the bed. Based on photographs and the dates of the incidents, CPSC staff determined that three of the eight incidents involved bed rails that were likely to have been manufactured to meet the requirements of the 2003 ASTM standard but appeared to be misassembled. The remaining three incident reports did not have enough information to make a determination of the age of the product or the cause of the incident. Table 1 provides a summary of the eight fatal incidents.

Table 1 – Summary of Fatal Incidents

	IDI	Date of Incident	Synopsis from IDI	Photo	Analysis
1	000913HWE6005	5/21/2000	6-month-old female victim had been sleeping in bed with her parents with a bed rail positioned on one side of the bed, when she was discovered unresponsive and wedged between the bed rail and the mattress. The victim was transported to the hospital via ambulance where she was pronounced dead.		Displacement–Bed rail was manufactured prior to 2003 ASTM standard and probably did not have a mechanism to prevent displacement from the mattress.
2	030730HCC1771	9/21/2002	A 5-month-old male was pronounced dead from asphyxia when he became entrapped by a portable bed rail. The bed rail had been improperly assembled. The child rolled-over and his head slipped between the fabric mesh panel and the top edge of the twin-size mattress, cutting off his circulation.		Misassembly–The mesh cover was not assembled over the lower horizontal bar.
3	031201HCC2146	8/2/2003	A 5-month-old female was placed in a queen-size bed to sleep. After approximately 20 minutes, the child's father went to check on her and found her unresponsive with her head trapped between the mattress and a plastic bed rail with a pillow on her face. The victim was taken to the hospital where she died three days later. An autopsy was performed which confirmed the cause of death as hypoxia due to being trapped between bed rail, mattress, and pillow.		Unknown - The information in the IDI was not sufficient to determine the type of bed rail, the way it was installed, or how the victim was entrapped.

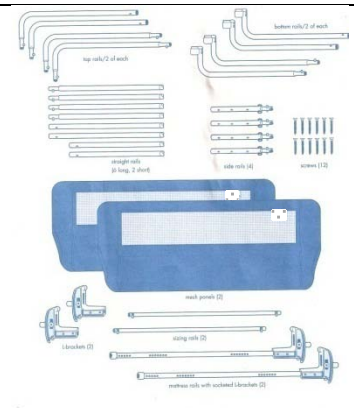
4	040727HCC2657	12/30/2003	The consumer's 4-month-old daughter was co-sleeping in an adult-sized bed with her 2-year-old sister when she unexpectedly rolled over and became wedged between the mattress and the portable bed rail. The infant child died as a result of positional asphyxia.	 	Displacement–Bed rail was manufactured prior to 2003 ASTM standard and did not have a mechanism to prevent displacement from the mattress.
5	050721HBB1979	8/28/2004	An 8-month-old female was placed on an adult twin-size bed while sleeping. The bed was equipped with a portable bed rail. The victim's grandmother checked on the victim after she had been sleeping for approximately 30 minutes. Everything was normal. After the victim had been sleeping for an additional 90 minutes, the victim's grandmother checked on the victim and found her face down, wedged between the mattress and the bed rail. The victim was taken to the hospital where she was pronounced dead from positional asphyxia.	 	Unknown–The information in the IDI was not sufficient to determine the type of bed rail, the way it was installed, or how the victim was entrapped.
6	050324HCC1605	10/09/2004	A 2-month-old female died of mechanical asphyxia after slipping between the mattress and a removable bed rail while sleeping in an adult bed with her mother.		Misassembly–The middle horizontal bar was not assembled.

7	070518HCC1504	11/6/2004	A 6-year-old female who had extreme cerebral palsy was found on her back lying across the head of the bed with her neck twisted and her head wedged between the mesh railing on the bed and the mattress. She was not breathing. CPR was administered until emergency personnel arrived. She was checked for vital signs and pronounced dead at the scene.		Unknown –The information in the IDI was not sufficient to determine the type of bed rail, the way it was installed, or how the victim was entrapped.
8	080925HCC2061	6/7/2007	A 21-month-old female died while sleeping with her 3-year-old brother on his twin-size mattress with bed rails. The victim was discovered after approximately eight hours with her head caught between the mattress and the bed rail. The cause of death was asphyxia due to being trapped between the mattress and bed rail.		Misassembly–The middle horizontal bar was not fastened.

Many bed rails require the consumer to assemble a large number of parts while carefully following multistep instructions. Installation of a bed rail onto a bed can require complex or physically demanding adjustments to the bed rail, particularly when reaching between the mattress and mattress foundation. A misassembled or improperly installed bedrail has the potential of moving away from the mattress and creating a hazardous gap.

CPSC staff is aware of three deaths associated with improper assembly of bed rails. Currently, most bed rails sold require extensive assembly by the consumer. Figure 8 shows examples of the parts that a consumer must assemble to form some bed rails, some of which have more than 20 parts and 10 pages of assembly instructions.

Bed rail–20 parts



Bed rail–40 parts

Bed rail–12 parts

Figure 8. Bed Rail Assembly Components

On September 23, 2010, CPSC staff's draft proposals to address misassembly and misinstallation were sent to a task group of the ASTM Subcommittee for Portable Bed Rails for review (see Appendix A, *CPSC staff draft letter to ASTM task group requesting development of performance requirements to address misassembly and misinstallation of bed rails*).

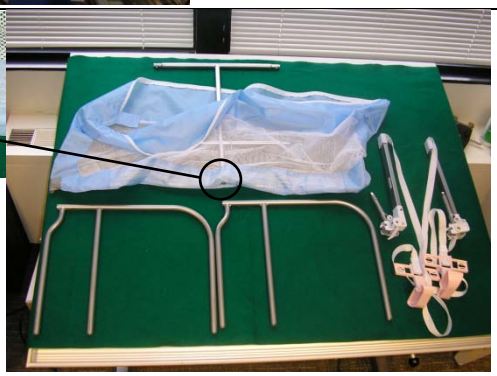
On November 12, 2010, the ASTM Subcommittee met to respond to CPSC staff's request. A task group, which had been formed to address CPSC staff's concerns, indicated that staff's request did not represent a practical approach because it required the technician (conducting third party testing) to determine what components are critical to the safe operation of the bed rail. The task group was also concerned that the proposed requirements were outside the scope of the standard because the standard was not intended to address hazards associated with products that are "… *blatantly misused or used in a careless manner that disregards the instructional literature and warning statements provided with each bedrail*."[9] In addition, manufacturers informed CPSC staff that preassembled bed rails were not feasible because preassembly would increase the size of packaging, and there is limited retailer shelf space. Instead, the task group suggested stronger labeling, same size fasteners and locking devices with visual or audible cues to address misassembly and misinstallation (see Appendix B, *ASTM Assembly Guide Task Group recommendations to address CPSC staff's proposal for misassembly*).

