The contents of this document will be discussed at the Commission Briefing scheduled for February 8, 2012.

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

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: FEBRUARY 22, 2012

February 1, 2012

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: Final Rule: Safety Standard for Portable Bed Rails

The Office of the General Counsel is providing for Commission consideration the attached draft final rule on a safety standard for portable bed rails.

Please indicate your vote on the following options:

I. Approve publication of the draft final rule in the *Federal Register,* without changes.

_____ _____
(Signature) (Date)

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

_____

_____

_____

_____ _____
(Signature) (Date)

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

_____ _____
(Signature) (Date)

IV. Take other action. (Please specify.)

_____

_____

_____

_____ _____
(Signature) (Date)

Attachments:

Draft *Federal Register* Safety Standard for Portable Bed Rails: Final Rule

Staff Briefing Package: Draft Final Rule for Portable Bed Rails, from Rohit Khanna, dated February 2012.

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[Billing Code 6355-01-P]

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1224

[CPSC Docket No. CPSC-2011-0019]

Safety Standard for Portable Bed Rails: Final Rule

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

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. In this rule, the Commission is issuing a safety standard for portable bed rails in response to the CPSIA.

DATES: The rule will become effective **[insert date six months after date of publication in the *Federal Register*]** and apply to product manufactured or imported on or after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the *Federal Register* as of **[insert date six months after date of publication in the *Federal Register*]**.

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

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Commission, 5 Research Place, Rockville, MD 20850; telephone (301) 987-2508 ; rkhanna@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background: Section 104(b) of 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. The term "durable infant or toddler product" is defined in section 104(f) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Portable bed rails (also referred to as "bed rail" or "bedrail") are one of the products identified by the Commission under section 104(f) of the CPSIA as durable infant or toddler products. On December 29, 2009, the Commission issued requirements for consumer registration of durable infant or toddler products and a bed rail was identified as a durable infant or toddler products that needed to comply with the registration card requirements. 76 FR 68668.

In the *Federal Register* of April 11, 2011 (76 FR 19914), we published a proposed rule that would incorporate by reference ASTM F2085-10a, "Standard Consumer Safety Specification for Portable Bed Rails" but with several modifications that strengthen the standard. In response to the proposed rule and based on comments to

DRAFT

the proposed rule, the ASTM Subcommittee on Portable Bed Rails, in collaboration with CPSC staff, developed a newer edition of the standard, ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails," which incorporates many of the proposed modifications in the proposed rule, with a few clarifications and modifications that strengthen the standard. ASTM F2085-12 contains more stringent requirements than its predecessor, ASTM F2085-10a, and would further reduce the risk of injury associated with portable bed rails. In this document, we are issuing a safety standard for portable bed rails, which incorporates by reference, the new voluntary safety standard developed by ASTM International (formerly known as the American Society for Testing and Materials), ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails." We summarize the proposed rule and discuss the final rule (including differences between the proposal and the final rule) in section F of this preamble. The information discussed in this preamble comes from CPSC staff's briefing package for the portable bed rails final rule, which is available on the CPSC's website at

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B. The Product

ASTM F2085-12, and its predecessor ASTM F2085-10a, define 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 ASTM F2085-12, and its predecessor, ASTM F2085-10a, 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

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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").

As discussed in the preamble to the proposed rule, a review of market information showed that there are products that differ from traditional, rigid portable bed rails in that they are constructed of nonrigid (also referred to as "non-rigid") materials, such as foam or inflatable materials. (76 FR at 19915 through 19916). Although these foam and inflatable products do not use the term "bed rails" in their packaging or labeling, we stated that such products meet the definition of a portable bed rail and should be included in the scope of the standard. However, most of the performance requirements in the ASTM standard, which pertain to traditional, rigid portable bed rails, did 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 revised ASTM F2085-12 standard now covers foam and inflatable products but would require that only certain relevant provisions of the standard apply to such bed rails.

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 F2085-12 and its predecessor, ASTM F2085-10a. However, as we stated in the preamble to the proposed rule (76 FR at 19916), guard rails that are used with crib mattresses on toddler beds are not covered under this voluntary standard. They are addressed under the Consumer Safety Specification for Toddler Beds. Other products that are not covered 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

DRAFT

full-size bed; and adult-size beds, where the rail is permanently attached to the bed (*i.e.*, bunk beds). ASTM F2085-12 now makes it clear that such products are not covered under the standard.

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 final rule.

C. Incident Data

The preamble to the proposed rule (76 FR at 19916 through 19917) summarized the data for incidents from January 1, 2000 through March 31, 2010, related to portable bed rails. For that period, 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. Of the 13 fatalities, there were two deaths that resulted from portable bed rail displacement, when the portable bed rail partially pushed away from beneath the mattress and allowed the child to fall into the opening and get trapped. There were three cases of portable bed rail misassembly. In three additional fatal incidents, not enough information was available to determine the contributing factor(s) that led to the hazardous entrapment scenario. The beds used in the eight cases mentioned previously were adult-size beds.

DRAFT

More information concerning these incidents is provided in the preamble to the proposed rule (76 FR at 19916 through 19917).

On the remaining five fatalities (out of 13), after publication of the proposed rule, we received additional information, through in-depth follow-up investigations on 4 deaths out of the 5 remaining fatalities that were listed as having insufficient information at the time of publication of the proposed rule. One of the 4 fatalities included among the incident data in the portable bed rail proposed rule is now known to have occurred from partial displacement of the bed rail, which led to the entrapment of the decedent. A second fatality listed previously as lacking sufficient information, still remains in that status. The third fatality is now known not to involve any portable bed rail; what was originally reported as a bed rail has now been confirmed to be a crib rail. Finally, it seems unlikely that the fourth fatality was associated with a portable bed rail. The decedent, co-sleeping with a sibling and a parent, suffocated. The role, if any, of a portable bed rail, now seems questionable. A fifth fatality could not be investigated because the victim's name was not released.

While preparing a final rule, CPSC staff also conducted a new search of the CPSC's epidemiological databases and found that there were 23 new portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. These incidents are reported to have occurred between 2009 and 2011. Four of the 23 incidents were fatal, and 19 were nonfatal incidents, 8 of which reported an injury. Among the 23 newly reported incidents that specified age (18 out of 23), three reported a child younger than 15 months old. The majority of the incidents (15 out of 18) reported the child's age to be between 15 months and 4 years.

DRAFT

Among the newly reported incidents, there were 4 fatalities. One resulted from a misinstalled bed rail, where the decedent was strangled by the straps of the reinforced anchor system. The second fatality occurred when the infant slipped through the torn section of the mesh and got caught when the bed rail flipped down and caught him at the neck. The remaining 2 fatalities lacked any information on the product or scenario-specific details.

Among the newly reported incidents, there were 19 nonfatal incidents resulting in 8 injuries. The 8 injuries sustained were mostly bumps and bruises; one case reported a laceration that was severe enough to require multiple stitches, and another reported a fractured collar-bone. None of the injuries required hospitalization. The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the data included in the proposed rule, including hinge-lock failure (8 incidents including 4 injuries and 1 fatality). The fatality was attributable, in part, to the hinge-lock failure of the bed rail and, in part, to the torn mesh panel). Other hazard patterns showed displacement of the bed rail (7 incidents, including 3 injuries, where the bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail); sharp surface (3 incidents, including 1 injury, due to sharp surfaces on the bed rail); misinstallation (1 strangulation fatality on the straps of the reinforced anchor system of the bed rail was reported to have been due to the improper misinstallation of the bed rail); and miscellaneous issues that included 4 incidents and 2 fatalities with insufficient information on the product or scenario and 2 non-fatal incidents (1 reporting hazards from broken screws and the other reporting design issues with the bed rail).

D. The ASTM Voluntary Standard

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. We have consulted with these groups regarding the ASTM voluntary standard, "Standard Consumer Safety Specification for Portable Bed Rails," throughout its development. In response to the proposed rule, and in comments to the proposed rule, the ASTM Subcommittee on Portable Bed Rails, in collaboration with the CPSC staff, developed a new ASTM standard on portable bed rails, ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails," which incorporates many of the proposed modifications in the proposed rule, with a few clarifications and modifications that strengthen the standard. ASTM F2085-12 contains more stringent requirements than its predecessor, ASTM F2085-10a, and it would further reduce the risk of injury associated with portable bed rails.

E. Response to Comments on the Proposed Rule

The preamble to the proposed rule invited comments concerning all aspects of the proposed rule. We received 16 comments. Eight commenters stated general support for the proposed rule. Eight commenters raised specific issues that are addressed by topic below.

We describe and respond to the comments in section E of this document and also describe the final rule. To make it easier to identify the comments and our responses, the word "Comment," in parentheses, will appear before the comment's description, and the word "Response," in parentheses, will appear before our response. We also have numbered each comment to help distinguish between different comments. The number

DRAFT

assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance, or the order in which it was received.

1. *Proposed Misassembly and Misinstallation Requirements*

(*Comment 1*) - One commenter questioned the need for a revised standard. Two commenters expressed concerns about the proposed requirements to address portable bed rail misassembly and misinstallation. The commenters stated that the proposed language is vague, arbitrary, and invites unacceptable variability in test conditions because there are too many possible misassembly options.

(*Response 1*) We believe that requirements are necessary to address the entrapment hazards that may result from the misassembly and misinstallation of portable bed rails based on our incident data. However, we agree that the proposed requirements of the proposed rule could be clarified and improved. After publication of the proposed rule, the ASTM Portable Bed Rail Subcommittee working group developed alternate performance requirements to address the commenters' concerns about testing and limited the misassembly possibilities to configurations most likely to present entrapment hazards. These requirements have been added to ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails," which improves upon the proposed test requirements in the proposed rule. In order to improve the misassembly requirements, ASTM F208-12 requires captive hardware to ensure that fasteners remain attached to their respective components before normal assembly and after normal disassembly. The addition of Figure 1 depicts types of captive hardware, including bolts that are free floating and that can retract but are not completely removable, as well as a pin that is retractable but is not removable without tools. Installation components are required to

DRAFT

be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly.

ASTM F2085-12 also addresses the issue regarding the potential for variability in misassembly test conditions. A significant difference between the proposed rule and ASTM F2085-12 is that there are no longer any test requirements or procedures to determine if a misassembled bed rail lacks sufficient vertical structure or provides sufficient visual cues that would notify a consumer that the bed rail is not assembled properly. Instead, the new standard focuses the testing on components that were identified in the incident data. The addition of figures and illustrations clarifies the pass and fail criteria of the requirements. Figure 5 in ASTM F2085-12 shows an example of a center horizontal structural component that is omitted; consequently, the bed rail's mesh fabric does not engage the center structural component. Figure 6 in ASTM F2085-12 shows additional examples of fail conditions, including a bed rail fabric with the bottom zipper misassembled,where the fabric cover can be zipped up without engaging the bottom horizontal bar. There also is an illustration of how the bottom bar can be omitted from insertion into the fabric sleeve or channel located at the base of the fabric component. Figure 7 in ASTM F2085-12 gives an example of a condition that is not to be tested; Figure 8 in ASTM F2085-12 gives an example of a tube that is inverted or interchanged; and Figure 9 shows an example of a test for unidirectional arm. Test personnel will conduct visual assessments of a bed rail after attempting to misassemble the bed rail. This will require some judgment to determine whether a bed rail can be misassembled using reasonable engineering judgment. We believe that the addition of such illustrations and figures will identify the misassembly combinations that actually

DRAFT

would occur and that will prevent unnecessary testing of an unlimited variety of test configurations.

2. *Foam and Inflatable (Nonrigid) Bed Rails*

(*Comment 2*) Several commenters requested that inflatable and foam bed rails be included in the scope. A few commenters stated that these types of bed rails should meet all of the requirements in the standard and/or have requirements to address a potential suffocation hazard.

(*Response 2*) Nonrigid portable bed rails are included in the scope of ASTM F2085-12 and will need to meet the general requirements to address sharp edges or point, small parts, and permanency of labels, as well as requirements for a new warning label. However, the standard was developed for rigid portable bed rails, and many of the test requirements would not be applicable to these products. Although we are not imposing additional requirements at this time, we expect the ASTM Subcommittee on Portable Bed Rails to continue to monitor these types of nonrigid portable bed rails and pursue the development of additional requirements, as necessary.

3. *Test Equipment: Mattress Platform and Sheeting Material*

(*Comment 3*) One commenter stated that the specifications for the Mattress Test Platform 2 and the bed sheeting requirements in ASTM F2085-10a - *Section 7.1.2.1 (and 7.1.1.1 for sheeting) Mattress Construction* are too restrictive and difficult to obtain.

(*Response 3*) We agree that the Mattress Test Platform 2 and the bed sheeting specification in ASTM F2085-10a are unnecessarily restrictive. ASTM F2085-12 removes the Intention Load Deflection ("ILD") test that is designed to test the firmness of a foam material and is relevant for Test Platform 1, which is a 4″-thick foam mattress.

DRAFT

Test Platform 1 was selected to use on a thin and not very firm mattress. Test Platform 2 is an inner spring mattress, and thus, not solid foam. It was selected for use on a thick mattress (10–11″). However, there is no concern about the foam firmness of Test Platform 2 because the inner spring design gives the mattress rigidity. Therefore, there is no need to have an ILD requirement and test for Test Platform 2. In addition, there is no practical way to test the foam in an inner spring mattress to the ILD test. ASTM F2085-12 also allows greater flexibility for available bed sheet types for use in testing. The change in the sheet specifications was based on our finding that sheets that provide the weight-per-ounce were not practical. We believe that a 50/50 cotton– poly sheet over the mattress is a basic requirement for the test and that the range in thread count would not otherwise affect the results. Accordingly, ASTM F2085-12 allows greater flexibility for available mattress and bed sheet types for use in testing.

4. *Double-Sided Bed Rails*

(*Comment 4*) Several commenters recommended that portable bed rails be sold in sets of two (double-sided) only, to reduce entrapment between the wall and a piece of furniture.

(*Response 4*) Double-sided bed rails currently, are available to consumers. However, we believe that the potential for entrapment between the bed and the wall is not related to, or limited by, the use of a single-sided bed rail, and there is no evidence to support the assertion that requiring double-sided bed rails will address this hazard. We believe that consumers should continue to be educated regarding a safe sleep environment for children, including being aware of and eliminating hazards that are caused by gaps between a mattress and a wall.

DRAFT

5. *Bed Sheet Changing*

(*Comment 5*) One commenter stated that the proposed standard does not address issues such as daily changing of bed sheets or other routine use that can cause movement or stress on the components of a bed rail and lead to an unsafe product.

(*Response 5*) A review of the incident data did not indicate that changing of bedding or other routine behavior contributed to fatal or nonfatal incidents due to additional stress on the component parts of a bed rail. The standard contains requirements that test the strength of the bed rail. We believe that these requirements are adequate to address potential stress-related failures.

6. *Mattress Systems*

(*Comment 6)* One commenter stated that the rulemaking proceeding does not address the fact that portable bed rails can be used in various mattress systems.

(*Response 6*) Our review of portable bed rail products showed that most portable bed rails are adjustable to fit various size mattresses. ASTM F2085-12 contains test requirements that evaluate the safety of portable bed rails on test platforms intended to represent the different types of adult beds available in the market.

7. *Warning Language*

In general, all eight comments that addressed the warning requirements appear to support the general approach to improving the warning language that was in ASTM F2085-10a. However, some comments raised specific issues and suggested that additional revisions to these requirements would be helpful.

(*Comment 7*) Several commenters requested more specificity in the warning language. One commenter stated that warning labels should include age limits because

DRAFT

bed rails should not be used with children younger than 2 years old. Another commenter noted the importance of describing the hazard more concisely than the warning in the current voluntary standard. One commenter stated that the proposed rule suggested that the revision to the entrapment hazard warning for critical installation components misleads consumers because it provides a false sense of security for those with children who can get in and out of an adult bed without help.

(Response 7) We agree that the primary bed rail warning label on the product and its retail packaging should include explicit age guidance and that the warning statements in the previous edition of the voluntary standard, ASTM F2085–10a, lacked this specificity. We believe that the new ASTM F2085–12 warning requirements address the public comments and are an improvement to the requirements in both the prior version of the voluntary standard and the proposed rule. The age at which children should not be using a bed rail has been made more explicit with the statement: "NEVER use with children younger than 2 years old"; and the statement immediately following: "Use ONLY with older children who can get in and out of adult bed without help," clarifies that children must meet both criteria. Additional revisions to the language, such as "Gaps in and around bed rails have entrapped young children and killed infants" clarify the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a more concise warning, which may increase the likelihood that consumers will take the time to read the warning and understand the information. For example, the proposed rule's warning requirements would result in a warning approximately 148 words long; whereas, the warning requirements in ASTM F2085–12 result in a much shorter warning of 102 words

DRAFT

long. The revised warning language is now written at a slightly lower grade level than the proposed rule warning language, so that more people who read the warning may be more likely to understand it.