Subsequently, CPSC staff has been participating in ASTM Subcommittee task group activities to refine and provide more detailed performance requirements to address scope, missassembly, misinstallation, and warning labels. Specifically, staff recommended that, if the bed rail can be misassembled, it must not be able to stand upright or it must provide a visual cue for misaligned parts. CPSC staff also recommended scope clarification (to include foam and inflatable bed rails) and additional labeling on the product to notify the consumer of the importance of using and correctly installing critical installation components. The recommended revisions to ASTM F2085 were balloted to the ASTM Subcommittee on February 24, 2011. Appendix C, *CPSC staff/ASTM Subcommittee Task Group proposed requirements to address scope, misassembly, misinstallation, and warning labels for portable bed rails*, provides detailed performance requirements with supporting rationale.

V. Prototype Bed Rail to Address Misassembly

CPSC staff is not aware of any bed rails currently on the market that would meet the staff's proposed requirements to address misassembly or misinstallation. While some redesign would be necessary, CPSC staff believes that some bed rails can be designed to reduce the incidence of misassembly and also fit in the current packaging size. ESME staff modified two bed rails to meet the staff proposed requirements, including minimal change to the packaging size (see Figure 9). Figure 10 shows how the bed rail would be assembled.

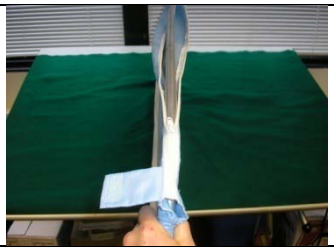
[9] ASTM F 2085-10a–statement in the Introduction.



Bed rail in packaged condition (20″ x 20″)	Bed rail parts–left, right, center metal frame; legs (2); mesh cover (note: the mesh cover is riveted to the center frame)

Figure 9. Modified Adjacent Style Bed Rail Meeting Staff's Proposed Requirements

Step 1. Frame assembly–attach left and right parts to the center part to form the frame (right)



Step 2. Slip mesh cover onto the frame

Step 3. Zip cover over the top bar

Step 4. Insert legs into covered frame

Figure 10. Steps to Assemble Modified Adjacent Style Bed Rail

Figure 11 shows examples of misassembly that do not allow the bedrail to remain upright or provide a visual cue that the fabric cover is not assembled correctly.

Misassembly of frame–this misassembly does not provide sufficient structure for the bed rail to remain upright.

Misassembly–failure to attach the fabric cover; the fabric cover hangs down more than 3 inches and provides a visual cue to the consumer that the bed rail has been misassembled

Figure 11. Examples of Misassembly that Provide Visual Cue

Figure 12 shows a modified mattress-top bed rail that would meet staff's proposed misassembly requirements. The bed rail was modified so that the consumer would need to pull out the sides to expand the rail. There are three internal telescoping rods that lock into place when fully expanded. The locking mechanism is a detent pin that engages and clicks when the rod is fully expanded. The final step is to insert the feet and foot rod, as shown in Step 3.

Step 1–Collapsed bed rail removed from packaging (approximately 20″ x 24″)

Step 2–The rail portion is expanded by pulling out the sides (approximately 42″ x 20″)

Step 3. Fully assemble bed rail by inserting the feet and foot bar in the expanded rail section (Note: the foot rod is not a critical component)

Figure 12. Modified Mattress-Top Style Bed Rail Meeting Staff's Proposed Requirements

VI. Conclusion

ESME evaluation of ASTM F 2085-10a and a review of the incident data indicate that the requirements to prevent a hazardous gap due to displacement of the bed rail from the mattress are adequate, provided that the bed rails are assembled and installed in accordance with the manufacturer's instructions. However, if the bed rail is misassembled or misinstalled on a bed, it could present an entrapment hazard. ASTM F 2085-10a does not address misassemby or misinstallation. CPSC staff recommends that bed rails meet additional requirements, as drafted in Appendix C, to address scope, misassembly, misinstallation, and warning labels.

APPENDIX A

CPSC staff draft letter to ASTM task group, requesting development of performance requirements to address misassembly and misinstallation of bed rails

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Rohit Khanna
Portable Bed Rails Project Manager
Office of Hazard Identification and Reduction

Tel: (301) 504-7546
Fax: (301) 504-0533
Email: rkhanna@cpsc.gov

September XX, 2010

Mr. Antonio S. Fernandes, Chairman ASTM F15.11
Director, Product Integrity and Safety
DOREL JUVENILE GROUP
Design and Development Center
25 Forbes Boulevard, Suite 4
Foxboro, MA 02035

Subject: Recommendations to ASTM F 2085-10, *Standard Consumer Safety Specification for Portable Bed Rails*

Dear Mr. Fernandes:

This letter presents recommendations from the U.S. Consumer Product Safety Commission (CPSC) staff* regarding ASTM F 2085-10, *Standard Consumer Safety Specification for Portable Bed Rails*, to address hazards to children posed by foreseeable misassembly and misinstallation of portable bed rails that can result in entrapment deaths.

CPSC staff is aware of two incidents involving entrapment fatalities resulting from misassembly of portable bed rails. In the first incident (IDI 050324HCC1605), a review of the in-depth investigation report showed that the portable bed rail's middle bar[1] was not installed. The gap created by the missing bar resulted in an entrapment death of a two month old infant. In the second incident (IDI030730HCC1771), the portable bed rail's mesh cover was not pulled over the lower bar and resulted in an entrapment death of a five month old infant.

These two incidents show that when portable bed rails are not assembled in accordance with the manufacturer's intended configuration, entrapment deaths can

* This letter was prepared by the CPSC staff; it has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

[1]CPSC staff believes that the middle bar for this bed rail provides support to the fabric/mesh to prevent excessive stretching.

occur. The current ASTM bed rail standard (F 2085-10) does not address misassembly or misinstallation. For this reason, CPSC staff recommends that the following proposed requirements be incorporated into the standard to address these foreseeable hazards.

CPSC Staff Recommendations to ASTM F 2085-10

Proposed requirement to address mis-assembly of portable bed rails:

3. Terminology
3.1.x *critical safety component, n* – any component of the bedrail that requires assembly or installation in order to meet the performance requirements in sections 6.1, 6.3 and 6.4.

5. General Requirements

5.6 Bedrails shall be designed such that if a critical safety component is misassembled or incompletely assembled, it will result in a bedrail without sufficient vertical structure to support itself.

Rationale: Components such as horizontal stabilizer bars and anchor straps are critical safety components. If these components are not assembled properly, the bed rail can present an entrapment hazard. Figures 1 and 2 show incident bed rails that were not properly assembled. IDI 050324HCC1605 involved an incident in which the middle bar was not installed, which resulted in an entrapment death. IDI030730HCC1771 involved an incident in which the mesh was not pulled over the lower bar, which resulted in an entrapment death. Both of these incidents show a need for the ASTM standard to include provisions that address foreseeable misassembly.

050324HCC1604 Exhibit 1(a) – This is a digital photo of hard copy photo in M.E.'s case file showing the bedrail that was involved in the incident. Note that the product does not have the middle bar that should have come with it when purchased.

Figure 1. Incident bed rail - IDI 050324HCC1605 A two month old female died of mechanical asphyxia after slipping between the mattress and a removable bed rail while sleeping in an adult bed with her mother.

PHOTO B: The caption depicts the investigator's assessment of the entrapment incident (bed rail unit installed improperly).

Figure 2. Incident bed rail - IDI030730HCC1771 - A five month old male was pronounced dead from asphyxia when he became entrapped by a portable bed rail. The bed rail had been improperly assembled. The child rolled over and his head slipped between the fabric mesh panel and the top edge of the twin-size mattress, cutting off his circulation.

Figure 3 shows an anchor strap intended to be buckled to the bed rail. If the strap is not used or if the strap is lost, the bed rail will not securely attach to the bed. CPSC staff recommends that this critical safety component be permanently attached to the bed rail and anchor.

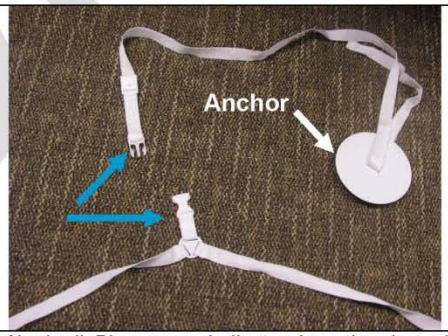


Figure 3. Misassembly of bed rail. Blue arrows indicate where the piece should be attached to the rest of the bed rail.

Proposed requirement to address misinstallation of portable bed rails:

Misinstallation of a bed rail is not addressed in the current standard. A misinstalled bed rail may detach from the mattress and form a hazardous gap. For example, if the anchor strap and anchor is not installed to the bed, the bed rail will not be securely attached to the bed.

5.7 Critical safety components used to secure the bed rail onto the bed shall:

1. be designed so that installation onto the bed can only be achieved in the manufacturer's intended configuration. Misinstallation or partial installation shall result in a bed rail without sufficient vertical structure to support itself **or**
2. have a permanent marking that identifies the component as a critical component and states that the component must be installed correctly for the safe operation of the bed rail. The marking shall include steps required for proper installation.

Rationale: A component, such as a locking clamp on a mattress-top bed rail or an anchor plate/strap like the ones shown in Figures 4 and 5, is a critical safety component and, if not installed properly, can result in an entrapment hazard.

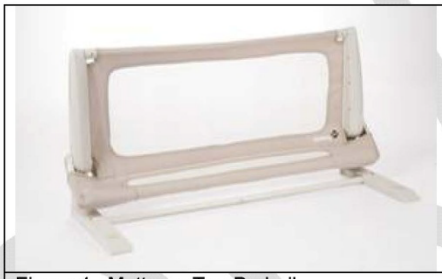


Figure 4. Mattress-Top Bedrail

Figure 5. anchor plate/strap

CPSC staff recommends that ASTM F 2085 be revised to include requirements to address foreseeable misassembly and misinstallation of portable bed rails, as detailed above. Two incidents are presented as examples to show that if bed rails are not assembled and installed properly, a fatal entrapment hazard can be created. The proposed language should reduce the likelihood of entrapment deaths occurring from foreseeable misassembly and misinstallation.

If you have any questions or would like any additional information or clarification regarding these recommendations, please feel free to call me at (301) 504-7546 or email me at rkhanna@cpsc.gov. Thank you for your consideration of these important consumer product safety concerns.

Sincerely,

Rohit Khanna

cc: Colin Church, CPSC Voluntary Standards Coordinator
Len Morrissey, ASTM International

Appendix B

Recommendations from the ASTM Assembly Guide Task Group on Bed Rails to Address CPSC Staff's Proposal for Misassembly

Designation: F 2085
Standard Consumer Safety Specification for Portable Bed Rails
Assembly Guide Task Group
DRAFT – November 3, 2010

CPSC Staff Recommendations to ASTM F 2085-10 with comments for task group consideration.

Proposed requirement to address mis-assembly of portable bed rails:

3. Terminology

3.1.x *critical safety component*, *n* – any component of the bedrail that requires assembly or installation in order to meet the performance requirements in sections 6.1, 6.3 and 6.4.

Challenges with 3.1

- The definition essentially requires that the technician evaluate the product via process of elimination which is not a practical approach to testing to determine which components would be classified as critical safety components.
- More importantly, all the products on the market now require that all components be assembled in order to meet section 6.4, essentially making all components critical and consequently diluting the importance of calling these components out.
- Finally all ASTM standards carry the following cautionary statement:

"This consumer safety specification is not intended to address all the hazards of bed rails that are either blatantly misused or used in a careless manner that disregards the instructional literature and warning statements provided with each bed rail."

Reference

6.1 *Structural Integrity*—All tests of 8.1 shall be performed sequentially. After testing in accordance with 8.1, there shall be no hazardous condition created as defined in Section 5.

6.3 *Enclosed Openings*—When tested in accordance with 8.2, there shall be no enclosed openings in the enclosed
structure of the portable bed rail that will permit passage of the Torso Probe shown in Fig. 2.

6.4 *Openings Created by Bed Rail Displacement of Adjacent Style Portable Bed Rails*—When tested in accordance

with the procedure in 8.3, there shall be no opening between the mattress and the bed rail that will permit passage of the Torso Probe shown in Fig. 2. Passage is defined as the entire Torso Probe passing the horizontal plane that extends from the top surface of the mattress toward the guard portion of the bed rail.