We disagree that the entrapment hazard warning for critical installation components misleads consumers. The purpose of the entrapment hazard warning is to alert consumers to the importance of installing the bed rail correctly. The statement in question—"Incorrect installation can allow the portable bed rail to move away from the mattress, which can lead to entrapment and death"—refers specifically to incorrect installation as the mechanism by which the bed rail can move away from the mattress. Nothing in the warning suggests that other mechanisms of entrapment exist that do not involve movement of the bed rail. Moreover, the bed rail itself includes a more comprehensive warning that discusses other sources of entrapment, such as the placement of the bed rail relative to the headboard or footboard of the adult bed, which clearly shows that other hazards and entrapment scenarios exist.

(*Comment 8*) One commenter stated that the warning labels should describe the materials used when producing the bed rails.

(*Response 8*) We disagree that the warning requirements should specify the materials used in the product. Warnings are intended to be used only to identify a significant hazard. The commenter has not identified what materials present a hazard or what a warning requirement would address. The consequences of exposure to the hazard and appropriate avoidance behavior in response to the hazard also are key pieces of information that should be present in a warning, unless this information can be inferred readily. The commenter did not specify any of this information. Thus, including in a

DRAFT

warning label a description of the materials used when the bed rail is produced is not appropriate at this time.

(*Comment 9*) Another commenter stated that there should be a strict warning about modification of the bed rail and the bed rail components.

(*Response 9*) We disagree that warning requirements should include provisions regarding modification of the bed rail and its components. We interpret this comment to indicate that the commenter seeks the addition of warning language to address the scenario of consumers intentionally altering the bed rail components. Our review of incident data does not support that consumers' intentional alteration of bed rail components leads to injury. Thus, mandating such warning language is not supported by the data.

8. *Adult Bed Rails*

(*Comment 10*) Two commenters stated that the scope of the rule should guarantee more stringent safety standards for all portable bed rails, including adult bed rails. These commenters note that bed rails are used routinely in nursing facilities, hospitals, and private homes. According to the commenters' data, between 1985 and 2009, the FDA received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds, including 408 deaths, 138 non-fatal injuries, and 185 near-misses due to staff intervention. To address these types of incidents, the commenters requested that the Commission take action on adult bed rails, including mandating warning labels, enforcing reporting requirements, recalls, and civil penalties, and engaging in greater collaboration with the FDA.

DRAFT

(*Response 10*) Section 104(b) of the Consumer Product Safety Improvement Act requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Accordingly, this rulemaking is limited to bed rails intended for use with children (typically from 2 to 5 years of age) to keep them from falling out of an adult bed. Comments pertaining to other bed rail products intended for use by older children or adults are outside the scope of this proceeding. With respect to bed rails intended for use by adults or older children, we are aware that some bed rails may be considered "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"); therefore, they are subject to regulation by the FDA. The 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. However, the commenters raised important issues regarding incidents with bed rails that were not intended to be either a part of, or an accessory to, a hospital bed or FDA-regulated pediatric bed. To the extent that there may be such bed rails that are not regarded as medical devices regulated by the FDA, but that are considered, instead, to be "consumer products" under the CPSA or otherwise subject to our jurisdiction, we will continue to review this issue and consider what actions are appropriate, if any.

9. Shipment Costs and Product Size

(Com*ment 11*) One commenter stated that shipping costs are a significant portion of the product's total cost and increasing the box size to contain a preassembled product could potentially increase the cost to ship the product by 50 percent. This commenter also stated that the proposed rule may result in adverse retail response to stocking bulkier

packages on shelves or in inventory, or retailers dropping products, or refusing to accept a price increase, thus, placing the cost burden on manufacturers.

(*Response 11)* Not all products would need to be preassembled or put in larger boxes. Retooled and redesigned components may allow manufacturers to use existing boxes. To the extent that a manufacturer decides to preassemble parts, or the portable bed rail, we agree that preassembling portable bed rails may require larger boxes and that shipping larger boxes is likely to increase shipping costs. It is possible that the increased shipping costs could be significant for some small firms. We also agree that if larger boxes for bed rails were required, they would need additional storage and shelving space. As a result, some retailers might choose to decrease the number or type of bed rail models they offer to the public, which, in turn, could result in decrease in product demand for some manufacturers.

F. Summary of ASTM F2085-12, "Standard Consumer Safety Specification for Portable Bed Rails"

When the Commission issued its proposed rule in April 2011, the Commission proposed incorporating by reference ASTM F2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*, with certain modifications, under a new 16 CFR part 1224, *Safety Specification for Portable Bed Rails.* The requirements for portable bed rails in ASTM F2085-12 incorporate many of the proposed changes in the proposed rule, with additional clarifications and improvements. Accordingly, 16 CFR part 1224 will incorporate by reference, without modification, ASTM F2085-12, which includes more stringent requirements that would further reduce the risk of injury associated with portable bed rails.

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1. Scope

ASTM F2085-10a provided that under section 1, *Scope*, 1.1: "This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature."

The proposed rule would not make any change to section 1.1. However the preamble to the proposed rule made clear that the standard did not cover guardrails that fall under the scope of the "Consumer Safety Specification for Toddler Beds", ASTM F1821; or side rails that connect the headboard to the footboard; conversion rails that convert a crib to a full-size bed; and adult-size beds, on which the rail is permanently attached to the bed. 76 FR 19916. Accordingly, to make the scope of portable bed rails explicit so that it does not include such products, ASTM F2085-12 now provides under section 1.1: "This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature. This consumer safety specification does not cover guardrails that fall under the scope of the Consumer Safety Specification for Toddler Beds, F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard."

The proposed rule also would revise section 1.4 of ASTM F2085-10a to state: "In addition to complying with section 1.4 of ASTM F2085-10a, 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." This section is addressed below in section 3, "Terminology," and section 5, "General Requirement."

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2. Referenced Documents

Consistent with the clarification in scope under section 1 (Scope)—that the new standard does not cover toddler beds—ASTM F2085 -12 includes in section 2, (Referenced Documents) ASTM F1821, "Consumer Safety Specification for Toddler Beds." In addition, ASTM F2085-12 includes Reference Document ASTM F1487, "Consumer Safety Performance Specification for Playground Equipment for Public Use" to specify the protusion gauge for entanglement used in the performance requirements.

3. Terminology

The proposed rule would revise the terminology in section 3 of ASTM F2085-10a, by creating the following new terms:

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

DRAFT

- 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.

In ASTM F2085-12 the following terminology and figures have been included in section 3:

- 3.1.4 *captive hardware*, n—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (see Fig. 1).

FIG. 1 Captive Hardware

- 3.1.6 *consumer adjustment*, n—those activities defined by the instructions to be taken by the consumer in order to properly fit and secure the bedrail to the mattress.
- 3.1.6.1 Discussion—Examples include sliding telescoping poles for proper fit, or initial adjustment for use, tightening of anchoring straps and positioning or changing of attachment components or locking pins.
- 3.1.7 *consumer assembly*, v—the fitting together of components of the bedrail according to manufacturer instructions.
- 3.1.8 *installation component*, n—component of the bedrail that is specifically designed to attach the bedrail to the bed and typically located under the mattress when in the manufacturer's recommended use position.

DRAFT

- 3.1.10 *misassembled bed rail*, n—a bed rail that has been assembled incorrectly but appears to function as a bedrail.
- 3.1.12 *non-rigid bed rail*, n—portable bed rail constructed of non-rigid materials, including but not limited to fabric or foam, or that requires air be inflated into the product to achieve structure.

The new standard, ASTM F2085-12, contains some, but not all, of the proposed terminology. Proposed sections 3.1.10, *foam bed rail*, and 3.1.11, *inflatable bed rail*, are terms that are now incorporated as *non-rigid bed rail* under new section 3.1.12 in ASTM F2085-12. ASTM F2085-12 does not add proposed section 3.1.12, *critical assembly component*, because all of the bed rail components are critical to safety. Proposed section 3.1.13, *critical installation component*, has been modified to make clear the purpose of the *installation component* under new section 3.1.8 in ASTM F2085-12. Proposed section 3.1.14, *misassembled/functional portable bed rail*, also has been modified to make clear under new section 3.1.10 in ASTM F2085-12 what is meant by *misassembled bed rail*. ASTM F2085-12 also adds additional terms for *captive hardware* under new section 3.1.4, *consumer assembly* under new section 3.1.7, *consumer adjustment* under new section 3.1.6, and new section 3.1.6.1 *Discussion*. These new sections create terminology to help testing laboratories differentiate between components that require consumer adjustment, such as straps and telescoping rods, and components that are fitted or fastened together for the bed rails' structure, and components that do not require consumer adjustment.

The basis for the new terminology is explained further under section 5 (General Requirements), section 6 (Performance Requirements), section 7 (Test Equipment),

DRAFT

section 8 (Test Methods), section 9 (Marking and Labeling), and section 11 (Instructional Literature).

4. Calibration and Standardization

The proposed rule would not make any changes to section 4 of ASTM F2085-10a (Calibration and Standardization). This section is unchanged in ASTM F2085-12.

5. General Requirements

The proposed rule would add a section 1.4.1 stating, "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."

New section 5.5 of ASTM F2085-12 provides that "Non-rigid bed rails need only meet the general requirements of Section 5, the performance requirement of 6.3, and the warning requirements of 9.3." This section provides that both foam and inflatable bed rails are covered under the term "non-rigid" but are not limited to foam and inflatable products that are also used as bed rails.

In addition, the proposed rule would add the following sections to ASTM F2085-10a:

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

DRAFT

- 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.

ASTM F2085-12 provides similar, but modified, language under new section 5.7 and section 5.8.

- 5.7 Installation components that are required to meet the performance requirements of 6.4, 6.5, and 6.6 shall be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly (this excludes any consumer adjustment).
- 5.8 For products requiring consumer assembly, supplied hardware used for assembly of the bedrail such as screws, nuts or bolts shall be captive hardware to their respective components.

The proposed rule's critical installation components would prevent components (such as anchor plates and straps) that are used to attach the bed rail to the bed from being discarded or lost. All installation component(s) would be attached permanently to a structural component(s) of the bed rail. ASTM F2085-12 combines 5.6, 5.6.1, and 5.6.2 of the proposed rule into new section 5.7 and section 5.8. Like the proposed rule, these sections in ASTM F2085-12 require all installation components to be permanently attached to a structural component(s) that is required to make up the bed rail. This prevents installation components from being discarded or lost. The wording in ASTM F2085-12 clarifies the difference between installation components will require consumer adjustment and those components are part of consumer assembly. Test personnel will be able to identify components subject to the misinstallation requirement and it addresses

DRAFT

the concern raised by commenters about the ambiguity of test requirements for installation components that are adjustable.

6. Performance Requirements

The proposed rule would add the following sections to ASTM F2085-10a:

- 6.9 *Determining Misassembled/Functional Portable Bed Rail* - 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.
- 6.9.1 The portable bed rail can be assembled without any critical assembly component.
- 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.
- 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.
- 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.
- 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.
- 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.

DRAFT

- 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.
- 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**.**

Under ASTM F2085-12, the following new sections and figures have been added:

- 6.9 Bedrail components requiring consumer assembly shall not be able to be misassembled when evaluated to 6.9.1.
- 6.9.1 *Determining Misassembled Bed Rail*—A bedrail shall be considered a misassembled bed rail if it appears to be a functional bedrail under any one of the conditions listed in 6.9.1.1, 6.9.1.2, or 6.9.1.3 and it does not meet the requirements of 6.4, 6.5, or 6.6.
- 6.9.1.1 The bedrail's fabric cover or mesh can be placed over the rigid frame structure without engaging all structural components of the frame as intended in final assembly (Fig. 5 and Fig. 6). When the bedrail is evaluated, zippers and other means of attachment should be fully fastened. If possible to fasten the means of attachments without engaging said structural components, evaluation for misassembly should account for that (see Fig. 6).
- NOTE 1—Any means of attachment, including, but not limited to, zippers, hooks and loops, and snaps, should be fully fastened. Fig. 7 represents a passing condition.
- 6.9.1.2 The bedrail can be consumer assembled with any horizontal structural components improperly positioned such as being inverted or interchanged,

DRAFT

without permanent deformation or breakage of the component or bedrail. This excludes consumer adjustment or universal components that are designed to be interchangeable (Fig. 8). For example:

(1) Horizontal structural components shall be interchanged (Components 1, 2, 3).

(2) Horizontal structural components shall be inverted (AB:BA); (CD:DC); (EF:FE).

- 6.9.1.3 Bedrails where the position of the arms are intended to be unidirectional are able to be assembled when the arms are rotated 180 degrees above the vertical axis (Fig. 9).

FIG. 5 Example of Fail Condition

FIG. 6 Examples of Fail Conditions

FIG. 7 Example of Condition Not To Be Tested

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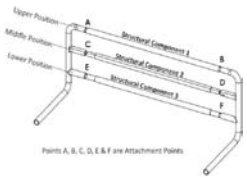

FIG. 8 Example of Tube Inverted or Interchanged

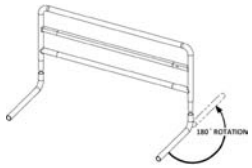

FIG. 9 Example of Test for Unidirectional Arm

The proposed rule contained performance requirements that did not exist in ASTM F2085-10a and were intended to address the risk of entrapment hazards associated with consumer misassembly of portable bed rails. The proposed rule contained test methods and performance criteria to determine if a misassembled bed rail provided sufficient visual cues for a consumer to identify that the bed rail was misassembled. If the misassembled bed rail did not stay upright, or the top rail collapsed after testing, the misassembly was considered to have a sufficient visual cue for the consumer to recognize that the product was not assembled correctly. This condition would be considered a passing result because the bed rail only could be misassembled in a way that was obvious to the consumer. Bed rails that are preassembled or designed to reduce the potential for consumer misassembly, without deforming or breaking parts, also would meet these requirements. CPSC staff developed two prototype bed rails to demonstrate that products could be redesigned to meet the proposed requirement.

ASTM F2085-12 provides a means for determining misassembled portable bed rails that is similar to the proposed rule, but targets specific misassembled portable bed

DRAFT

rail scenarios, such as missing horizontal components, fastening the fabric mesh without engaging a horizontal bar, and assembling parts to the wrong components or inverted components.

ASTM F2085-12 addresses misassembly by identifying criteria similar to the proposed rule, but it contains additional figures and illustrations showing examples of passing and failing bed rails that have been misassembled. ASTM F2085-12 section 5.8 is equivalent to section 6.9.2 of the proposed rule, and it requires that nuts and bolts be attached to the bed rail structure to prevent the consumer from discarding or misplacing the fasteners. ASTM F2085-12 section 6.9.1.1 is equivalent to sections 6.9.3 and 6.9.4 of the proposed rule. These requirements identify a misassembled bed rail as a bed rail that can be assembled without a part or without the fabric engaging the entire frame as intended by the manufacturer. These requirements directly address the fatal incidents where the horizontal bar was not used or where the fabric was not installed properly over the bottom horizontal bar. ASTM F2085-12 sections 6.9.1.2 and 6.9.1.3 are equivalent to section 6.9.4 of the proposed rule and require that bed rail components not be interchanged or inverted. This prevents the consumer from assembling a component in a backward or upside-down position.

The primary difference between ASTM F2085-12 and the proposed rule is that ASTM F2085-12 does not have a physical test that establishes pass and fail criteria to determine whether a misassembled bed rail appears to be functional as proposed in section 6.10.1 of the proposed rule. Determination of whether a misassembled bed rail appears to be functional (failing the standard) or appears <u>not</u> to be functional (passing the standard) is up to the judgment of the testing laboratory. The figures that show examples

DRAFT

of passing and failing bed rails will provide guidance to testing laboratories in making the determination. The new requirements reduce the potential for numerous test configurations, eliminate the testing of zippered products for sag variability, reduce the possibility of misassembly of adjustable components for installation, and improve repeatability of testing between labs.

7. Test Equipment

The proposed rule did not suggest any changes to the test platforms in ASTM F2085-10a. However, we received comments to the proposed rule that the specifications for the Mattress Test Platform and the bed sheeting requirements in ASTM F2085-10a under *Section 7.1.1.1 and 7.1.1.2* are too restrictive. In response to the comments, ASTM F2085-12 modifies the language to make it easier to test the mattresses and sheeting.

ASTM F2085-10a provided under section 7. Test Equipment, 7.1.1 *Test Platform* 1 7.1.1.1 *Mattress Construction*:

- The mattress shall be of standard twin size, 38 by 74.5 in. 6 0.5 in. (0.97 by 1.89 m + 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft3 +0.2, –0 (16 kg/m3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd2 (161 g/m2). The sheet shall be laundered once before use in an automatic home washer, using hot

DRAFT

water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.