6.4.1 Bed rails that are marketed as being usable on a bed that has a mattress support that is solid rather than a box spring shall be tested on Platform 3, as defined in 7.1.3, in accordance with 8.3.

5. General Requirements

5.6 Bedrails shall be designed such that if a critical safety component is misassembled or incompletely assembled, it will result in a bedrail without sufficient vertical structure to support itself.

Challenges with 5.6

- In layman's terms this requirement is suggesting that the bedrail collapse in some way in order to offer the user/installer a visual cue that the product is missing a critical component. However the means in how one determines whether or not sufficient vertical structure is achieved is not indicated.
- The action of misassembly or incomplete assembly is subjective and does not define the necessary combinations of misassembly approaches necessary in order for a test technician to either replicate or reproduce results. The subjective nature of the statement offers an infinite number of opportunities but no clear direction on how to test for conformance.

Rationale: Components such as horizontal stabilizer bars and anchor straps are critical safety components. If these components are not assembled properly, the bed rail can present an entrapment hazard. Figures 1 and 2 show incident bed rails that were not properly assembled. IDI 050324HCC1605 involved an incident in which the middle bar was not installed, which resulted in an entrapment death. IDI030730HCC1771 involved an incident in which the mesh was not pulled over the lower bar, which resulted in an entrapment death. Both of these incidents show a need for the ASTM standard to include provisions that address foreseeable misassembly.

Proposed requirement to address misinstallation of portable bed rails:

Misinstallation of a bed rail is not addressed in the current standard. A misinstalled bed rail may detach from the mattress and form a hazardous gap. For example, if the anchor strap and anchor is not installed to the bed, the bed rail will not be securely attached to the bed.

5.7 Critical safety components used to secure the bed rail onto the bed shall:

1. be designed so that installation onto the bed can only be achieved in the manufacturer's intended configuration. Misinstallation or partial installation shall result in a bed rail without sufficient vertical structure to support itself **or**

2. have a permanent marking that identifies the component as a critical component and states that the component must be installed correctly for the safe operation of the bed rail. The marking shall include steps required for proper installation.

Challenges with 5.7

- Number 1 essentially requires that the technician evaluate the product by guessing in which manner a consumer is likely to deviate from a manufacturers intended configuration. Similar to aforementioned misassembly challenges, this approach is not a practical means of testing as it is not repeatable or reproducible within technicians or between various testing laboratories. The issue with respect to sufficient vertical structure remains in number 1 again does not define how sufficient vertical structure is achieved or determined.
- Number 2 is achievable, with the exception of making the product with steps required for proper installation. These markings would require that bedrails include all the instructional literature printed directly on the product which is impractical and dilutes the intent.
- Finally all ASTM standards carry the following cautionary statement:

"This consumer safety specification is not intended to address all the hazards of bed rails that are either blatantly misused or used in a careless manner that disregards the instructional literature and warning statements provided with each bed rail."

Rationale: A component, such as a locking clamp on a mattress-top bed rail or an anchor plate/strap like the ones shown in Figures 4 and 5, is a critical safety component and, if not installed properly, can result in an entrapment hazard.

Proposal for Misassembly

3 Terminology

3.x.1 Critical Safety Component – the center and bottom horizontal structural component of the bedrail that requires consumer assembly and that spans the full length of the bedrail connecting the two vertical sides of the bedrail. See figure.7

Rationale: the face of the product is the area of greatest concern with respect to entrapment.

5.X Assembly Hardware

5,X.1 Fasteners included with the product intended to be assembled by the consumer must be of the same type.

Rationale: This requirement address the potential mismatch of assembly hardware by consumers.

6.X. Locking and Latching Mechanisms

6.x.1 Locking and Latching Mechanisms must provide one of the following indicators when locked or latched according to the manufacturer's instructions:

6.x.1.1 An audible cue that indicates the latch is locked.

6.x.1.2 A visual indication that the latch is locked.

Rationale: This requirement provides consumers clearly discernable, recognizable auditory, or visual cues that indicate correct locking of the bedrail to address false latch potentials.

Proposal for Misinstallation

9.0 Marking and labeling

9.4 Critical Safety Components must be labeled with the warning exactly as stated in 9.3.3.1. The warning statements shall be in contrasting colors, permanent, conspicuous, and san serif style font. In warning statements, the safety alert symbol "!" and the word "WARNING" shall not be less than 0.20 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.10 in. (2.5 mm) high.

9.3.3.1"!" WARNING Critical Safety Component: Death Can Occur If This Piece Is Not Installed.

11.x Instructions shall also include the following:

11.x.1 A complete parts list identifying all components. Critical safety components must be called out as such on the parts list.

11.x.2 A list and image of tools necessary for installation.

11.x.3 Where consumer assembly is required, full-size depictions of assembly hardware

11.1.1 The instructions shall contain the warning statements, required by 9.3.1 in the same exact format, and shall address the statements in 9.3.2. In addition, instructions shall address the following:

11.1.1.1 Discontinue use if damaged, broken or if parts are missing.

11.1.1.2 Keep these instructions for future reference

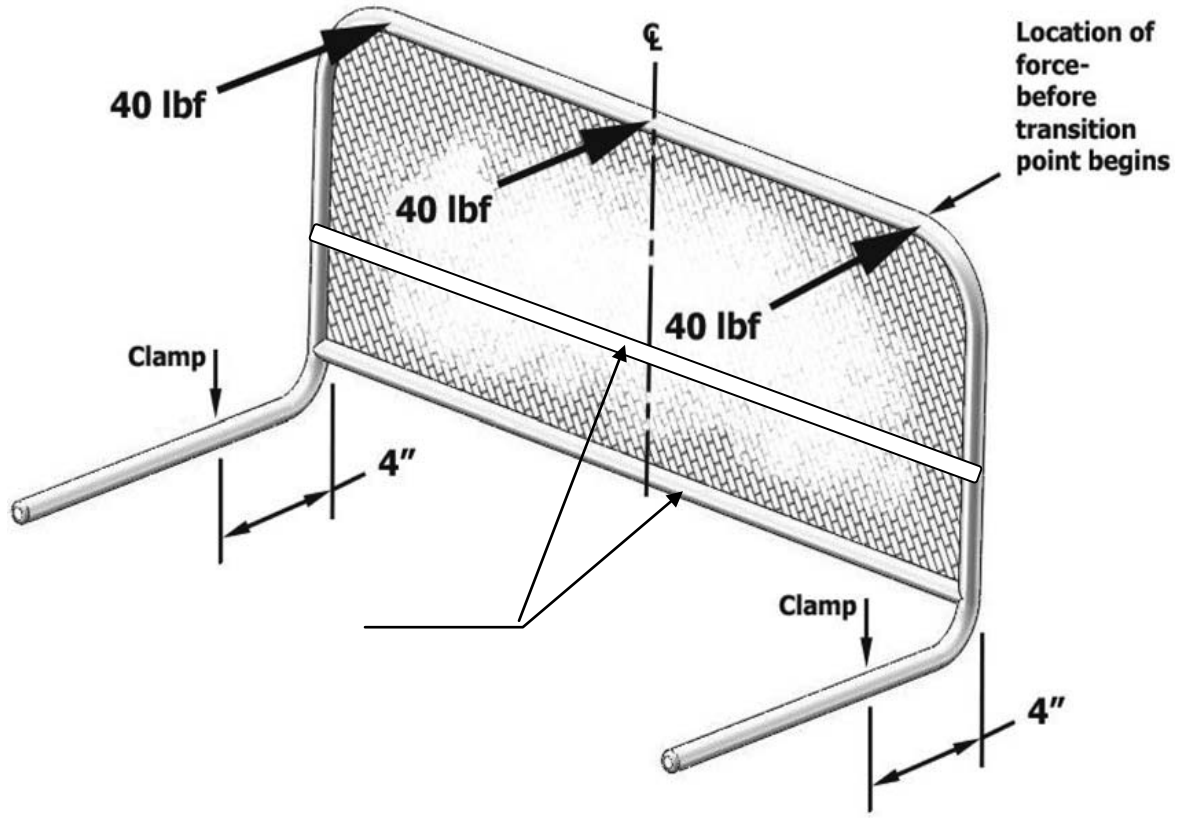


FIG. 7 Structural Integrity Critical Safety Components

APPENDIX C

CPSC staff/ASTM Subcommittee task group proposed requirements to address misassembly and misinstallation of portable bed rails

Revisions to include foam and inflatable bed rails in the scope of the standard with new definitions for both foam and inflatable bed rails:

1. Scope
1.5 *Foam* and *inflatable* bed rails need only meet the General Requirements of section 5, the performance requirement of 6.3 Enclosed Openings and the warning requirement of 9.3.1.

3. Terminology
3.1.10 *foam bed rail*, n—portable bed rail constructed primarily of non-rigid materials such as fabric or foam.
3.1.11 *Inflatable bed rail*, n – a portable bed rail constructed primarily of non-rigid material that requires air be inflated into the product to achieve structure.

Rationale:
Foam and inflatable bed rail products meet the definition of a portable bed rail per ASTM F 2085 and should be included in the scope. Only the General Requirements of section 5, the performance requirement of subsection 6.3, Enclosed Openings, and the warning requirement of subsection 9.3.1 of Section 9, Marking and Labeling requirements apply to foam and inflatable portable bed rails products.

Revisions to include terminology, misassembly, misinstallation performance and test methods:

3.1.12 *critical assembly component*, *n* – any component of the bed rail that requires consumer assembly in order to meet the performance requirements of sections 6.1 *Structural Integrity*, 6.3 *Enclosed Openings,* 6.4 *Openings Created by Bed Rail Displacement of Adjacent Style Portable Bed Rails,* 6.5 *Openings Created by Displacement of Mattress-Top Portable Bed Rails and* 6.6 *Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers' Beds*.
3.1.13 *critical installation component, n* - any component of the bedrail that is used to attach the bedrail onto the bed.
3.1.14 *misassembled/functional bed rail, n*- a bed rail that has been assembled incorrectly but appears to function as a bedrail. Misassembly/functionality is determined by meeting one of the criteria listed in 6.9

5. General Requirements
5.6 *Critical Installation Components* that are also *critical assembly components* and that meet the definition of a misassembled/functional bedrail shall meet 5.6.1 or 5.6.2.
5.6.1 Critical installation components shall be permanently affixed to a structural component(s) of the bedrail.
5.6.2 If a critical installation component(s) is also a critical assembly component and may result in a *misassembled/functional bed rail*, the bed rail shall meet 6.10.1.

6. Performance Requirements

6.9 *Determining Misassembled/functional bed rail* - a bedrail shall be considered a misassembled/functional bed rail if it meets one of the criteria in 6.9.1, 6.9.2, 6.9.3, or 6.9.4.

6.9.1 The bedrail can be assembled without any critical assembly component.

6.9.2 The bedrail can be assembled without the supplied fasteners such as screws, nuts, or bolts that are not captive to a critical assembly component such as the frame.

6.9.3 The bedrail's fabric cover or mesh can be placed over the rigid frame structure without engaging critical parts of the frame as intended in final assembly.

6.9.4 The bedrail can be assembled by improper placement of any critical assembly component such as an inverted or an interchanged part, without permanent deformation or breakage.

Rationale: These criteria give the technician guidance to determine configurations for misassembly or incomplete assembly. Criteria in 6.9.1 through 6.9.3 the above have resulted in fatal incidents. Criteria in 6.9.4 could potentially result in a fatality. Examples are shown below:

<table>
<tr><td>  </td><td>  </td></tr>
<tr><td>1. Bed rail incompletely assembled without middle bar Ref: IDI 050324HCC1605 (Criteria 6.9.1)</td><td>2. Bed rail misassembled without the middle bars attached to the end post. This is a misassembly because the screws were not use. Ref: IDI 080925HCC2061. (Criteria 6.9.2)</td></tr>
<tr><td>  </td><td>   </td></tr>
<tr><td>3. Bed rail misassembled - fabric cover does not engaging the bottom bar. Ref: 030730HCC1771 (Criteria 6.9.3)</td><td>4. Bed rail misassembled - upside down placement of critical assembly component (right picture)
(Criteria 6.9.4)</td></tr>
</table>

6.10 *Determining Acceptability of Misassembled/functional bed rail misassembled/functional bed rails* shall meet 6.10.1, 6.10.2, 6.10.3 or 6.10.4*.*

6.10.1 The bed rail shall not remain upright or the vertical height shall decrease by 6 inches at any point along the top rail when tested to 8.7.

Rationale: this requirement provides the test lab technician criteria to determine if a misassembled bed rail lacks sufficient vertical structure.