ASTM F2085-12 provides under new section 7:

- 7. Test Equipment, 7.1.1 *Test Platform I* 7.1.1.1 *Mattress Construction*—The mattress shall be of standard twin size, 38 by 74.5 in. ± 0.5 in. (0.97 by 1.89 m ± 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft3 +0.2, –0 (16 kg/m3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.

ASTM F2085-10a provided under section 7. Test Equipment, 7.1.2 *Test Platform 2*, 7.1.2.1 *Mattress Construction*:

- The mattress shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick. The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd2 (161 g/m2). The sheet shall be laundered once before use in an automatic home washer using hot water setting and longest normal cycle with the manufacturer's

DRAFT

recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.

ASTM F2085-12 provides that under new section 7.1.2. *Test Platform* 2:

- 7.1.2.1 *Mattress Construction* - The mattress shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick. The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.

ASTM F2085-12 also deletes section 7.1.2.2 of ASTM F2085-10a, which provides:

- 7.1.2.2 *Mattress Performance* – The foam shall have an Indentation Load Deflection (ILD) of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.

In response to comments to the proposed rule that asserted that the specifications for the mattress platform and sheeting material were unduly restrictive (Comment 3 and Response 3), ASTM F2085-12 removed the Intention Load Deflection ("ILD") test that is designed to test the firmness of a foam material because it was not appropriate for a rigid mattress under Test Platform 2. In addition, we agreed that purchasing sheets that provide the weight per ounce is not practical and that the range in thread count would not otherwise affect the results. Accordingly, we believe that the new requirements are an improvement over the existing standard.

The proposed rule would add the following section to ASTM F2085-10a on the force gauge:

DRAFT

- 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) to clarify the manner in which the force will be applied under the proposed test method to determine acceptability of vertical structure of a misassembled/functional portable bed rail.

ASTM F2085-12 does not have a test to determine acceptability of the vertical structure of a misassembled/functional portable bed rail. Accordingly, under the new section, reference to the vertical structure of a misassembled/functional portable bed rail is omitted. However, because the force gauge is used for other tests in the standard, section 7.6 of ASTM F2085-12 states:

- 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).

8. Test Methods

The proposed rule would add the following sections to ASTM F-2085-10a:

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

DRAFT

- 8.7.3 Gradually apply 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 that would most likely vertically deform the bed rail (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 Portable Bed Rail*:
- 8.8.1 If possible, attempt to assemble the bed rail in a misassembled configuration(s), as defined in 6.9 *Determining Misassembled/Functional Portable 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 8.8.1 through 8.8.2 for all misassembly configurations discovered in 6.9.

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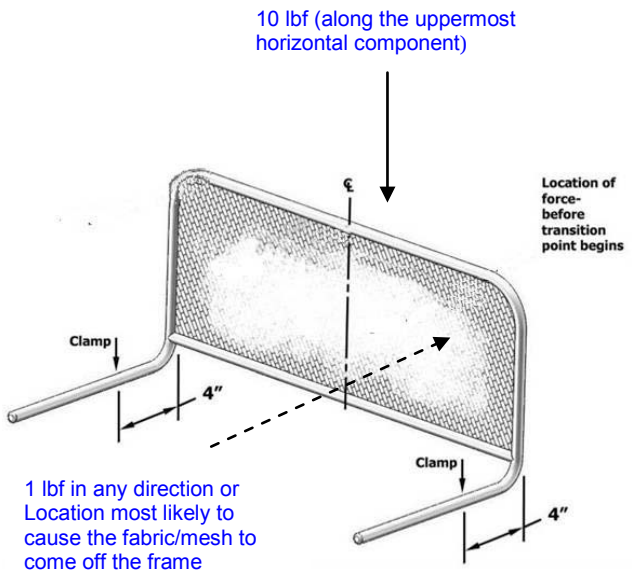

Figure 8: Determining misassembly/functional bed rail test setup

Section 6 in ASTM F2085-12 establishes requirements for determining misassembled portable bed rails, by targeting specific misassembled portable bed rail scenarios, such as missing horizontal components, fastening the fabric mesh without engaging a horizontal bar, and assembling parts to the wrong components or inverted components. ASTM F2085-12 does not have a test to determine acceptability of the vertical structure of a misassembled/functional portable bed rail. The testing laboratories are in the best position to determine whether a misassembled bed rail appears to be functional (failing the standard) or appears not to be functional (passing the standard). Accordingly, we believe that the new requirements under sections 5 (General Requirements) and 6 (Performance Requirements) are an improvement over the proposed rule's test requirements; accordingly, our proposed requirements in section 8 are not necessary.

DRAFT

9. Marking and Labeling

The proposed rule would make the following revisions to section 9, Marking and Labeling of ASTM F085-10a:

- 9.3.1.1 ⚠ **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 portable bed rail.
- 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.
- 9.4.1. The warning must including [sic] the following, exactly as stated below:

WARNING – ENTRAPMENT HAZARD

⚠ NEVER use portable 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.

ASTM F2085-12 adopts some of the requirements in the proposed rule, but clarifies the warning label. The new provisions state:

- 9.3.1 The warning statements shall include the following wording, exactly as stated below:

⚠WARNING

DRAFT

SUFFOCATION AND STRANGULATION HAZARD

Gaps in and around bed rails have entrapped young children and killed infants. NEVER use with children younger than 2 years old. Use ONLY with older children who can get in and out of adult bed without help. NEVER use in place of crib.

NEVER use unless bed rail is tight against mattress, without gaps, and at least 9 inches from headboard and footboard. Do not fill gaps with pillows, blankets, or other items that can suffocate children.

NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use ONLY on adult bed.

- 9.3.2 For manufacturers' specific bed rails, the warning statements shall also address the following:

  Use only on (*manufacturer insert applicable bed and mattress/platform information*).

- 9.4 At least one installation component must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning shall 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" 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 The following warning shall be addressed:

  ⚠WARNING – ENTRAPMENT HAZARD

DRAFT

NEVER use bed rail without properly securing bed rail to bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death.

Note 2—Addressed means that verbiage other than what is shown can be used as long as the intent is the same or information that is product-specific is presented.

We believe that the new ASTM F2085–12 warning requirements address the comments received on the proposed rule and improve the requirements in the prior version of the voluntary standard and the proposed rule. The age at which children should not be using a portable bed rail has been made explicit with the statement: "NEVER use with children younger than 2 years old." Also, the statement immediately following that: "Use ONLY with older children who can get in and out of adult bed without help," clarifies that children must meet both criteria: they must be at least 2 years old, and they must be able to get in and out of an adult bed without help. Additional revisions to the language, such as the statement: "Gaps in and around bed rails have entrapped young children and killed infants," clarifies for consumers the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a considerably more concise warning, which may increase the likelihood that consumers will take the time to read the warning and encode the information. For example, the proposed rule's warning requirements would have resulted in a warning approximately 148 words long; whereas, the warning requirements in ASTM F2085–12 result in a warning that is 102 words long. The revised warning language also is written at a slightly lower grade level

DRAFT

than the proposed rule warning language, and people who read the warning may be more likely to understand it.

10. Permanency of Label and Warnings

The proposed rule would not make any change to section 10 of ASTM F2085-10a "Permanency of Label and Warnings." This section is unchanged in ASTM F2085-12.

11. Instructional Literature

We proposed to revise section 11.1 of ASTM F2085-10a to state:

- 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.

ASTM F2085-12 incorporates this provision but adds clarifying language in section 11.1.1. ASTM F2085-10a provided that:

- 11.1.1 The instructions shall contain the warning statements, required by 9.3.1 in the exact format, and shall address the statements in 9.3.2. In addition, instructions shall address the following: Discontinue use if damaged, broken or if parts are missing.

ASTM 2085-12 section 11.1.1. now states:

- 11.1.1 The instructions shall contain the warning statements, required by 9.3.1 in the exact format, and where applicable, shall address the statement 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.

DRAFT

The revised requirement helps clarify that the instructions are appropriate for manufacturers' specific bed rails, including the manufacturer's applicable bed and mattress/platform information that was revised in section 7 (Test Equipment).

12. Keywords

The proposed rule would not change section 12 of ASTM F2085-10a "Keywords." This section is unchanged in ASTM F2085-12.

13. Conforming Edits

ASTM F2085-12 provides conforming edits, including renumbering the figures to incorporate the addition of figures in section 3 (Terminology), and section 6 (Performance Requirements). ASTM F2085-12 also provides additional rationale for the changes in its appendix. The appendix is nonmandatory information and may be viewed in the ASTM F2085-12 standard under "Appendix (Nonmandatory Information); XI. Rationale."

14. Additional Change to the Final Rule

On our own initiative, we revised § 1224.1, "Scope, application, and effective date," by replacing "This part 1224 establishes…" with "This part establishes…." This is a non-substantive change intended to simplify the sentence structure in § 1224.1.

G. Effective Date

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be a least 30 days after publication of the final rule. 5 U.S.C. 553(d). The preamble to the proposed rule indicated that the standard would become effective 6 months after publication of a final rule. We sought comment on how long it would take manufacturers of portable bed rails to come into compliance with the rule. One

DRAFT

commenter stated that 6 months allowed for too much delay of administrative enforcement of the new requirements. One commenter stated that if a CPSC mandatory regulation differed from the ASTM standard, a minimum of 1 year is appropriate to allow adequate time for manufacturers to bring products into compliance with the new requirements. Because ASTM has published a new standard that was approved as of January 1, 2012, and because the final rule adopts the new standard as a CPSC mandatory regulation, we believe 6 months is an adequate length of time for manufacturers to comply with the new requirements. We believe that manufacturers would benefit from the additional 6 months after publication of a final rule to review the new requirements thoroughly and to ensure that new portable bed rails manufactured or imported after that date are in compliance with the new requirements, including the fabrication of new labels, as well as the retooling and redesign of products. Accordingly, the final rule provides that the rule will be effective 6 months after publication of the final rule in the *Federal Register*. A 6 month effective date should also enable the Commission to complete the required rulemaking with regard to the notice of requirements regarding the accreditation of laboratories to conduct the requisite third party testing to this new portable bed rails standard.

H. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601–612, requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule. The final regulatory

flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis; a summary of the assessment of the agency of such issues; and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of, and where feasible, an estimate of, the number of small entities to which the rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the 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. a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

2. The Market

Typically, portable bed rails are produced and/or marketed by juvenile product manufacturers and distributors or by furniture manufacturers and distributors. When the

DRAFT

proposed rule was published, we were aware of 14 manufacturers or importers supplying bed rails to the U.S. market. We are now aware of at least 17 known manufacturers or importers supplying bed rails to the U.S. market. Thirteen are domestic manufacturers (76 percent), and three are domestic importers (17 percent). The remaining firm has an unknown supply source, and there is no publically 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; an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 12 of the domestic manufacturers and three of the domestic importers known to be supplying portable bed rails to 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. Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard F2085–10a (the previous voluntary standard). Among them, four are JPMA-certified as compliant with ASTM F2085–10a, and one firm claims compliance. Of the three importers, one firm is JPMA-certified as ASTM compliant with ASTM F2085–10a, and one firm claims to be in compliance. All seven firms, which are either JPMA-certified or claim compliance with ASTM F2085–10a, are small. However, none of these firms meets the requirements of the current voluntary standard, ASTM F2085–12.

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JPMA estimates that current annual sales of portable bed rails are approximately 750,000 units, and retail sales are approximately $20 million. 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 in recent years, and bed rails remain in use for 3 to 5 years, then currently, 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 do 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.

3. Impact of the Standard on Small Business

There are 17 firms currently known to be producing or selling portable bed rails in the United States. Of these firms, 12 are small domestic manufacturers, and three are small domestic importers. The remainder of this analysis focuses on these 15 small domestic firms.

Small Domestic Manufacturers

The impact of the draft final rule on small manufacturers may differ, based on whether they compliant with the preceding ASTM standard, ASTM F2085-10a. Of the 12 domestic manufacturers, five produce portable bed rails that are certified as compliant by JPMA or claim to be in compliance with ASTM F2085-10a.

The products of the firms that are not in compliance with ASTM F2085-10a may require substantial modifications to meet ASTM F2085-12. The costs associated with these modifications could include product redesign, development and marketing staff time, product testing, and focus group expenses. It is possible that some firms may

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change the type of materials used to make portable bed rails, resulting in some cost increase. Costs may also rise if additional materials are required, or the products need to be redesigned. The actual costs of product modifications are unknown, but they 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 on the firms that produce portable bed rails that are compliant with ASTM F2085-10a may be less significant. Firms already in compliance with ASTM F2085-10a may require fewer modifications in order to bring their product into compliance with the current voluntary standard. Some firms may opt to preassemble component(s) rather than redesign their product. If firms decide to preassemble products, then portable bed rails may require larger shipping boxes. Shipping larger boxes is likely to increase shipping costs, and increased shipping costs may be significant in some cases. Larger boxes will also require greater storage space and may cause some retailers to reduce portable bed rails from their shelves and inventories.

All manufacturers will need to modify existing warning labels. Costs associated with the new warning label would be low because no new materials are used. However, eliminating the specified test methods in the proposed rule and reducing the number of testing configurations as well as reducing the number of warnings may result in a small reduction in costs. At least four small manufacturers' product lines consist primarily or entirely of nonrigid portable bed rails. These firms may need to alter the warning label and requirements for enclosed openings; but otherwise, these firms are not likely to be affected significantly by the voluntary standard.

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Additionally, once the final rule and the notice of requirements is in effect, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements.

Small Domestic Importers

All three small domestic importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the current voluntary 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.

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

4. *Alternatives*

Section 104 of the CPSIA requires the Commission to adopt a mandatory standard substantially the same as, or more stringent than, the voluntary standard, if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. One alternative would be to set an effective date later than the staff-recommended 6 months. This would allow suppliers (and

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manufacturers) additional time to modify and/or develop compliant portable bed rails, thereby spreading the associated costs over a longer period of time.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Paperwork Reduction Act

This 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). The preamble to the proposed rule (76 FR at 19922 through 19923) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. OMB has assigned control number 3041-0149 to this information collection. We did not receive any comment regarding the information collection burden of the proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 17 manufacturers rather than the 14 manufacturers initially estimated in the proposed rule.

Accordingly, the estimated burden of this collection of information is modified as follows:

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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)	17	2	34	1	34

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

There are 17 known firms that supply portable bed rails to the U.S. market. All 17 firms are assumed to use labels on their products and their packaging, but they would need to make some modifications to their existing labels. The estimated time required to make these modifications 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 17 firms x 2 models per firm = 34 annual hours. We estimate that the hourly compensation for the time required to create and update labels is $28.36 (Bureau of Labor Statistics, September 2011, 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 $964 ($28.36 per hour x 34 hours = $964.24, which we have rounded down to $964).

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this final rule to the OMB.

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

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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 this final rule for portable bed rails, as "consumer product safety standards." Furthermore, the designation of "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

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certified. We intend to issue a notice of requirements in the near future to explain how accredited laboratories can become recognized by CPSC as third party conformity assessments bodies to test to the new portable bed rails standard.

Additionally, because portable bed rails covered by this final rule are "children's products," they must comply with all other applicable CPSC requirements, such as the lead content and phthalates 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

For the reasons stated in the preamble, the Commission amends 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.

1224.1 Scope, application, and effective date.

1224.2 Requirements for portable bed rails.

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 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**].

§ 1224.2 Requirements for portable bed rails.

(a) Each portable bed rail as defined in ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails*, approved January 1, 2012, must comply with all applicable provisions of ASTM F2085-12. 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) [Reserved]

Dated:_____

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

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Staff Briefing Package

Draft Final Rule for Portable Bed Rails
February 2012

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

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Table of Contents

EXECUTIVE SUMMARY iii

BRIEFING MEMORANDUM iv

TAB A: Comments to NPR 26

TAB B: Comparison of ASTM F2085-12, Standard Consumer Specification for Portable Bed Rails, with the Proposed Requirements in the NPR docket # CPSC-2011-0019 111

TAB C: Human Factors Staff's Response to NPR Comments and Revised Requirements Associated with Warning Statements for Portable Bed Rails 136

TAB D: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011 145

TAB E: Final Regulatory Flexibility Analysis of Draft Final Rule for Portable Bed Rails 149

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EXECUTIVE SUMMARY

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 promulgate consumer product safety standards for certain durable infant and toddler products. These product standards should be identical to applicable voluntary standards or more stringent, if the Commission determines that additional requirements would further reduce the risk of injury associated with the product.

This briefing package assesses the effectiveness of the voluntary standard for portable bed rails and presents staff's recommendations for a draft final rule to address potential hazards to children associated with these products.