6. 10.2 The fabric cover or mesh shall have a permanent sag a minimum of 3 inches after tested in accordance with 8.8.

Rationale: the fabric mesh is often a critical assembly component – it should be designed to engage the horizontal bars and to secure to the frame. This requirement provides the test lab technician criteria to determine if a misassembled fabric mesh provides a sufficient visual cue.

Fail – the misassembled fabric is not attached to bottom rail and does not sag. This does not provide a visual cue that the bedrail fabric is misassembled

Pass – the fabric is not attached to the frame but sags over 3 inches from its correctly assembled position. This provides a visual cue that the fabric is not attached to the

6.10.3 The fabric cover will not fit over the frame without tearing.
6.10.4 Mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a ½ inch protrusion out of the plane of the rail**.**

7. Test Equipment
7.6 *Force Gauge* – gauge shall have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of ± 0.25 lb (1.11N).

8. Test Methods

8.7 *Test Method for Determining Acceptability of Vertical Structure of a misassembled/functional bed rail:*
8.7.1 If possible, attempt to assemble the bedrail in a misassembled configuration(s) as defined in 6.9 *Determining Misassembled/functional bed rail*

8.7.2 Firmly secure the misassembled bed rail on a table top or other stationary flat surface using clamps. The clamps should be located 4 to 6 inches from the intersection of the bedrail legs to the vertical plane (see figure 8).
8.7.3 Gradually apply a force of 10 lb using a ½ inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component to most likely vertically deform the bedrail (see figure 8). Apply the force over a period of 5 seconds; hold the force for 10 seconds and release.
8.7.4 Repeat 8.7.1 through 8.7.3 for all misassembly configurations discovered in 6.9.

8.8 *Test Method for Determining Fabric Sag Acceptability of a misassembled/functional bed rail:*
8.8.1 If possible, attempt to assemble the bedrail in a misassembled configuration(s) as defined in 6.9 *Determining Misassembled/functional bed rail*
8.8.2 Gradually apply a force of 1 lb using a ½ inch disc on the fabric/mesh in any direction or location along the fabric/mesh that is most likely to cause it to come off of the frame (see figure 8). Apply the force over a period of 5 seconds, hold for an additional 10 seconds and release.
8.8.3 Repeat 8.8.1through 8.8.2 for all misassembly configurations discovered in 6.9.

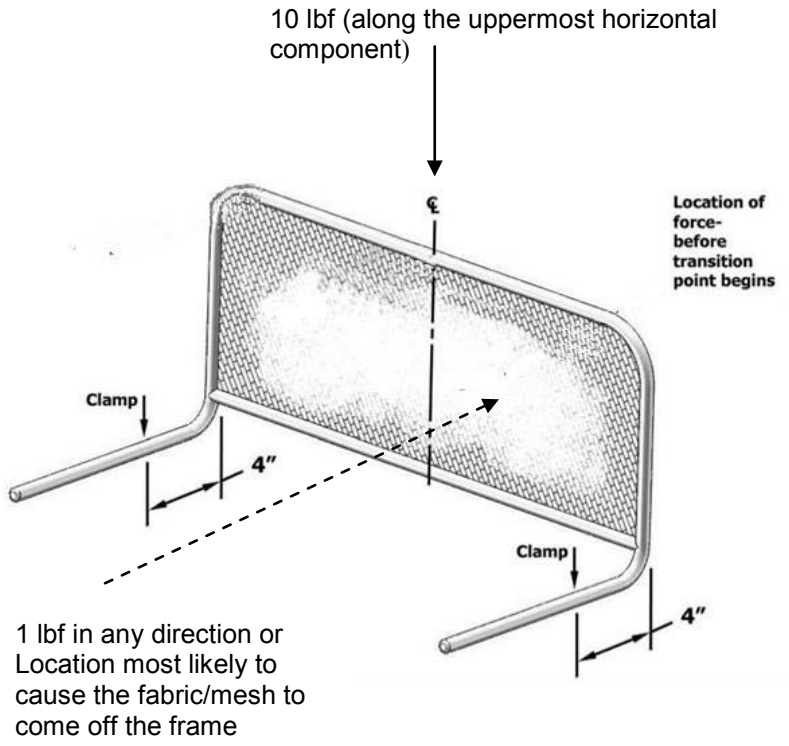


Figure 8: Determining misassembly/functional bed rail test setup

Rationale: the purpose of these tests are to provide the lab technician a methodology to determine if a misassembled bedrail lacks sufficient vertical structure or provides sufficient visual cues to allow the consumer to recognize that the product is misassembled.

Revisions to include marking and labeling critical installation components:

9. Marking and Labeling

9.4 *Critical installation components* must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning shall be in contrasting colors, permanent, conspicuous, and san serif style font. In the entrapment hazard warning statement the safety alert symbol "⚠ " and the words "WARNING - ENTRAPMENT HAZARD" shall not be less than 0.20 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.10 in. (2.5 mm) high.

9.4.1

WARNING – ENTRAPMENT HAZARD

⚠

NEVER use bed rail without installing this part onto bed.
Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death.

Rationale: *Section 5.6, 9.4* - Components, such as a locking clamp on a mattress-top bed rail or an anchor plate/strap are critical installation components. If these components are not installed properly, the bed rail will not be secure and may move away from the mattress and can result in an entrapment hazard. The warning requirement is added to emphasize the importance of proper installation of key components.

Revisions to include instructional literature for installation components:

11. Instructional Literature

11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, installation, maintenance, cleaning, operating and adjustment instruction and warnings, where applicable, shall be included.

Rationale: This requirement will add clear instructional literature for installation components to provide consumers easy to understand information for securing bed rails on beds.

TAB D: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Portable Bed Rails

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: February 10, 2011

TO : Rohit Khanna
Project Manager, Portable Bed Rails

THROUGH: Gregory B. Rodgers, Ph.D.
Associate Executive Director
Directorate for Economic Analysis

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Samantha Li
Economist
Directorate for Economic Analysis

SUBJECT : Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Portable Bed Rails

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 requires that the U.S. Consumer Product Safety Commission (CPSC) evaluate the current existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. While portable bedrails are not mentioned explicitly in section 104, they are a durable toddler product of longstanding interest to the agency. Upon review, CPSC staff recommends that the Commission adopt the voluntary ASTM International (or ASTM, formerly known as the American Society for Testing and Materials) standard for portable bed rails (F 2085–10a *Standard Consumer Specification for Portable Bed Rails*) with a few modifications.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that CPSC staff prepare an initial regulatory flexibility analysis and make it available to the public for comment when the general notice of proposed rulemaking is published. The initial regulatory flexibility analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the initial regulatory flexibility analysis must contain:

(1) a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
(2) a description of the reasons why action by the agency is being considered;
(3) a succinct statement of the objectives of, and legal basis for, the proposed rule;
(4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
(5) identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

Additionally, the initial regulatory flexibility analysis must contain a description of any significant alternatives to the proposed rule, which accomplish the stated objectives of the proposed rule, while reducing the economic impact on small entities.