In April 2011, the Commission published a notice of proposed rulemaking (NPR) for portable bed rails to adopt the ASTM International (formerly known as the American Society for Testing and Materials) ("ASTM") voluntary standard, ASTM F2085-10a, *Standard Consumer Safety Specification for Portable Bed Rails*, with additional requirements to strengthen the standard to reduce the risk of injury associated with portable bed rails. The NPR solicited information and comments concerning all aspects of the proposed rule. The CPSC received 16 comments on the NPR. Eight comments expressed general support for the proposed rule and eight comments raised other issues.

In November 2011, ASTM balloted a revision to the standard that contained the additional requirements contained in the NPR, with a few clarifications and modifications, and addressed the comments received on the NPR. The revised ASTM standard was approved and published in January 2012. The staff's draft final rule to address hazards associated with portable bed rails incorporates the newly published ASTM F2085-12 *Standard Consumer Safety Specification for Portable Bed Rails*, which is more stringent than the previous standard.

The impact of the draft final rule on small manufacturers will vary depending on whether they were compliant with the previous version of the voluntary standard. The firms that were not in compliance with the previous version may require substantial modifications to meet the current voluntary standard. The actual costs associated with these changes are unknown but could be significant for some firms. The impact on firms that were in compliance with the previous voluntary standard may be less significant. However, even portable bed rails compliant with the previous voluntary standard will require some modifications.

CPSC staff recommends that the Commission proceed with publication of the final rule for portable bed rails under section 104(b) of the CPSIA, as drafted by the Office of the General Counsel. CPSC staff also recommends an effective date of 6 months after publication of the final rule.

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BRIEFING MEMORANDUM

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

This document has been electronically approved and signed.

Memorandum

DATE: February 1, 2012

TO: The Commission
Todd A. Stevenson, Secretary

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

FROM: DeWane Ray, Assistant Executive Director
Office of Hazard Identification and Reduction
Rohit Khanna, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Staff's Draft Final Rule 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) to study and develop safety standards for certain infant and toddler products. The term "durable infant or toddler product" is defined in section 104(f) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. Portable bed rails (also referred to as "bed rail" or "bedrail") are one of the products identified by the Commission under section 104(f) of the CPSIA as durable infant or toddler products. On December 29, 2009, the Commission issued requirements for consumer registration of durable infant or toddler products and a bed rail was identified as a durable infant or toddler product that needed to comply with the registration card requirements. 76 FR 68668.

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, at an ASTM International (formerly known as the American Society for Testing and Materials) ("ASTM") subcommittee meeting regarding the ASTM portable bed rail voluntary standard. Staff participates in the ASTM meetings on an ongoing basis.

This briefing package assesses the effectiveness of the portable bed rail voluntary standard and presents staff's recommendations for a final rule to address potential hazards associated with portable bed rails.

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II. BACKGROUND

A. Pre-NPR Standard Activity

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

On October 3, 2000, an advance notice of proposed rulemaking (ANPR) was published in the *Federal Register* (65 FR 58968) 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 partially (away from the mattress) and the child rolls into the gap between the mattress and the bed rail. Once entrapped, the child can asphyxiate.

ASTM F2085, *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 first edition of the standard included labeling requirements but did not contain performance requirements to address 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 to the ASTM standard that was substantially the same as staff's draft proposed standard; accordingly, the NPR was deferred. The revised ASTM standard was approved and published in June 2003. In 2008, ASTM published another standard revision that included a structural integrity test to address incidents involving hinge lock mechanism failures. From 2009 to 2010, minor revisions to the standard were published (ASTM F 2085-10a).

B. NPR Standard Activity

On April 11, 2011, an NPR for portable bed rails was published in the *Federal Register* (76 FR 19914) to adopt ASTM F2085-10a, with additional requirements to strengthen the standard to reduce the risk of injury associated with portable bed rails. (On the same date, a withdrawal of the October 3, 2000, ANPR was published in the *Federal Register* (76 FR 19926)). The proposed additional requirements in the NPR included: (1) revisions to the 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; (3) a new performance requirement and warning label requirement to address the potential for fatal entrapment incidents related to misinstallation; and (4) a revised warning label to specify the intended user age for portable bed rails. These additional requirements were developed by staff, in collaboration with the ASTM Portable Bed Rail Subcommittee and balloted on February 10, 2011. On November 7, 2011, ASTM balloted a revision to the standard that contained the additional requirements and that was approved by the committee; a revised standard was published in January 2012 (ASTM F2085-12). Staff's draft final rule incorporates by reference the new portable bed rail standard ASTM F2085-12.

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III. DISCUSSION

A. NPR Comments

In the NPR, the Commission solicited information and comments concerning all aspects of the proposed rule. Staff received 16 comments on the NPR. Eight comments stated general support for the proposed rule and the other eight comments raised other issues that are addressed, by topic, below. All of the NPR comments can be found in Tab A. Staff has addressed these comments, in detail, in the attached memos at Tabs B, C, and E. Following is a summary of the comments and staff's responses.

PROPOSED MISASSEMBLY AND MISINSTALLATION REQUIREMENTS

Comments: One commenter questioned the need for a revised standard noting that misassembly of a portable bed rail does not present a significant hazard. In addition, there were two comments that expressed concerns that the proposed language related to misassembly and misinstallation is vague, arbitrary, and invites unacceptable variability in test conditions.

Staff Response: Staff disagrees with the comment that misassembly of portable bed rails does not need to be addressed. As stated in the NPR, most bed rails currently in the market are difficult for the consumer to assemble correctly due to the number of components and complexity of the fastening hardware. Staff identified fatal incidents involving misassembled bed rails and concluded that requirements were needed to address this hazard pattern. Staff agrees, in part, with the other comments. After publication of the NPR, the ASTM Portable Bed Rail Subcommittee working group developed alternate performance requirements to address the commenters' concerns about testing and limited the misassembly possibilities to configurations most likely to present entrapment hazards. These requirements have been added to the new edition of the ASTM standard that is incorporated in staff's draft final rule. The requirements in ASTM F2085-12 are simpler and clearer, compared to the proposed NPR test requirements. ASTM F2085-12 addresses public comments and concerns regarding the NPR including issues such as the potential for numerous test configurations, the complexity of testing zippered products, the difficulty in determining misassembly of adjustable components, and the lack of repeatability of testing between testing laboratories.

A significant difference between the NPR and ASTM F2085-12 is the removal of proposed test methods in the latter to determine whether a misassembled bed rail lacks sufficient vertical structure or provides sufficient visual cues that would notify a consumer that the bed rail is not assembled properly. Instead, the new standard focuses the testing on components that were identified in the incident data. This approach should reduce the number of misassembly combinations and prevent unnecessary testing, as compared to the proposed requirements in the NPR. The addition of figures and illustrations clarifies the pass and fail criteria of the requirements. Test personnel will conduct visual assessments of a bed rail after attempting to misassemble the bed rail. This will require some judgment to determine whether a bed rail can be misassembled. Test personnel are trained to understand the intent of the standards for which they provide testing services, and competent laboratories should be capable of making reasonable engineering judgments.

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FOAM AND INFLATABLE (NON-RIGID) BED RAILS

Comments: There were several comments supporting the inclusion of inflatable and foam bed rails in the scope. A few commenters stated that these types of bed rails should meet all of the requirements in the standard; and/or have requirements to address a potential suffocation hazard.

Staff Response: Non-rigid portable bed rails are included in the scope of ASTM F2085-12 and are required to meet the general requirements to address sharp edges or points, small parts, and permanency of labels, as well as a requirement for a new warning label. However the standard was developed for rigid, portable bed rails and many of the test requirements would not be applicable to these products. Staff requested that ASTM evaluate these types of products including the potential risk of strangulation associated with straps used to secure the bed rail on to the bed. The ASTM subcommittee agreed to continue to monitor these types of non-rigid, portable bed rails and pursue development of additional requirements, as necessary.

TEST EQUIPMENT: PLATFORM AND SHEETING MATERIAL

Comment: One commenter stated that the specifications for the Mattress Test Platform 2 and the bed sheeting requirements in ASTM F2085-10a - *Section 7.1.2.1 (and 7.1.1.1 for sheeting) Mattress Construction* are too restrictive and difficult to obtain.

Staff Response: CPSC staff agrees that the Mattress Test Platform 2 and the bed sheeting specification are unnecessarily restrictive. ASTM F2085-12 removes the Indentation Load Deflection (ILD) test that is designed to test the firmness of a foam material and is relevant for Test Platform 1, which is a 4" thick foam mattress. Test Platform 1 was selected to represent a mattress that was both thin and not very firm. Test Platform 2 is an inner spring mattress, and thus not solid foam. It was selected to be thick (10-11"). There is no concern about the foam firmness of Test Platform 2, because the inner spring design gives the mattress rigidity. Therefore, there is no need to have an ILD requirement and test for Test Platform 2. In addition, there is no practical way to test the foam in an inner spring mattress to the ILD test, thus in order to ensure a mattress meets this requirement, it would be necessary to track down the supplier of the foam in the mattress to obtain a suitable test piece. ASTM F2085-12 was also revised to allow greater flexibility for available bed sheet types for use in testing. Finding sheets that provide the previously specified weight per ounce is not practical. The subcommittee believes that having 50/50 cotton poly sheets over the mattress should be the basic requirement. A slight difference in thread count should not affect the results.

DOUBLE-SIDED BED RAILS

Comment: Several commenters recommended that portable bed rails be sold only in sets of two (double-sided) to reduce entrapment between the wall or a piece of furniture.

Staff Response: Double-sided bed rails currently are available to consumers. Staff is not aware of entrapment incidents between the wall and the bed that have occurred because of the use of either a single or double portable bed rail. An entrapment between the bed and the wall can occur without the use of any type of portable bed rail and there is no evidence to support the contention that requiring double-sided bed rails will address this hazard. However, consumers

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should continue to be educated regarding safe sleep environments to address the hazard of entrapment between the wall and the mattress.

BED SHEET CHANGING

Comment: One commenter stated that the CPSC does not address issues like daily changing of bed sheets or other routine use that will result in movement or stress on the portable bed rail components which may make the product unsafe.

Staff Response: A review of the incident data did not indicate that changing of bedding or other routine behavior contributed to fatal or nonfatal incidents due to additional stress on the components of the portable bed rails. The ASTM standard contains requirements that test the strength of the bed rail. CPSC staff believes that these requirements are adequate to address stress-related failures.

MATTRESS SYSTEMS

Comment: One commenter stated the rulemaking proceeding does not address the fact that portable bed rails can be used in various mattress systems.

Staff Response: Staff's review of bed rail products showed that most bed rails are adjustable to fit various mattress sizes. The ASTM standard contains test requirements that evaluate the safety of portable bed rails on test platforms intended to represent the different types of adult beds available in the market.

WARNING LANGUAGE REVISIONS

Comment: One commenter stated that warning labels should include age limits because bed rails should not be used with children younger than 2 years old. Another commenter noted the importance of describing the hazard more concisely than is done in the current voluntary standard. One commenter stated that the NPR revision to the primary warning provides a false sense of security for the caregiver of children who can get in and out of an adult bed without help; and the commenter further asserted that the proposed wording of the entrapment hazard warning for critical installation components is misleading because correct installations can also result in entrapment and death.

Staff Response: Staff agrees that the primary bed rail warning label on the product and its retail packaging should include explicit age guidance and that the warning statements in the previous edition of the voluntary standard, ASTM F2085–10a, lacked this specificity. The proposed revision to the warning language in the NPR did not make this explicit. Staff believes that the new ASTM F2085–12 warning requirements address the public comments and are an improvement to the requirements in both the prior version of the voluntary standard and the NPR. The age at which children should not be using a bed rail has been made more explicit with the statement: "NEVER use with children younger than 2 years old"; and the statement immediately following: "Use ONLY with older children who can get in and out of adult bed without help," clarifies that children must meet both criteria. Additional revisions to the language, including the warning: "Gaps in and around bed rails have entrapped young children

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and killed infants" clarify for consumers the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a more concise warning, which may increase the likelihood that consumers will take the time to read the warning and understand the information. For example, the NPR warning requirements result in a warning of approximately 148 words; whereas, the warning requirements in ASTM F2085–12 result in a much shorter warning of 102 words. The revised warning language also is written at a slightly lower grade level than the NPR warning language, which means that people who read the warning may be more likely to understand it better.

Staff disagrees that "the entrapment hazard warning for critical installation components misleads consumers, because correct installations can also result in entrapment and death." The purpose of the entrapment hazard warning is to alert consumers to the importance of installing the bed rail correctly. The statement: "Incorrect installation can allow the portable bed rail to move away from the mattress, which can lead to entrapment and death," refers specifically to incorrect installation as the mechanism by which the bed rail can move away from the mattress. Nothing in the warning suggests that other mechanisms of entrapment exist that do not involve movement of the bed rail. Moreover, the bed rail itself includes a more comprehensive warning that discusses other sources of entrapment, such as the placement of the bed rail relative to the headboard or footboard of the adult bed, which clearly shows that other hazards and entrapment scenarios exist.

Comment: One commenter stated that the warning labels should describe the materials used to produce the bed rails. Another commenter stated that there should be a strict warning about modification of the bed rail and the bed rail components.

Staff Response: Staff disagrees that the warning requirements should specify the materials used in the product. Warnings should be used only to identify a significant hazard. The commenter has not identified what hazard such a warning requirement would be intended to address. The consequences of exposure to the hazard and appropriate avoidance behavior in response to the hazard also are key pieces of information that should be present in a warning, unless this information can be readily inferred. The commenter does not specify any of this information. Thus, including a description in a warning label of the materials used to produce the bed rail is not appropriate at this time.

Staff also disagrees that warning requirements should include provisions regarding the modification of the bed rail and its components. Staff interprets the commenter's statements as seeking the addition of warning language to address intentional alteration of the bed rail components by consumers. Staff's review of the incident data does not support the premise that intentional modification of bed rail components by consumers led to injury. Thus, mandating such warning language is not supported by the data.

ADULT BED RAILS

Comments: Two commenters stated that the scope of the rule should guarantee more stringent safety standards for all portable bed rails, including adult bed rails. These commenters note that

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bed rails are used routinely in nursing facilities, hospitals, and private homes. According to the commenters' data, between 1985 and 2009, the U.S. Food and Drug Administration ("FDA") received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds, including 408 deaths, 138 nonfatal injuries, and 185 near-misses, where injuries were prevented due to staff intervention. To address these types of incidents, the commenters requested that the Commission take action on adult bed rails, including mandating warning labels, enforcing reporting requirements, recalls, and civil penalties, and engaging in greater collaboration with the FDA.

Staff Response: Section 104(b) of the Consumer Product Safety Improvement Act requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. Accordingly, this rulemaking is limited to bed rails intended for use with children (typically from 2 to 5 years of age) to keep them from falling out of an adult bed. Comments pertaining to other bed rail products intended for use by older children or adults are outside the scope of this proceeding. With respect to bed rails intended for use by adults or older children, CPSC staff is aware that some bed rails may be considered "devices" under the Federal Food, Drug, and Cosmetic Act ("FDCA"), and therefore, they are subject to regulation by the FDA. As stated in the preamble to the NPR, the 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. However, the commenters raised important issues regarding incidents associated with bed rails that are not intended to be either a part of, or an accessory, to a hospital bed or FDA-regulated pediatric bed. To the extent that there may be such bed rails that are not regarded as medical devices regulated by the FDA, but are considered instead to be "consumer products" under the CPSA or otherwise subject to CPSC's jurisdiction, staff will continue to review this issue and consider what actions, if any, are appropriate.

SHIPMENT COSTS AND PRODUCT SIZE

Comment: One commenter stated that shipping costs are a significant portion of the product's total cost and increasing the box size to contain a preassembled product could potentially increase the cost to ship the product by 50 percent.

Staff Response: Staff agrees that preassembling portable bed rails may require larger boxes, and that shipping larger boxes is likely to increase shipping costs. It is possible that the higher shipping costs could be significant for some manufacturers.

Comment: The same commenter stated that the proposed rule may result in adverse retail response to stocking bulkier packages on shelves or in inventory, or may result in retailers dropping products or refusing to accept price increases, thus, placing the cost burden on manufacturers.

Staff Response: Staff agrees that, all else equal, larger boxes for bed rails would need additional storage and shelving space. As a result, some retailers might choose to decrease the number or model of bed rails they offer to the public, which could, in turn, have the effect of reducing sales by manufacturers.

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B. *Incident Data (Tab E)*

NPR Incident Data

The NPR summarized the data for incidents related to portable bed rails from January 1, 2000 through March 31, 2010. For that period, CPSC 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. Of the 13 fatalities, there were two deaths which 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 3 cases of portable bed rail misassembly. In 3 additional fatal incidents, the contributing factor(s) that led to the hazardous entrapment scenario could not be determined. The beds involved in all eight cases were adult-size. The remaining 5 (of the 13) fatal incidents had no product or scenario-specific information.

Follow-up on NPR Reported Fatal Incidents

Since the publication of the NPR, staff received additional information through in-depth, follow-up investigations on 4 of the 5 fatal incidents that had been categorized as having insufficient information in the NPR. One of the four fatalities (document number 0427019066) that was included among the incident data in the portable bed rail NPR is now known to have occurred from partial displacement of the bed rail, leading to the entrapment of the decedent. Another fatality, (document number 0406130408), listed earlier as lacking sufficient information, remains in that status; CPSC field investigators were unable to establish contact with anyone with firsthand knowledge of the product or the scenario of the incident. The third fatality (document number 0717000449) is now known not to have involved any portable bed rail; what originally was reported as a bed rail has been confirmed to be a crib rail. Finally, it seems unlikely that the fourth fatality (reported in document number 0442078182) was associated with a portable bed rail. The decedent, co-sleeping with a sibling and a parent, died from suffocation. The role, if any, of a portable bed rail, now seems questionable.

New Incident Data

The Directorate for Epidemiology, Division of Hazard Analysis (EPHA) conducted a new search on November 9, 2011 of the CPSC's epidemiological databases[1] to determine the number of new incidents reported since the data presented in the NPR (Tab E). The new search

[1] CPSC databases that were searched included the In-Depth Investigations (INDP) file, the Injury or Potential Injury Incidents (IPII) file, and the Death Certificates (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor are they a sample of known probability of selection. 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. The date of extraction for reported incident data on portable bed rails was 11/09/2011. All data coded under product code 4075 and age as 6 years or younger (to accommodate any physically disabled children) was extracted. Upon careful joint review with the CPSC's Directorate for Engineering Sciences staff, some cases was considered out of scope (for example, adult bed rails).

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UNDER CPSA 6(b)(1)

showed that there were 23 portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. Four of the 23 incidents were fatal, and 19 were nonfatal, 8 of which reported an injury. Among the fatalities, one resulted from a misinstalled bed rail (X1190536A), where the child was strangled by the straps of the reinforced anchor system. The second fatality (I1170672A) occurred when an infant slipped through the torn section of the mesh and got caught when the bed rail flipped down and caught him at the neck. The remaining two fatalities (0906085374 and 0948097318) lack any product information or scenario-specific details. Eight of the 19 nonfatal incidents resulted in injuries. Most of the injuries were bumps and bruises; one incident reported a severe laceration and another reported a fractured collarbone. None of the nonfatal injuries required hospitalization.

Among the incidents that reported age (18 out of 23), 3 involved a child younger than 15 months. The majority of the incidents (15 out of 18) reported the child's age to be between 15 months and 4 years.

The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the NPR, and they are as follows:

- *Hinge-lock failure:* There were 8 incidents, including 4 injuries and 1 fatality, where the hinge-lock mechanism failed to keep the side panel in an upright position. The hazard in the fatality was a combination of hinge-lock failure and torn mesh panel (see below).
- *Displacement of bed rail*: There were 7 incidents, including 3 injuries, where the bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail.
- *Sharp surfaces:* There were 3 incidents, including 1 injury, due to sharp surfaces on the bed rail.
- *Worn or poor quality fabric on mesh panel:* There was 1 fatal incident, which was attributable, in part, to the torn mesh panel and, in part, to the hinge-lock failure of the bed rail (see above).
- *Misinstallation:* One strangulation fatality on the straps of the reinforced anchor system of the bed rail was reported to have been due to the improper installation of the bed rail.
- *Miscellaneous or unknown issues:* There were 4 incidents, including 2 fatalities with insufficient information on the product or scenario. Of the 2 nonfatal incidents, 1 reportedly involved hazards from broken screws, while the other reported design issues with the bed rail.

C. Staff's Draft Final Rule

The NPR for portable bed rails proposed to adopt ASTM F2085-10a, *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.

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UNDER CPSA 6(b)(1)

Staff concluded that these additional requirements were necessary to further reduce the risk of injury associated with portable bed rails. The intent of the NPR was to provide coverage for newer bed rail products made of foam or inflatable materials; to address fatal incidents due to misassembly; to address potential fatal incidents due to misinstallation; and to emphasize warnings to specify intended user age.

Following publication of the NPR, the ASTM Portable Bed Rail Subcommittee collaborated with staff and held several meetings and webinars to develop similar requirements to address the additional requirements in the NPR and the issues that were raised in the NPR comments. These discussions focused on improving the NPR requirements, by simplifying test procedures, clarifying language, providing graphics and figures to illustrate acceptable and failing performance criteria and test configurations, and to clarify warning statements. The Directorate for Engineering Sciences, Mechanical Engineering Division (Tab B) and Human Factors Division (Tab C) provide detailed information on the rationale and supporting information for the draft final rule, as well as the changes from the NPR.

Misassembly Requirement Clarification

A significant difference between the NPR and the ASTM F2085-12 requirements is the removal of the proposed specific test methods associated with the misassembly performance requirements in the latter. The determination of whether there is the potential for bed rail misassembly will depend upon the judgment of qualified test personnel. The clarification of the misassembly performance requirements and examples of correct evaluation conditions in the new ASTM standard provide sufficient guidance for test personnel to make performance evaluations based upon sound engineering judgment. The requirements in the new ASTM standard are equivalent to the NPR's intent to reduce the potential for misassembly. Specifically, the new ASTM standard addresses the NPR's misassembly requirements with the following provisions:

1. Nuts and bolts are to be "captive" (*i.e.*, attached to the bed rail structure) to prevent the consumer from discarding or misplacing the fasteners. This requirement directly addresses fatal incidents where the exclusion of a fastener was a contributing factor.
2. A misassembled bed rail is identified as one that can be assembled without a supplied component or without engaging the entire frame as intended by the manufacturer. This requirement addresses directly fatal incidents where the horizontal bar was missing or where the mesh/fabric was not installed correctly over the bottom horizontal bar.
3. Components cannot be interchanged or inverted. This requirement will prevent the consumer from assembling the component in the backwards or upside down position, where the orientation impacts safety.

Warnings Clarification

Staff also engaged the ASTM Subcommittee on Portable Bed Rails to address issues on warnings that were raised in the comments and to clarify the warning statements.

The warning requirements in the new ASTM standard address the public comments received on the NPR and are superior to the requirements in the NPR. The age at which children should not be using a bed rail has been made explicit with the statement: "NEVER use with children younger than 2 years old," and the statement immediately following this: "Use ONLY with older

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children who can get in and out of adult bed without help," clarifies that children must meet both criteria: they must be at least 2 years old, and they must be able to get in and out of an adult bed without help. Additional revisions to the language, such as "Gaps in and around bed rails have entrapped young children and killed infants" clarify the mechanism by which children are dying or becoming injured.

The new ASTM standard contains a more concise warning, which may increase the likelihood that consumers will take the time to read the warning and follow the information. For example, the NPR warning requirements result in a warning approximately 148 words long, whereas, the new ASTM standard warning is 102 words long. The new warning language also is written at a slightly lower grade level than the NPR warning language, meaning that people who read the warning may be more likely to understand it.

The following table summarizes the relevant sections of ASTM F2085-10a, the proposed modifications to ASTM F2085-10a, and the final standard, ASTM F2085-12.

TABLE 1: CPSC Staff-Recommended Changes to the Proposed Rule for Portable Bed Rails – Underline Denotes Text Addition and Strikethrough Denotes Text Deletion

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature.	No change in NPR to address toddler beds.	1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature. <u>This consumer safety specification does not cover guardrails that fall under the scope of Consumer Safety Specification F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard.</u>
No section in ASTM	Proposed Section 1224.2(b) (1) *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.	Addressed in Section 5 General Requirements
2. Referenced Documents	Same as ASTM F 2085-10a	F1487 <u>Consumer Safety Performance Specification for Playground Equipment for Public Use</u> <u>F1821 Consumer Safety Specification for Toddler Beds.</u>

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UNDER CPSA 6(b)(1)

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
3. Terminology	Proposed Section 1224.2 (b)(2) revised the terminology in section 3 of ASTM F 2085-10a by creating new terms 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.	3.1.4 *captive hardware, n*—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (see Fig. 1). 3.1.6 *consumer adjustment, n*—those activities defined by the instructions to be taken by the consumer in order to properly fit and secure the bedrail to the mattress. 3.1.6.1 *Discussion*—Examples include sliding telescoping poles for proper fit, or initial adjustment for use, tightening of anchoring straps and positioning or changing of attachment components or locking pins. 3.1.7 *consumer assembly, v*—the fitting together of components of the bedrail according to manufacturer instructions. 3.1.8 *installation component, n*—component of the bedrail that is specifically designed to attach the bedrail to the bed and typically located under the mattress when in the manufacturer's recommended use position. 3.1.10 *misassembled bed rail, n*—a bed rail that has been assembled incorrectly but appears to function as a bedrail. 3.1.12 *non-rigid bed rail, n*—portable bed rail constructed of non-rigid materials, including, but not limited to, fabric or foam or that requires air be inflated into the product to achieve structure. **FIG. 1 Captive Hardware**
4. Calibration and Standardization	No Change	No change

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ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
5. General Requirements Foam and inflatable bed rails are not covered. No requirements for installation components are in this edition of the standard.	Proposed section 1224 2(b)(1) stated 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. 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 (new section 5.6.1) would provide 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 2085–10a.	5.5 Non-rigid bed rails need only meet the general requirements of Section 5, the performance requirement of 6.3, and the warning requirements of 9.3. 5.7 Installation components that are required to meet the performance requirements of 6.4, 6.5, and 6.6 shall be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly (this excludes any consumer adjustment). 5.8 For products requiring consumer assembly, supplied hardware used for assembly of the bed rail, such as screws, nuts or bolts shall be captive hardware to their respective components.
6. Performance Requirements	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 ASTMF 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	6.9 Bed rail components requiring consumer assembly shall not be able to be misassembled when evaluated to 6.9.1. 6.9.1 *Determining Misassembled Bed Rail*—A bedrail shall be considered a misassembled bed rail if it appears to be a functional bedrail under any one of the conditions listed in 6.9.1.1, 6.9.1.2, or 6.9.1.3 and it does not meet the requirements of 6.4, 6.5, or 6.6. 6.9.1.1 The bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging all structural components of the frame as intended in final assembly (Fig. 5 and Fig. 6). When the bedrail is evaluated, zippers and other means of attachment should be fully fastened. If possible to fasten the means of attachments without engaging said structural components, evaluation for misassembly should account for that

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UNDER CPSA 6(b)(1)

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	2085–10a), 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 2085–10a). 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 2085–10a 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 2085–10a would provide that mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a 1⁄2 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.	(see Fig. 6). NOTE 1—Any means of attachment, including, but not limited to, zippers, hooks and loops, and snaps, should be fully fastened. Fig. 7 represents a passing condition. 6.9.1.2 The bedrail can be consumer assembled with any horizontal structural components improperly positioned such as being inverted or interchanged, without permanent deformation or breakage of the component or bedrail. This excludes consumer adjustment or universal components that are designed to be interchangeable (Fig. 8). For example: *(1)* Horizontal structural components shall be interchanged (Components 1, 2, 3). *(2)* Horizontal structural components shall be inverted (AB:BA); (CD:DC); (EF:FE). 6.9.1.3 Bed rails where the positions of the arms are intended to be unidirectional are able to be assembled when the arms are rotated 180° about the vertical axis (Fig. 9). Center horizontal structural component is omitted consequently the fabric does not engage the center structural component. FIG. 5 Example of Fail Condition Bedrail fabric with bottom zipper misassembled, fabric cover can be zipped up without engaging the bottom horizontal bar. Bottom bar can be omitted from insertion into fabric sleeve or channel located at the base of the fabric component. FIG. 6 Examples of Fail Conditions Bedrail fabric with a zipper that is not fully engaged. The zipper cannot be fully engaged due to interference with the middle bar. FIG. 7 Example of Condition Not To Be Tested

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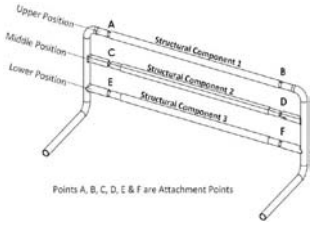
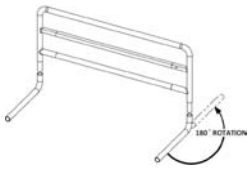
ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
		 FIG. 8 Example of Tube Inverted or Interchanged  FIG. 9 Example of Test for Unidirectional Arm
7. Test Equipment 7.1.1 Platform 1 7.1.1.1 *Mattress Construction* The mattress shall be of standard twin size, 38 by 74.5 in. 6 0.5 in. (0.97 by 1.89 m + 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft^3 +0.2, –0 (16 kg/m3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer, using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.	No change	7.1.1.1 *Mattress Construction*—The mattress shall be of standard twin size, 38 by 74.5 in. ± 0.5 in. (0.97 by 1.89 m ± 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft^3 +0.2, –0 (16 kg/m^3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 ~~180~~ threads per square inch. ~~and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer, using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.~~

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UNDER CPSA 6(b)(1)

ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
7.1.2 Test Platform 2 7.1.2.1 Mattress Construction - The mattress[6] shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick.[7] The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.	No change	7.1.2 Test Platform 2 7.1.2.1 Mattress Construction - The mattress[6] shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick.[7] The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have ~~180~~ 100 to 300 threads per square inch. ~~and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.~~
7.1.2.2 *Mattress Performance* - The foam shall have an Indentation Load Deflection (ILD)[4] of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.	No change	~~7.1.2.2 *Mattress Performance* - The foam shall have an Indentation Load Deflection (ILD)[4] of between 28 and 33 when tested in accordance with Test Methods D3574, Method B1.~~
No Section	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.	7.6 *Force Gauge*—Gauge shall have a minimum range of 0 to 50 lb (222 N) with a maximum tolerance of 60.25 lb (1.11 N).
No Section	(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	N/A - ASTM F2085-12 does not have test requirements to determine if a misassembled bed rail is acceptable.

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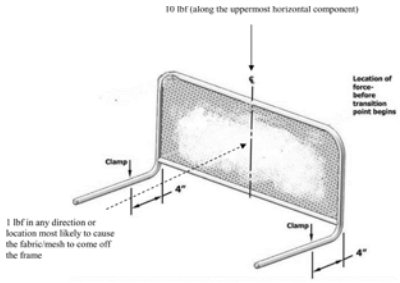
ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	structure and also determine the sufficiency of visual cues for portable bed rail misassembly. Under a new section 8.7 of ASTM F 2085–10a, the proposed test method for determining acceptability of vertical structure of a misassembled/functional 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 2085–10a). The clamps should be located 4 to6 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 10seconds and releasing (new section 8.7.3 of ASTM F 2085–10a); 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 2085–10a). The proposed test method for determining fabric sag acceptability of a misassembled/functional portable bed rail (new section 8.8 of ASTM F 2085–10a) 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, and depicted in new Figure 8.  	

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ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
	Figure 8: Determining missassembly/functional portable bed rail test setup. 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 2085–10a); 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 2085– 10a).	
9. Marking and Labeling 9.3.1 The warning statements shall include the following, exactly as stated below: 9.3.1.1 Suffocation and Strangulation Hazard. 9.3.1.2 Death or Serious Injury Can Occur. 9.3.1.3 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 bed rail. 9.3.1.4 **BED RAIL USE:** Bed rail can trap young children against mattress, headboard, or footboard. 9.3.2 The warning statements shall also address the following: 9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib. 9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up). 9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard. 9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	(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	9.3.1 The warning statements shall include the following wording, exactly as stated below: ⚠WARNING SUFFOCATION AND STRANGULATION HAZARD Gaps in and around bed rails have entrapped young children and killed infants. NEVER use with children younger than 2 years old. Use ONLY with older children who can get in and out of adult bed without help. NEVER use in place of crib. NEVER use unless bed rail is tight against mattress, without gaps, and at least 9 inches from headboard and footboard. Do not fill gaps with pillows, blankets, or other items that can suffocate children. NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use ONLY on adult bed. 9.3.2 For manufacturers’ specific bed rails, the warning statements shall also address the following: Use only on (*manufacturer insert applicable bed and mattress/platform information*). In addition, ASTM 2085-12 created new sections that require labeling on installation components. This

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ASTM F 2085 – 10a Section #	NPR Language	ASTM F 2085-12
9.3.2.5 For manufacturers' specific bed rails: *(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	under a new section 9.4 of ASTM F 2085–10a. A new section 9.4 of ASTM F 2085–10a would require the entrapment hazard warning to be in contrasting colors, permanent, conspicuous, and sans serif-style font.	requirement is similar to the NPR. 9.4 At least one installation component must be labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning shall 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" 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 The following warning shall be addressed: ⚠WARNING – ENTRAPMENT HAZARD NEVER use bed rail without properly securing bed rail to bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death. NOTE 2—Addressed means that verbiage other than what is shown can be used as long as the intent is the same or information that is product-specific is presented.
10. Permanency of Labels and Warnings	No change	No change
11. Instructional Literature	(ix). Instructional Literature (Proposed § 1224.2(b)(10)). This proposed section would revise the language in section 11.1 of ASTM F 2085–10a 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.	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. 11.1.1 The instructions shall contain the warning statements, required by 9.3.~~1in the same exact format, and shall address the statements in~~, and, where applicable, 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. 11.2 Warning statements located within the instructional literature shall meet the same requirements as specified in 9.3.