The Product

As specified in the current ASTM standard (F 2085–10a), a portable bed rail is a device intended to be installed on the side of an adult bed and/or on the mattress surface to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2- to 5-years-old). They include bed rails that only have a vertical plane that presses against the side of the mattress but does not extend over it (referred to as "adjacent type bed rails"), as well as bed rails that extend over the sleeping surface of the mattress (called "mattress-top bed rails"). Staff considers portable bed rails constructed primarily from nonrigid materials, such as fabric, foam, or an inflatable device, to be in the scope of the voluntary standard.

Both portable bed rails made for a specific manufacturer's adult-size beds and "universal" portable bed rails that can attach to any adult-size bed are included under the voluntary standard. However, guard rails, which are used with crib mattresses on toddler beds, are not covered under the voluntary standard. They are covered by the CPSC's proposed rule for toddler beds,[10] as opposed to the staff-recommended proposed rule for portable bed rails.[11]

Other products not covered by the staff-recommended proposed standard include:

- Side rails that connect the headboard to the footboard and may or may not have any barrier purposes;
- Conversion rails intended to convert a crib to a full-size bed; and
- Adult-size beds, where the rail is attached permanently to the bed (for example, bunk beds).

[10] Federal Register link: http://www.cpsc.gov/businfo/frnotices/fr10/toddler.pdf.
[11] Guard rails are (1) sold with a crib, or (2) can be purchased separately to convert a crib to a toddler bed.

The Market for Portable Bed Rails

Typically, portable bed rails are produced and/or marketed by juvenile product manufacturers and distributors or by furniture manufacturers and distributors. Currently, there are at least 14 known manufacturers or importers supplying bed rails to the U.S. market, all of whom are domestic. Ten are domestic manufacturers (71 percent); and three are domestic importers (21 percent).[12] The remaining firm has an unknown supply source, and there is no publicly available information regarding its size.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of portable bed rails is small if it has 500 or fewer employees, and an importer is considered small if it has 100 or fewer employees. Based on these guidelines, nine of the domestic manufacturers and all of the domestic importers known to be supplying the U.S. market are small. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary certification program for several juvenile products.[13] Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard (36 percent). Among them, four are JPMA-certified as compliant with the current ASTM standard, and one firm, whose bed rails are not JPMA-certified, claims compliance. Of the three importers, one firm is JPMA-certified as ASTM compliant, and one firm claims compliance (14 percent). All seven firms, which are either JPMA-certified or claim compliance with the ASTM standard, are small.

JPMA estimates that current annual sales of portable bed rails are approximately 750,000 units, and retail sales are approximately $20 million. This estimate is similar to a 2003 sales estimate provided by JPMA.[14] No information is available about the average product life of bed rails, but if, for example, bed rail sales are assumed to have remained constant, and bed rails remain in use for three to five years, then there might be 2.25 million to 3.75 million bed rails in use.

National estimates of bed rail product-related injuries are not available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of youth bed rails. Therefore, the risk of injury associated with the number of products in use cannot be calculated.

Reason for Agency Action and Legal Basis for Draft Proposed Rule

Section 104 of the CPSIA requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. CPSC

[12] These manufacturers and importers were identified using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.
[13] JPMA has run this program since 1976, beginning with high chairs. Products submitted voluntarily by manufacturers are tested against the appropriate ASTM standard, and only passing products are allowed to display JPMA's Certification Seal. See http://www.jpma.org/content/safety/overview for more information.
[14] Memorandum from Terrance R. Karels, EC, dated April 10, 2003, Subject: Bed Rails Update.

staff worked closely with the ASTM subcommittee to revise the ASTM standard for portable bed rails (F 2085–10a) to address know hazards. In addition, CPSC staff is proposing a modification of the voluntary standard that will prevent critical components of portable bed rails from being misinstalled and misassembled. CPSC staff believes that the more stringent requirements will address known hazard patterns and, thereby, help to reduce injuries.[15]

CPSC staff identified 132 cases of bed rail-related incidents from January 1, 2000 to March 31, 2010. The CPSC databases searched were the In-Depth Investigation database, the Injury or Potential Injury Incident database, and the Death Certificate file. The hazards associated with these incidents included: displacement of bed rails (69 incidents); worn or poor quality fabric on mesh panels (17 incidents); sharp surfaces (14 incidents); hinge lock displacement (11 incidents); misassembly (7 incidents); and miscellaneous other or unknown issues (14 incidents).

CPSC staff believes the staff-recommended proposed rule potentially would address the 87 incidents involving displacement, misassembly, and hinge lock displacement.

Compliance Requirements of the Draft Proposed Rule

CPSC staff recommends adopting the ASTM voluntary standard (F 2085–10a) for portable bed rails with a few modifications. Key components of the current ASTM standard (F 2085–10a) include:

- structural integrity requirements–intended to prevent hazards, such as small parts, sharp edges, and splinters;
- requirements for enclosed openings and displacement openings–intended to prevent torso entrapments within the bed rail and between the mattress and the portable bed rail;
- requirements for openings between bedposts–intended to prevent entrapment between the headboard/footboard and the portable bed rail; and
- protrusion requirements–intended to prevent strangulation hazards that may result from children's clothing or loose strings catching on protrusions.

The voluntary standard also includes: (1) requirements for several features to prevent entrapment and cuts (minimum and maximum opening size, and hazardous sharp points or edges); (2) marking and labeling requirements; (3) requirements for the permanency and adhesion of labels; and (4) requirements for instructional literature.

CPSC staff recommends adding to the existing standard the following requirements:

- A requirement that critical assembly components[16] be designed to minimize a misassembled/functional bed rail.[17] The design shall be such that a misassembled bed

[15] Memorandum from Risana Chowdhury, Directorate for Epidemiology, dated February 16, 2011, Subject: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries; 2000–Present.
[16] A critical assembly component refers to any component of the bed rail that requires consumer assembly to meet the performance requirements of the staff-recommended proposed standard.

rail lacks sufficient vertical structure or provides sufficient visual cues to allow the consumer to recognize that the product is misassembled.