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Summary

Staff's draft final rule to address hazards associated with portable bed rails incorporates the new ASTM F2085-12 standard. The issues raised in public comments regarding the potential for infinite test configurations, testing of zippered products, need for consumer adjustment during installation, testing repeatability, and better warning statements have been adequately addressed in the new ASTM standard.

D. Potential Small Business Impact

Most 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 17 known manufacturers or importers supplying bed rails to the U.S. market. Thirteen are domestic manufacturers (76 percent), and three are domestic importers (17 percent). The remaining firm has an unknown supply source, and there is no publically available information regarding its size. Based on U.S. Small Business Administration guidelines, 12 of the domestic manufacturers and all of the domestic importers known to be supplying the U.S. market that are likely to be affected by the draft final rule are small, as described in the Directorate for Economic Analysis memo (Tab E).

It is possible that the draft final rule could have a significant impact on some small firms. The impact of the draft final rule on small manufacturers will vary based on whether they were compliant with the previous version of the voluntary standard (F2085-10a). If manufacturers are not in compliance with ASTM F2085-10a, that may require substantial modifications to meet the requirements of the current voluntary standard (F2085-12). The costs associated with these modifications include: staff time for redesign, development, marketing, and product/market testing. The actual costs are unknown, but could be significant for some firms. The impact on manufacturers that are compliant with F2085-10a may be less significant. However, even portable bed rails compliant with the previous voluntary standard will require some modifications to meet F2085-12. Additionally, preassembled products may require larger shipping boxes. Larger boxes will likely increase shipping costs and require greater storage space. This could lead some retailers to decrease the number or model types of bed rails they offer to the public.

E. Effective Date of Final Rule

The Administrative Procedure Act ("APA") generally requires that the effective date of a rule be a least 30 days after publication of the final rule. 5 U.S.C. 553(d). The preamble to the proposed rule indicated that the standard would become effective 6 months after publication of a final rule. CPSC sought comment on how long it would take manufacturers of portable bed rails to come into compliance with the rule. One commenter stated that if a CPSC mandatory regulation differed from the ASTM standard, a minimum of 1 year is appropriate to allow adequate time for manufacturers to bring products into compliance with the new requirements. Because ASTM has published a new standard as of January 2012, which will be incorporated into the final rule as a CPSC mandatory regulation, CPSC staff believes 6 months is an adequate length of time for manufacturers to comply with the new requirements. A 6 month effective date should also enable the Commission to complete the required rulemaking with regard to the Notice of

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Requirements regarding the accreditation of laboratories to conduct the requisite third party testing to this new bed rails rule.

One commenter stated that 6 months allowed for too much delay of administrative enforcement of the new requirements. CPSC staff believes that manufacturers would benefit from the additional 6 months after publication of a final rule to review the new requirements thoroughly and to ensure that new portable bed rails manufactured or imported after that date are in compliance with the new manufacturing requirements such as new labels, and retooling and redesign of products as appropriate. Likewise, the time allows for the accreditation of laboratories to do mandatory third party testing. Accordingly, the draft final rule provides that the rule will be effective 6 months after publication of the final rule in the *Federal Register*.

IV. ENVIRONMENTAL CONSIDERATIONS

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5.(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

V. STAFF RECOMMENDATION

The NPR for portable bed rails proposed:

- Incorporating by reference ASTM F2085–10, *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.

Staff's draft final rule to address hazards associated with portable bed rails is the same as the newly published ASTM F2085-12. The issues raised in the NPR's public comments regarding the potential for infinite test configurations, testing of zippered products, need for consumer adjustment during installation, testing repeatability, and better warning statements have been adequately addressed in the new ASTM standard.

CPSC staff recommends that the Commission proceed with the rulemaking process for portable bed rails by voting to publishing the final rule, as drafted by the Office of the General Counsel. CPSC staff also recommends an effective date of 6 months after publication of the final rule.

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TAB A: Comments to NPR

TAB A

CPSC-2011-0019-0003 - Drew Goldsmith
CPSC-2011-0019-0004 - Jennifer Davis
CPSC-2011-0019-0005 - Laura Myers
CPSC-2011-0019-0006 - Ken Walsh
CPSC-2011-0019-0007 - Fredlisha Lansana
CPSC-2011-0019-0008 - Bryan Rainey
CPSC-2011-0019-0009 - Dawneen Huckins
CPSC-2011-0019-0010 - Michael Coons
CPSC-2011-0019-0011 - Carla Silver
CPSC-2011-0019-0012 - Janet Wells, National Consumer Voice for Quality Long-Term Care
CPSC-2011-0019-0013 - Robert Waller, JPMA
CPSC-2011-0019-0014 - Nancy Cowles, Kids in Danger
CPSC-2011-0019-0015 - Donald Mays, Consumers Union
CPSC-2011-0019-0016 - Rachel Weintraub, Consumer Federation of America
CPSC-2011-0019-0017 - Gloria Black
CPSC-2011-0019-0018 - Ken Walsh

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PUBLIC SUBMISSION

Tracking No. 80c32c48
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0003
Comment Drew Goldsmith

Submitter Information

Name: Drew Goldsmith

General Comment

First, the instructions for assembling traditional, rigid, portable bed rails should be clearer and more closely monitored by the CPSC. Instructions should be more specific and include pictures depicting actors assembling the rails.

Warning labels should include age limits since children younger than 2 should not use these products. Warning labels should also include the materials used when producing the bed rail products.

Regarding inflatable portable bed rails, the CPSC should include specific regulations thereof and not just rely on general regulations to ensure the safety of those rails. Rather, the CPSC should take the time to study and propose targeted safety regulations of inflatable bed rails.

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Tracking No. 80c35e0b
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Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0004
Comment from Jennifer Davis

Submitter Information

Name: Jennifer Davis

General Comment

These inflatable and fabric bed rails should be included in the definition "bed rails" fully and should have to meet all requirements of the others. Regardless, of the material if these products can injure a child, they should have to fully conform to all regulations.

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Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0005
Comment from Laura Myers

Submitter Information

Name: Laura Myers

General Comment

My name is Laura Myers and I am for the new regulation regarding Safety Standard for Portable Bed Rails [CPSC Docket No. CPSC-2011-0019]. This new ruling is much safer for children. Hopefully this new ruling will reduce the number of injuries and fatalities that were reported. I also agree that the portable bed rails need to be assembled properly for further safety. Given the purpose of the Consumer Product Safety Commission, the current product is failing to meet the requirements. However, the CPSC has been on top of this issue for a very long time and has been changing and adding to the rules constantly to keep children safe. I would like to propose that consumers that purchase this product call the manufacturer for help with assembling this product for safety measures. This can also lessen injuries and fatalities. It will also reduce disassembly that causes injuries.

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Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0006
Comment from Ken Walsh

Submitter Information

Name: Ken Walsh

General Comment

There are concerns over the proposed rule for Portable Bed Rails regarding the potential evaluation method for a Misassembled/Functional Portable Bed Rail. The proposed method for the determination of a misassembled bed rail indicates that a bed rail must not be allowed to be misassembled and fail the mechanical requirements listed in the ASTM standard. The concern is the potential infinite number of configurations that a bed rail may be setup or misassembled in and evaluated against. A few examples include but are not limited to;

1. Screws/Nuts/Bolts – The amount of torque applied to hardware may make a difference between passing/failing. If there are multiple hardware connections should a piece of hardware be purposely left off the assembly, and if so which one.
2. The amount of tension that should be applied to the adult bed attachment strap can also make the difference between passing and failing of the torso probe.
3. The amount of tension applied to a mattress top bed rail make the difference between the passing and failing of the wedge probe.
4. The full/partial assembly of components (*i.e*, support rails, support feet, cross safety rail, bed attachment strap) can make the difference between a product passing and failing.

Our three major concerns are (1) the infinite number of assembly/testing configurations (2) the repeatability of this test between manufacturers and independent test labs and (3) the consistency with which this proposed test can be applied at testing facilities. The repeatability of testing should strive for consistency and that is missing with this proposed evaluation. This proposed test method would be an extremely huge challenge to manufacturers that design product as well as to the independent testing facilities that will be forced to conduct this evaluation to an infinite amount of misassembled configurations.

In closing I would like to state that the safety of the juvenile product is what is most important. The safety of any juvenile product is extremely dependant on the proper/correct assembly of the product and also the specified, intended use of the juvenile product.

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Tracking No. 80c429d8
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0007
Comment from Fredlisha Lansana

Submitter Information

Name: Fredlisha Lansana

General Comment

To Whom it May Concern:

I am totally for the idea of revising the requirements for the durable, portable, bed rails for toddlers/babies. Judging by the reports of incidents alone, the idea to enhance this particular safety feature is a no brainer. My Son has been one to have his head stuck in between rails and my daughter is infamous for falling out of the bed. With my third child coming alone, I take comfort in knowing that someone in high places is considering the safety of my children, just as much as I am. There are too many incidents happening world wide with the portable bed rails as of now, I know that when my child's head was stuck, I kept replaying in my mind what would have happened had I not walked in. Do what you must to keep us consumers safe is my plea.

This is in response to Docket ID CDSC-2011-0019-0001.

Thank You,

Fredlisha Lansana

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Tracking No. 80c79b38
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0008
Comment from Bryan Rainey

Submitter Information

Name: Brian Rainey

General Comment

Please make sure that there is a set standard of guidelines which will allow for proper attachment of the portable bed rails of any kind or material to any bed. I am a concerned parent. I read some of the incidents and do not wish anything like this to happen to my son or even to any other child in the world. Furthermore, I am in favor of these standardized guidelines. I hope they are in place as soon as possible.

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PUBLIC SUBMISSION

Tracking No. 80e349bd
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Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0009
Comment from Dawneen Huckins

Submitter Information

Name: Dawneen Huckins

General Comment

As a parent having safety concerns for products that I have purchased or may purchase in the future for my child, I concur with this agency's proposed rule changes regarding more stringent standards for the manufacture of child bed rails. It is unfortunate that so many children have died or been injured by an item that was installed by their parents in order to protect them.

I believe that the additional warnings on the assembly components of the bed rails will cause the parent that is assembling the bed rails to think twice before skipping a step because it seems too difficult.

I also believe that the additional warning regarding the suffocation risks with fabric and mesh units will help consumers make a more informed purchase decision. I have purchased the mesh-over-tubing model thinking that the mesh would provide softer support and prevent possible head injuries if my daughter were to roll into the unit in her sleep. After 2 weeks of using the unit, I noticed that her stuffed animals and dolls were getting lodged between the unit and her mattress, alerting me to the possibility that the same could happen to my daughter. While I allowed her to continue to use the unit, I did make adjustments to the space between the unit and her mattress to minimize the risk of my daughter getting stuck. Had a warning been enclosed with the assembly directions or a tag attached to the mesh as proposed, I would have purchased a different product.

As parents, we do everything that we can to ensure the safety of our children. We purchase products such as bed rails to protect our children, not to endanger them. While most of us take the time to research these types of purchases, information that it transparent and truthful is not always easy to find.

The proposed changes will not only help ensure that bed rail designs are keeping our children safe as they are intended to do, but they will also help parents make informed decisions about their purchases.

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Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0010
Comment from Michael Coons

Submitter Information

Name: Michael Coons

General Comment

I am writing in support of the proposed rulemaking on CPSC-2011-0019. Portable bed rails will save countless lives of infants and children. Everyday children and infants sleep in adult beds and they should be protected, the two or three feet fall from modern mattresses is excessive and would be extremely dangerous for an infant or small child. All bedrails should meet the ASTM standard as to provide maximum protection against falling. The specification should not be voluntary as manufacturers of railings will attempt to cut costs and create ineffective products. As the proper installation of portable bedrails is detrimental to proper and effective operation, warning labels should be highly visible and connection points clearly labeled. In addition strict warning about modification of the bed rail and bed rail installation components should be clearly labeled. Upon reading the proposal, one specification that I wanted to direct your attention to was the idea of an inflatable bedrail, without proper regulation inflatable products may pose a suffocation hazard if a infant or small child is laying with their face in or towards the inflatable bed rail. Please address this in the proposal, as the ASTM standard for inflatable bed rails should be thoroughly detailed as to prevent suffocation.

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Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0011
Comment from Carla Silver

Submitter Information

Name: Carla Silver

General Comment

I am writing in support of proposed rulemaking on CPSC-2011-0019, 16 CFR Part 1224, Safety Standard for Portable Bed Rails. As a mother, grandmother and Certified Safety Professional, I value the life of our children. We should ensure that products made to protect our children are designed and tested to demonstrate a specific level of safety performance. Portable side rails are used by parents to protect their children from falling out of beds. To realize that what you assumed was safe only caused the death of your child by entrapment is heart breaking.
All bedrails should meet the new proposed ASTM F 2085-10a requirements. In review of the statistical data on the fatalities associated with the death of children under the age of two, misassembled and improperly installed bed rails were the two leading causal factors which by entrapment resulted in death. The new performance requirements and associated test methods to address portable bed rail misassembly by designing the structure to only be functional if assembled properly is ingenious. To aid in this assembly, I suggest that all component connection points be labeled or color coded therefore ensuring easy and correct assembly. Also the requirement to ensure that all critical components are attached i.e. screws, anchor plates and strap combinations, not only helps reduce the number of assembly parts and frustration of the assembler, but also ensures that critical safety components cannot be inadvertently left off by the installer. This will lessen the risk for improper assembly and installation of the bed rails which has led to creating the entrapment areas. The change in the symbols and wording of the warning labels to reflect suffocation, strangulation, entrapment and the criteria that children under two should not be placed in adult beds with or without bedrails is an administrative control. Although this does not prevent a person from using the bedrails with children under the age of two it at least defines the hazard more concisely than the previous warning label.
The addition of inflatable bed rails to the standard is needed since these are being marketed currently as fall protection devices for children. I noticed that these currently come in two styles – wedges that lay on top of the bed and those that lay under the fitted sheet. In a review of advertisements by three manufacturers, I noticed that only two specified the use of this product for children over the age of two. By including this product within the ASTM F2085-10a, the appropriate marketing and warning labels will address this issue therefore notifying the consumer of the intended use and safety issues.

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Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0012
Comment from Janet Wells

Submitter Information

Name: Janet Wells
Organization: The National Consumer Voice for Quality Long-Term Care

General Comment

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The National CONSUMER VOICE for Quality Long-Term Care formerly NCCNHR

John Weir, President
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www.theconsumervoice.org

June 27, 2011

The Honorable Inez Moore Tenenbaum
Chairman
Consumer Product Safety Commission
Room 502
4330 East West Highway
Bethesda, Maryland 20814

RE: Proposed Rulemaking - Safety Standard for Portable Bed Rails
CPSC Docket No. CPSC-2011-0019; 16 CFR Part 1224

Dear Ms. Tenenbaum:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates on behalf of long-term care consumers across care settings. Our membership consists primarily of consumers of long-term care and services, their families, ombudsmen, individual advocates, and citizen advocacy groups. The Consumer Voice has over 36 years' experience promoting quality care and consumer protection; we achieve this through legislative and policy advocacy, consumer education, and raising public awareness. Prevention of unnecessary deaths and injuries from bed rail entrapment and bed rail-related falls is an area of concern that the Consumer Voice has addressed for many years, and we appreciate the opportunity to submit comments on these proposed regulations and hope to engage in further dialogue about the role of the CPSC in protecting people who use bed rails and related devices. On behalf of our members, we respectfully submit comments on proposed Safety Standards for Portable Bed Rails which will modify ASTM F2085-10a in order to guarantee more stringent safety standards for portable bed rails and reduce bed rail-associated adverse events.

Bed rails are routinely used in nursing facilities, hospitals, and private homes based on a pervasive myth that they are a safe, benign, effective means of fall prevention. Many well-meaning family members of frail elders believe that the "security" of a bed rail will keep their loved one safe from falls. However, research and the experiences of family members who have lost loved ones tell the real story. Between 1985 and 2009, the Food and Drug Administration received reports of 803 incidents of patients caught, trapped, entangled, or strangled in hospital beds. These included 480 deaths, 138 non-fatal injuries, and 185 near misses due to staff intervention. Most of the victims were

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frail, elderly, and confused or children. Federal regulations prohibit their use in nursing homes as physical restraints; and there is strong agreement among professionals in multiple fields—including researchers, practitioners, government administrators, and consumer advocates—that the use of bed rails should be curtailed and alternatives to fall prevention provided. Some health care professionals and researchers advocate banning them because the risks they pose outweigh any medical benefits for many users. [See the attached Consumer Voice special report, *The Myth of Bed Rails: A Consumer Protection Issue*, for a discussion of concerns about bed rails in the long-term care environment.]

A decade has passed since the Consumer Voice (under its former name, the National Citizens' Coalition for Nursing Home Reform) participated in the FDA's Hospital Bed Safety Work Group. Since that time, deaths in nursing homes and assisted living facilities have continued; and the research and advocacy of the daughter of one victim, Gloria Black of Portland, Oregon, has refocused attention on the tragic consequences of the government's failure to take the forceful action on adult bed rails that it has taken on children's cribs and children's bed rails. Ms. Black's family, following the recommendation of the assisted living facility in which she lived, purchased the device that ultimately killed her mother. The device was one of many available to consumers that carry no warning information about the danger to users—dangers that may be obvious only after a tragic accident has occurred. These tragedies are likely to multiply as more and more elderly receive care in their homes rather than in institutional settings. The Consumer Voice endorses Ms. Black's comments on these regulations.

We are concerned that overlap between FDA and CPSC jurisdiction has weakened rather than strengthened the government's ability or inclination to regulate the manufacture and marketing of bed rails, which are sold to the public over the internet and in walk-in medical supply stores with no warning about the serious risk they pose to children or frail adults. The CPSC recalled drop-rail baby cribs after a handful of deaths, and yet there has been no effective remedy by either the FDA or the CPSC after more than 800 *reported* bed rail deaths, injuries, and near escapes. (From our constituents' experience, we know that many bed rail deaths are not reported and are classified as the result of natural causes.) We urge the CPSC to work with the FDA in a concerted, coordinated effort to recall unsafe bed rails and bed rail-type products; to inform the public, health care providers and workers about dangers related to their use and patients' right to refuse them; and to prohibit their use with vulnerable, at-risk individuals.

Proposed Changes to ASTM F2085-10a

While the Consumer Voice supports the proposed changes to ASTM F2085-10a, we do not believe it goes far enough. We request that CPSC apply its standards to all manufacturers of portable bed rails, regardless of who is the user of that bed rail (children, the elderly, or other adults living with disabilities) and that you genuinely address and do everything within your authority to prevent "adverse events." Adverse events typically mean *death by asphyxia/suffocation and aggravated injury* that occur when an individual tries to climb over or around a bed rail.

The CPSC proposes to: 1) include foam and inflatable products among those regulated by ASTM F2085-10a; 2) provide definitions of critical installation and assembly

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components; 3) offer guidance and conduct testing to determine whether bed rails are misassembled; 4) propose a test to verify structural integrity and functioning of the products; and 5) improve marketing and labeling to highlight the risk of entrapment and suffocation. These are all worthy improvements, but more work needs to be done to truly protect consumers, whether they are children or adults. Continued reports of deaths on hospital bed rails since the conclusion of the FDA work group's efforts suggest the need for a more concerted interagency effort to address the *inherent* danger of products that can entrap at-risk users or cause falls that result in serious injuries or death. Proper assembly and structural integrity tests may identify correctable problems, but the CPSC should look closely at why bed rail deaths have continued since the FDA took similar action a decade ago.

The Consumer Voice makes the following recommendations:

1. Require warning labels on external and internal packaging to have graphic symbols illustrating ways people become trapped in bed rails or fall when trying to evade them—pictures have more power than words. (One suggestion is to use graphics similar to those now required on cigarette packages.) Additional warning stickers should also be placed on the bed rail or device itself.
2. Between 1993 and 2005, the CPSC issued several recalls, corrective actions, and settlement of claims against manufacturers of youth bed rails shown to cause harm. <u>These same enforcement actions and recalls should be applied to all bed rail products, regardless of the age of the user.</u>
3. The Consumer Voice strongly supports SaferProducts.gov and applauds the CPSC for initiating this new consumer reporting system. We urge stronger cooperation and collaboration between the CPSC and the FDA in standardizing and simplifying the collection of reports of adverse events related to bed rails by health and long-term care providers and other users, including family members and other home caregivers. This should include both web-based reporting and a 1-800 number.
4. We urge the CPSC to enforce health care provider and manufacturer reporting of adverse events using available enforcement tools, including civil fines for companies that do not report adverse events.

The Consumer Voice requests that, as the federal agency charged with protecting consumers, you take aggressive action to work with your federal partners, the FDA and the Centers for Medicare and Medicaid Services, to combat unnecessary deaths and injuries of people of all ages from bed rails and related devices. The Consumer Voice stands ready to work with your agency to advance the protection of our most vulnerable citizens

Sincerely,

Sarah Wells

Sarah F. Wells
Executive Director

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

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The Myth of Benign Bed Rails: A Consumer Protection Issue

By Omoniyi Adekanmbi

Contents:

1. *Use of Restraints in Medical Facilities*
2. *Bed Rails as Fall Prevention Tools*
3. *Bed Rail-Related Adverse Events*
4. *Alternatives to Bed Rail Use for Fall Prevention*
5. *Federal Action to Protect Consumers*
6. *State Ombudsman Perspectives*
7. *Conclusions*

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2. Use of Restraints in Medical Facilities: Who Is Restrained? How and Why?

Physical restraints are often used in nursing homes and hospitals as a method of fall prevention. While definitions of restraints vary, they are generally acknowledged as any manual method or physical or mechanical device, material or equipment attached to or adjacent to an individual that impede freedom of movement and that cannot be removed by the individual him/herself (Capezuti, 2004; Hamers et al., 2004; Vassallo et al., 2004; Gallinagh et al., 2002). Restraints include vests, waist belts, chairs with tables, and bed side rails (bilateral and unilateral). Bed rails are the most commonly used form of restraint (DeLetter et al., 2008; Hamers et al., 2004; Gallinagh et al., 2002).

The most common reasons given by providers for the use of restraints are to avoid wandering, control restlessness and aggressive behavior and prevent falls from bed - fall prevention being the single most commonly reported reason for the use of restraints (DeLetter et al., 2008; Capezuti, 2004; Hamers et al., 2004). Patients who are evaluated by nursing staff as having the greatest risk for falls are the most likely to be restrained; these are most commonly patients who are frail and have low coordinated mobility, restlessness, altered mental status or cognitive impairment (dementia, Alzheimer's disease, delirium), or illness associated with confusion, such as prior stroke (Capezuti, 2004; Hamers et al., 2004). An observational study conducted in a rehabilitation ward found that all patients with dementia, Parkinson's disease, bone or rheumatologic abnormalities and epilepsy were restrained. However, no relationship was found between actual history of falling and application of restraints (Gallinagh et al., 2002). It appears that the use of restraints is driven more by the staff's *belief* that they are necessary to protect individuals who might fall, based on criteria such as age, functionality and cognition, than to prevent future falls in those who have already fallen.

Other factors like reduced functionality and care-dependency also influence restraint use. The same study from Gallinagh and colleagues mentioned above found that the majority of restrained elderly patients were very dependent on nursing staff for personal care and activities of daily living. Moreover, physically restrained patients were also more likely to be treated with opiates, diuretics and antipsychotics than non-restrained patients. Importantly, the increased prescription of diuretics may increase restlessness and distress in patients, leading to the application of restraints (Gallinagh et al., 2002). A prospective observational

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study conducted in the psychogeriatric unit of an acute psychiatric hospital in Germany found that 30% of all patients were restrained; low cognitive status, serious motility impairment and inability to autonomously carry out activities of daily living were all positively and significantly correlated with the use of restraints. Again, no significant difference between the frequency of falls in restrained or unrestrained patients was observed and the only two fall-related fractures that were recorded over the study period were sustained by restrained residents (Bredthauer et al., 2005).

Some family members and residents also favor the application of side rails for fall prevention. Ralphs-Thibodeau and colleagues found that patients with reduced functional independence and higher cumulative illness at time of admission were more likely to self-select to have bed rails raised (Ralphs-Thibodeau et al, 2005). Other studies have also found that many residents and relatives agree with nursing staff that restraints are an acceptable method of fall prevention (Vassallo et al., 2005). It appears that both providers and some residents and family members share a preference for raised bed rails based on the belief that they are a safe and effective mean of fall prevention. However, data available in the literature indicate that this might not be the case.

3. Bed Rails as Fall Prevention: How Effective Are They?

A large body of research has focused on the effectiveness of bed rails as a method of fall prevention, as they are the most commonly used and there is a prevailing belief that rails are benign and effectual. The conclusion that can be drawn from research, though, is that use of restraints does not lower bed fall rates, recurrent bed fall rates, or injurious bed fall risk among residents, even residents with impaired cognitive function. Si and colleagues found there were no serious injuries associated with removal of bed rails in a short-stay nursing home rehabilitation center and for most residents raised bed rails did not enhance safety (Si et al, 1999). Furthermore, reducing the use of restraints may actually significantly decrease the incidence of minor injuries due to falls from bed and the incidence of falls among residents. Many studies have actually suggested that the fall rate among restrained residents is equivalent to or in fact *greater than* the fall rate among unrestrained residents (Tan et al., 2005; Capezuti, 2004; Capezuti et al, 2002; Capezuti et al, 1998; Capezuti et al, 1996). One investigation of fall rates in nursing homes across six states found that a resident's likelihood

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of sustaining a serious injury decreased significantly after restraints were removed (Capezuti et al., 2007; Neufeld et al., 1999).

4. Bed Rail-Related Adverse Events: What Are the Risks?

Many studies also suggest that in addition to being an ineffective mean of fall prevention, bed rails pose significant risks to residents by heightening the dangers associated with falls from bed, causing physical and psychological deterioration, injury and even death (Todd et al., 1997). Studies investigating the use of physical restraints with older adults have reported adverse outcomes, including worsened cognitive impairment, incontinence, pressure ulcers, functional decline, nosocomial infections, psychiatric morbidity, injuries from falls while restrained and accidental death (Sullivan-Marx et al., 2001). Use of side rails has been correlated with behavioral symptoms like physical or verbal aggression, especially in residents with dementia, agitation and physical symptoms like urinary and fecal incontinence and nosocomial infections in residents. Restrained patients may suffer psychological effects like anger, demoralization, low self-esteem, depression, humiliation, reduced social functioning (Capezuti, 2004; Capezuti et al., 2002). Other hazards of bedrails include loss of dignity or freedom, worsening aggression or confusion, and deteriorated physical ability and strength (Marcy-Edwards, 2005).

In addition, rather than mitigating injury, bed rails heighten the risk and dangers associated with a fall. The purpose of the bed rail is to signal to residents to get assistance when they want to leave the bed. However, cognitively impaired residents, who are among the most frequently restrained, view the rail as a hindrance to try to squeeze through or climb over or around (Capezuti et al., 2007). Raised bed rails aggravate the risk of injury from the fall because they add up to an additional two feet to the fall height (Capezuti, 2004). vanLeeuwen and colleagues found that of 92 falls with bed rail position recorded over a seven year span at an acute care hospital, 60 residents fell while bedrails were raised (vanLeeuwen et al, 2001). Over half of these residents had been climbing over the rail when they fell; four had climbed through them, three squeezed between end of bedrails and bed end and two patients jumped over rails. Residents who fell when rails were raised were more likely to be non-rational at the time than those who fell when rails were lowered. Residents are also more likely to strike their heads if fall while trying to climb over the rails. While bed

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rails may decrease the risk of a fall by 10-15% they actually increase the risk of injury from a bed fall by 20% (Span, 2010).

In addition to aggravated injury from a fall, residents are at risk of entrapment in bed rails resulting in serious injury or death by asphyxiation (Parker and Miles, 1997). Entrapment occurs when patients slip through the side rail bars and the space between the rails, between the rails and the mattress or between the head- or foot-board, side rail and mattress (Hyman, 2008; Capezuti, 2004; see Figure 1). The head or neck is the most frequently trapped body part (Todd et al, 1997). Asphyxiation occurs when the resident is caught between mattress and bed rail, between the headboard and rail, head stuck in rail, or strangulated by vest restraint between the rails (Joint Commission on Accreditation of Healthcare Organizations, 2002). "A person will roll into the slot next to the rail, the mattress slides to the other side, doubling the side of the gap, and the patient drops into the gap – mattress presses against his chest and he suffocates" (Span, New York Times "New Old Age" blog, 2010). It has been suggested that air mattresses pose a particular danger to residents (Miles, 2002). From 1994 and 2000, 35 deaths due to entrapment between bedrails and air mattresses were reported to the FDA.

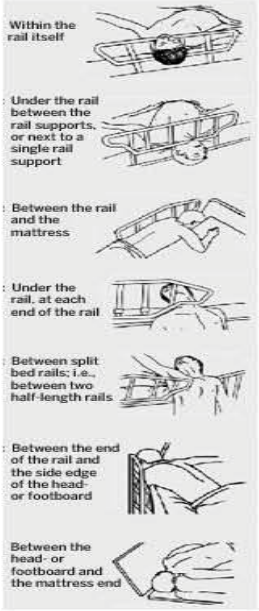

Figure 1. *Common forms of bed rail entrapment.* Source: Hyman, 2008, *Bed Rail Entrapments Still A Serious Problem.*

Patients that are more likely to become entrapped are frail, low weight, restless, mentally or behaviorally impaired and confused, on psychoactive/sedative drugs, have low mobility and advanced age – the same patients that are also more likely to be restrained (Capezuti, 2004; FDA, *Practice Hospital Bed Safety Guide*; JCAHO, 2002; O'Keefe, 2004; Miles, 2009; Todd et al., 1997). Between 1985 and 2009, the FDA received reports of 803 incidents of patients caught, trapped, entangled or strangled in hospital beds. These included 480 deaths, 138 non-fatal injuries, and 185 near misses due to staff intervention Most of the patients were frail, elderly and confused (FDA, *Practice Hospital Bed Safety Guide).*

5. Alternatives to Bed Rail Use for Fall Prevention: Is there a safer way?

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Bed rails may provide some benefits to residents, such as being a hand hold for getting in and out of bed, reducing the risk of fall during transport, helping having easy access to controls and personal care and a feeling of comfort and security to residents and their families (FDA, *A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The facts. 2010*). However, the severe risks that they pose for entrapment-related death, heightened injuries from falls, skin bruising, cuts, scrapes and psychological trauma question whether potential benefits outweigh risks. It has been suggested that bed rails are not appropriate for patients who can be independently mobile without them, patients with intact mental capacity who do not want them, or patients with severe confusion who are mobile enough to climb over them (Healey et al, 2008).

There are also many alternatives that provide the same benefits as bed rails without the risks. For example, manufacturers provide beds that can be raised and lowered close to the floor. Beds may also be kept in the lowest position with wheels locked to mitigate the risk of injury from a fall. Staff can also place mats on the floor next to the bed, use transfer or mobility aids, and increase patient monitoring (FDA, *A Guide to Bed Safety Bed Rails in Hospitals, Nursing Homes and Home Health Care: The facts. 2010*). In 2002 the JCAHO has also set forth recommendations for safer application of bed rails including re-evaluating beds for entrapment potential, implementing appropriate changes to bed for at risk patients (such as using retrofit kits, bed rail netting, clear padding, Velcro or anti-skid mats) and keeping patients under higher observation. According to Dr. Steven Miles, physician and bioethicist, "the idea that older people fall out of bed is actually vastly overstated. You can use some handgrips along the bed if a person likes to use that to stand up. You can have a low bed. You can have a concave mattress on the bed that's got kind of a little valley in it, and often that's all that it takes."

6. Federal Action to Protect Resident and Consumers: What is lacking?

In light of the numerous safer alternatives to bed rails, it is surprising that no legislative and consumer protection action has been taken to curtail their use. According to Parker and Miles (1997), "bedrails are an invalidated treatment and their use should be curtailed radically." O'Keefe (2004) argued that if a drug had demonstrated the same safety

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record as bed rails its use would have been curtailed unless there was the "most rigorous evidence that {its} benefits outweigh the risks". The U.S. Food and Drug Administration (FDA)'s actions to address bed rail safety have consisted only of safety alerts, brochures and guidance documents. In 1992, the FDA issued the safety alert *Potential Hazards with Restraint Devices*, warning of serious injuries, strangulation, and asphyxiation due to bed rails. However, in February 2011 the document has been marked as "archived" and does no longer constitute current information. In 1995, the FDA issued *Entrapment Hazards with Hospital Bed Side Rails*, in which the organization acknowledged that no universal standards exist for the design of bed rails, but did not propose enacting legislation to establish such regulations. This document too was archived in February 2011 and does no longer constitute current information.