- A requirement that critical installation components[18] that are also critical assembly components be permanently affixed to structural components of the bed rail. Alternatively, critical components should provide visual cues to the consumer to indicate misassembly. In addition, critical installation components must be labeled with a warning.[19]

Staff believes that all portable bed rails currently on the market will require modifications in order to meet the critical assembly component requirement. In order to bring their bed rails into compliance, manufacturers could preassemble any critical safety component, thereby reducing the incidence of misassembly or partial assembly. Alternatively, manufacturers could opt to redesign their products entirely. Additional testing beyond what is specified in the ASTM standard would be required to ensure that the bed rail, if misassembled, lacks sufficient vertical structure, or provides sufficient visual cues, such as sagging fabric or mesh, to indicate misassembly.[20]

Manufacturers may need to redesign existing portable bed rails to meet the staff-recommended critical installation component requirement. In addition, firms also would need to revise current warning labels to include a more detailed description of the mechanisms creating the entrapment hazard.

Portable bed rails constructed primarily of nonrigid materials or foam and inflatable bed rails must meet requirements of the voluntary standard. These requirements cover hazardous sharp points and edges, small parts, warning labels, and enclosed openings. The staff-proposed requirements for misinstallalation and missassembly do not apply to nonrigid products.

Other Federal Rules

The Commission is in the process of implementing Sections 14(a)(1) and 14(d)(2) of the Consumer Product Safety Act (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA). Section 14(a)(1) requires every manufacturer of a product which is subject to a product safety rule to certify that the product complies with all applicable safety rules. Section 14(d)(2)(A) requires the Commission to establish protocols and standards (i) for ensuring that a children's product is tested periodically and when there has been a material change in the product, (ii) for the testing of random samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable

[17] A misassembled/functional bed rail refers to a bed rail that has been assembled incorrectly or without one or more critical assembly components and appears to function as a bed rail but does not have the structural integrity to meet the performance requirements for the staff-recommended proposed standard.
[18] A critical installation component refers to any component of the bed rail that is used to attach the bedrail onto the bed.
[19] Memorandum from Mark Kumagai, Mechanical Engineering, dated February 22, 2011, Subject: Evaluation of ASTM F 2085-10a, *Standard Consumer Specification for Portable Bed Rails*.
[20] Ibid.

safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

Since portable bed rails now will be subject to a mandatory standard, they will be subject to the certification requirements of Section 14(a)(1) when that rule is final. Moreover, portable bed rails are children's products and will eventually be subject to the third-party testing requirements of Section 14(d)(2)(A).

Impact on Small Businesses

There are 13 firms currently known to be producing or selling portable bed rails in the United States. One is a large domestic manufacturer, nine are small domestic manufacturers, and three are small domestic importers. The remainder of this analysis focuses on the 12 small domestic firms.

Small Domestic Manufacturers

The impact of the staff-recommended proposed standard on small manufacturers could differ based on whether they are compliant with the voluntary ASTM standard F 2085-10a. Of the nine small domestic manufacturers, five produce bed rails that are certified as compliant by JPMA or claim to be in compliance with the voluntary standard.

The products of the four noncompliant manufacturers may require substantial modifications to meet both the ASTM standard and the staff-proposed requirements. The costs associated with these modifications could include: product design, development and marketing staff time, product testing, and focus group expenses. There may be increased costs of production as well, particularly if additional materials are required. The actual cost of such an effort is unknown, but could be significant for some firms. However, the impact of these costs may be lessened if they are treated as new product expenses and amortized.

The impact of the staff-recommended proposed standard on the five compliant firms may be less significant because they are compliant already with the voluntary standard. However, even ASTM-compliant bed rails currently on the market will require modifications to meet the staff-recommended changes. Any product redesign would entail costs similar to those outlined for non-ASTM-compliant firms. Some ASTM-compliant firms may opt to preassemble the critical assembly components, rather than redesign their products. Preassembled products may require larger shipping boxes, and there may be higher shipping costs associated with shipping larger boxes. To the extent that retailers charge high stocking and inventory fees, firms may face additional costs. Manufacturers may be able to offset these fees if they are able to pass on some of them to consumers.

While preassembly may reduce product redesign costs, meeting the staff's recommended requirement that critical installation components be affixed permanently may also require some product redesign. As previously mentioned, there will be some costs associated with redesign.

In addition, all manufacturers will need to modify existing warning labels. A new warning label poses a small burden because it represents a minor modification. Costs associated with the new warning label would be low because no new materials are used.

At least one small manufacturer's product line consists entirely or primarily of nonrigid portable bed rails. This firm may need to alter the warning label but otherwise is not likely to be affected significantly by the staff-recommended proposed standard.

Additionally, all manufacturers eventually will be subject to third-party testing and certification requirements, when that rule becomes final. There likely will be some additional costs associated with third party testing and certification.

Small Domestic Importers

Of the three small domestic importers, two import bed rails that are certified compliant by JPMA or claim to be in compliance with the voluntary standard. All of these small importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the new requirements of the staff-recommended proposed standard. The cost to importers may increase; and, in turn, they may pass on some of those increased costs to consumers. Some importers may respond to the rule by discontinuing the import of their portable bed rails. However, the impact of such a decision may be lessened by replacing the noncompliant portable bed rail with a complying product or another juvenile product. Deciding to import an alternative product would be a reasonable and realistic way for most importers to offset any lost revenue, given that most import a variety of products. However, for small importers whose product lines rely largely on bed rails, substituting another product may not be realistic. The impact on these small importers likely would be more significant.[21]

As is the case with manufacturers, all importers will eventually be subject to third-party testing and certification requirements, and consequently, will experience additional costs.

Alternatives

Under section 104 of the CPSIA, one alternative that would reduce the impact on small entities is to make the voluntary standard mandatory, with no modifications. Adopting the current voluntary standard without any changes potentially could reduce costs for manufacturers and importers. Five of the nine small manufacturers, and two of the small importers who are already compliant with the voluntary standard, would have a reduced burden. However, firms that are not in compliance with the ASTM standard still may require substantial product changes in order to meet the voluntary standard.

A second alternative would be to set an effective date later than the staff-recommended six months. This would allow suppliers additional time to modify and/or develop compliant bed rails and spread the associated costs over a longer period of time.

[21] This applies to at least one small importer.