In 1999, the FDA formed the Hospital Bed Safety Workgroup (HBSW) in partnership with representatives from the hospital bed industry, national healthcare organizations, patient advocacy groups and other federal agencies. The workgroup's goal was to improve the safety of hospital beds for patients most at risk of entrapment by developing dimensional guidelines, measurement tools and educational materials to assist manufacturers, caregivers and consumers. As part of these efforts, in 2003 the HBSW published the *Clinical Guidance for The Assessment and Implementation of Bed Rails In Hospitals, Long Term Care Facilities, and Home Care Settings*. The guidance provides a uniform set of recommendations for caregivers in all settings to use when assessing their patients' need for and possible use of bed rails.

In 2006, the HBSW issued the *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* which provides recommendations for manufacturers of new hospital beds and for facilities with existing beds. In the *Practice Hospital Bed Safety Guide* published in 2009 the workgroup identified seven potential zones of entrapment in the hospital bed system, the rails, mattress, and bed frame (see Figure 2). The *Guidance*, however, only contains test protocols for the first four entrapment zones previously indentified; to date no dimensional guidance or test methods have been developed for Zones 5, 6, and 7. The FDA states that recommendations for dimensional limits and testing were established for zones 1 through 4 because these zones were most frequently reported as the sites of entrapments. The recommendations also address only certain hospital beds, excluded

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are air-fluidized beds, bariatric beds, pediatric beds, infant cribs, and pressure-reduction products such as air mattresses.

Notably, the guidelines set forth in the *Hospital Bed System Dimensional and Assessment Guidance* and all HBSW documents do not establish legally enforceable responsibilities on the part of providers or manufactures. Because there are no legal requirements, the FDA dimensional guidance and HBSW documents might be viewed as representing a "best practice" rather than obligation (FDA, *HBSW/FDA Frequently Asked Questions on Entrapment Issues*). As the *Practice Hospital Bed Safety Guide* states, "the FDA regulates hospital beds through post-market activities such as analyzing reports of product problems and adverse events {it} does not regulate the design of the beds, it offers safety guidance to industry."

Figure 2, Zones of Entrapment in the Hospital Bed System. Source: FDA, *Practice Hospital Bed Safety* Guidance

Notably, the *Guidance* states that as "the FDA recognizes that legacy beds have the potential for dimensional change over time through wear and tear or substitution of new mattresses and other components not contemplated in the original bed system {the agency} does not intend to take enforcement actions for failure to submit reports of corrections and removals." This mix of mattress, rail and frame, however, poses a significant danger to patients and residents. Hyman (2008) states "a bed system that was reasonably safe {…} may become relatively unsafe if any component is changed tomorrow." The author also notes that the safety of a bed rail/mattress/frame system can change over time as bodyweights and sizes vary, there are different bed, rail and mattress configurations and mattresses shrink over time. Hyman argues "the ideal solution is to not have any beds or bed systems that present unreasonable risks of entrapment".

While the FDA has not issued a statement against the use of bed rails, the federal Centers for Medicare and Medicaid Services (CMS) has taken a stance against their use in facilities that receive Medicare or Medicaid funding. The Code of Federal Regulations on

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CMS requirements for long-term care facilities, 42 CFR 483.13 provides that "the resident has the right to be free from any physical or chemical restraints imposed for discipline or convenience, and not required to treat the resident's medical symptom." CMS requires nursing homes that receive Medicare and Medicaid funding to utilize restraints only when other, less severe alternatives do not address a resident's medical needs and the benefits have been shown to outweigh the potential risks (*Federal Centers for Medicare and Medicaid Services (CMS) Publication 100-07, State Operation Manual*). In 2007, the Director of CMS's Survey and Certification Group issued a statement that falls do not constitute self-injurious behavior or a medical symptom that warrants the use of a physical restraint *(Federal Centers for Medicare and Medicaid Services, Clarification of Terms Used in the Definition of Physical Restraints as Applied to the Requirements for Long Term Care Facilities).* In the same statement the Survey and Certification Group Director stated, "Growing evidence supports that physical restraints have a limited role in medical care. Restraints limit mobility and increase the risk for a number of adverse outcomes. Physical restraints certainly do not eliminate falls. In fact in some instances reducing the use of physical restraints may actually decrease the risk of falling." It appears that the position of CMS is that restraints are not a safe and effective medical practice and their utilization should be curtailed.

Unfortunately, the government agency charged with protecting the public from dangerous products, the U.S. Consumer Product Safety Commission (CPSC), has not taken a similar stance to protect consumers from unsafe bed rails. While CPSC has issued standards, alerts, recalls and other actions to protect the public from unsafe youth bed rails, no action appears to have been taken to specifically protect elderly individuals from dangerous medical bed rails. Between 2001 and 2007, the CPSC worked in conjunction with ASTM International (formerly known as American Society of Testing Materials) to establish mandatory guidelines for portable bed rails used to prevent children from falling from bed. In 2003, the revised ASTM standard F 2085-03 on Bed Rails was approved which changed the design of most bed rails so that the rails would fit snugly against a mattress, preventing the formation of a hazardous gap in which children could become entrapped. In 2008, ASTM published another revision to the standard that included a structural integrity test to address fall incidents involving hinge lock mechanism failures. In the following years additional minor revisions were made. The current edition of the standard is ASTM F2085-10a

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"Standard Consumer Safety Specification for Portable Bed Rails" and was last updated in 2010.

Between 1993 and 2005, the CPSC also issued several recalls, corrective actions, and settlement claims against manufacturers of youth bed rails shown to cause harm:

- 1993 - a safety alert was issued about a bed rail entrapment hazard with *Rainbow Mountain Inc.*'s model 3210 "Toddler Beds with Guard Rail";
- 1994 -CPSC worked with *Cosco, Inc* to recall some of its toddler bed guard rails.
- 1995 - CPSC required *Okla Homer Smith Furniture Manufacturing Company* and *Welsh Juvenile Products* to recall and replace drop side rails that had missing or loose slats and crib side rails that had missing or loose spindles.
- 1996 - CSPC issued a safety alert about portable cribs/playpens sold by *All Our Kids* that posed a strangulation hazard to young children
- 1998 - *Safety 1st* was required to pay a civil penalty of $175,000 to settle allegations that it violated the Consumer Product Safety Act by failing to report in a timely manner a defect with the "Safekeeper" toddler bed rails that enabled the support bars to separate from the rail
- 2003 - *Babi Italia* was required to recall crib drop-side rails for about 2,000 "Tiffany" and "Josephine" model cribs.
- 2005 - CPSC provisionally imposed a $4 million penalty against *Graco Children's Products Inc.* for failing to inform the government in a timely manner about more than 12 million products that posed a danger to young children nationwide, including toddler bed rails.

Very recently, on April 11, 2011, CPSC published in the Federal Register a notice of proposed rulemaking (NPR) to modify ASTM F2085-10a in order to guarantee more stringent safety standard for portable bed rails, thus reducing bed rails-associated adverse events. The main proposed changes are: 1) include foam and inflatable products among those regulated by ASTM F2085-10a; 2) provide definitions of critical installation and assembly components; 3) offer guidance and propose a test to determine if the bed-rails are misassembled; 4) propose a new test to verify structural integrity and functioning of the products; 5) improve the marking and labeling to highlight the risk of entrapment and

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suffocation. The CPSC is currently inviting comments on the NPR. Written comments must be received by June, 27, 2011 in order to be taken in consideration.

Although the focus of ASTM F2085-10a and CPSC proposed modifications is children safety, the regulations are not restricted to portable bed rails use with children.

7. *State Ombudsmen Perspectives*

In March 2010, the Consumer Voice, then NCCNHR, conducted a five-question survey of State Long-Term Care Ombudsmen to determine nursing facility bed rail practices in their individual states and their perceptions of their use. Responses were obtained from twelve states: Colorado, Delaware, Florida, New Hampshire, New Mexico, Nevada, North Dakota, Rhode Island, Washington, West Virginia, Wisconsin, and Wyoming.

The first three questions asked about recent adverse events and reporting practices.

1. How many bed rail deaths and injuries occurred in your state in the last year?
2. Have you seen an increase or decrease in the number of bed rail deaths and/or injuries in the past one to three years?
3. Is there a state requirement to report these deaths or injuries to the State Survey Agency or other Federal Agencies such as the FDA?

Four states (Colorado, Nevada, Washington, and Wisconsin) reported at least one resident death as a result of a bed rail in the past year, with Colorado reporting two deaths. West Virginia lacked the data as the state does not require facilities to report adverse events due to bed rails. Nevada reported that the bed rail related death was the first to occur in the state in several years. Two states, New Mexico and Wyoming, reported a decrease in the number of bed rail-related adverse events in the past three years. Delaware, New Hampshire, North Dakota, Washington, and Wisconsin had not witnessed a change in the three year time period, while Colorado and West Virginia also lacked the data to make a determination. In response to reporting requirements, the majority of states (Colorado, New Mexico, Nevada, Washington, Wyoming, and Wisconsin) require facilities to report adverse events to either the state survey or licensing agency. New Hampshire and West Virginia require deaths or injuries related to bed rails to be reported only if they occur as a result of abuse or neglect.

The last two questions focused on ombudsmen's perceptions as consumer advocates on the use of bed rails:

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4. Do you believe there should be warning labels on bed rails that explain the dangers?
5. Do you have any other thoughts about the extent of this problem and how we can prevent these incidents?

Ombudsmen from eight of the twelve states reported that they believed warning labels should be required for bed rails to make consumers aware of the possible dangers. Almost all ombudsmen reported having concerns about the risks posed by bed rails. Suggestions given to prevent future adverse events included regular and ongoing education to providers and caregivers, continual in-service, pressure on physicians to reduce bed rail orders, increased public awareness of the dangers, utilization of safer alternatives, discontinuing the use of bed rails for high risk patients, and, importantly, establishing legislation to regulate the utilization of bed rails.

8. *Conclusions*

For seventy years bed rails have been used routinely in nursing facilities and hospitals based on a pervasive myth that they are safe, benign, effective means of fall prevention (Talerico & Capezuti, 2001). Over the last two decades, however, a great amount of research has proved that this is not the case. The incidence of bed rail-related adverse events, including psychological distress, injury and death, is shocking and calls for legislative action to protect residents and patients in medical facilities and consumers at home. There is strong agreement between professionals from multiple fields, including researchers, practitioners, government administrators, and advocates that the utilization of bed rails should be curtailed.

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PUBLIC SUBMISSION

Tracking No. 80eb43e0
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0013
Comment from Robert Waller

Submitter Information

Name: Robert Waller
Organization: Juvenile Products Manufacturers Association

General Comment

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June 27, 2011

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

Re: NOTICE OF PROPOSED RULEMAKING (NPR): CPSIA SECTION 104:

Safety Standard for Portable Bed Rails: 16 CFR Part 1224

CPSC DOCKET Number: 2011-0019

Dear Mr. Stevenson:

These comments are submitted by the Juvenile Products Manufacturers Association (JPMA), a national not-for-profit trade organization representing 95% of the prenatal to preschool industry, on behalf of our member companies that manufacture and distribute a wide array of infant products in the United States and Canada. JPMA represents approximately 250 companies in the United States, Canada, and Mexico who manufacture, import and/or distribute infant products such as cribs, car seats, strollers, bedrails, bedding, and a wide range of accessories and decorative items. JPMA has been recognized as an organization dedicated to enhancing children's product safety. JPMA's extensive history of leadership in juvenile product safety includes the development of a comprehensive Certification Program to help guide parents and caregivers toward purchasing juvenile products that are built with safety in mind. JPMA continues to work with government officials, consumer groups, and industry leaders on programs to educate consumers on the safe selection and use of juvenile products. *Safe & Sound for Baby* and Baby Safety Month are only a few of the programs JPMA sponsors to keep today's safety conscious parents informed.

The Consumer Product Safety Commission ("Commission" or "CPSC") invited comments on 16 CFR Part 1224 pursuant to Section 104 of the Consumer Product Safety Improvement Act ("CPSIA"), which directs the Commission to issue mandatory regulation on durable infant products. In response to the request of the Commission's staff, the JPMA submits the following comments for your consideration on the April 6, 2011, Federal Register Notice regarding 16 CFR Part 1224 Safety Standard for Portable Bed Rails ("NPR"). JPMA hopes that these comments will assist the Commission in effectively implementing regulations in a consistent manner with hazard based requirements under ASTM F 2085 -10a consensus, hazard based Safety Standards for Portable Bed Rails and other existing or proposed ASTM Standards promulgated for similarly situated or constructed products. JPMA has previously submitted extensive comments on a variety of CPSIA issues. These comments provide our views on the

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proposed requirements of 16 CFR Part 1224. JPMA reserves the right to supplement or amend its comments as appropriate.

JPMA and its members appreciate and support the efforts being made by the CPSC to ensure infant product safety and share in the pursuit of this goal. This is readily seen in the dedication they have shown to the development, creation, and continuation of the voluntary standards process under the comprehensive scope of the ASTM and the standard setting process. The advancement of the bed rail standard is an example of this process.

JPMA encourages the Commission to harmonize their final rule with the ASTM F 2085-10a. As a result, JPMA is noting several areas of concern regarding; *1) Conclusions derived from incident data 2) Engineering Assessment 3)Critical Assembly Components 4) Impact on businesses both small and large and 4) Implementation.*

Incident Data Conclusions

As reported by the CPSC, displacement of the bed rail was involved in 69 of the 132 incidents reported between January 2000 and March 2010, making it the primary hazard pattern with 52% of the total incidents. Changes made to the ASTM standard in 2003 included requirements to address the CPSC's primary concern of entrapment between the mattress and the bedrail. The inclusion of the *"openings created by displacement"* requirement has directly contributed to the elimination of entrapment incidences by requiring manufacturers to make product design changes generally consisting of; *1) stiffening of the rail structure to limit deflection* and *2) the introduction of anchoring systems to eliminate the possibility of mattress moving and shifting.*

Objective evidence of the effectiveness of this change is illustrated in the reduction of incidents reported by the CPSC for entrapment. Since the adoption of the 2003 version of the ASTM standard requirements, the number of incidents has decreased from 22 injuries and 10 fatalities to 11 injuries and 3 fatalities.

More importantly, and as indicated in the NPR, "Fatalities and Nonfatal Injuries", from the year 2000 forward, there were 13 child fatalities reported to the CPSC that were coded as involving bedrails. Most of the decedents (9 out of 13) were under 1 year old; two were between 1 and 2 years old; and two decedents, both physically handicapped, were 6 years old. Therefore from 2000 to 2010 and over a 10 year span, there were zero fatalities involving children of the intended use age of 2 to 5 years as provided in the scope of the standard.

It is also notable that because 11 of the 13 deaths involved children under 2 years old, the CPSC Health Sciences Staff concludes that 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

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children under 2 years old, parents of infants continue to use this product with their infants.

Consequently the direct cause is misuse of the product for underage children. JPMA recommends the CPSC work with ASTM in a joint effort to better define ways to communicate the intended age grade of the product. Packaging, instructional material, product markings and information campaigns are some areas where potential improvement may lie.

JPMA also recommends that the CPSC should focus on educating consumers about proper creation and maintenance of a safe sleep environment. Bed rails are not intended to be used with infants and are not a substitute for a crib.

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. Understandably any conclusion on the data can, at best, be implied and not validated due to the inability to recreate the circumstances at the immediate time of the incident. Reported experience suggests that secondhand or used product may be involved.

Additionally the assumption that misassembly caused the three fatalities identified is flawed. For example, photos provided for IDI 080925HCC2061 illustrate a middle bar not completely fastened to the vertical uprights. Based on the limited information and photo the CPSC has inferred and noted in the NPR that the omission of these fasteners resulted in the fatality. Unfortunately we cannot make this assumption for the following reasons:

1. The bedrail may have been manufactured and certified to a previous version of the 2003 standard prior to inclusion of the openings created by displacement,
2. Regardless of manufacturing date, it is uncertain if the bedrail depicted meets the requirements for "*openings created by displacement*", which leads to the question of whether or not the omission of the hardware was the cause of the incident and not the performance of the bedrail itself relative to displacement.

JPMA suggests that the CPSC investigate the date coding of the products involved in the three fatal incidents that the CPSC associated with misassembly. The assumption is made by the CPSC that the causal reason for these three fatalities is misassembly; however it is unknown if this incident would have occurred if the product passed the test relative to openings created by a displacement test from the 2003 standard. CPSC Heath Sciences Staff conclusion includes a finding that portable bed rails pose the most significant risk to infants and young children under 2-years-old. However, CPSC's own broader study indicates that the primary problem is placement of infants well under 2 years of age in adult beds rather than suitable sleep environments. Fatality rates for this population with products produced and adhering to the 2003 ASTM standards (which already incorporate CPSC staff's dynamic performance test requirements related to

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dislodging of portable rails during normal use and reasonably foreseeable abuse situations) are actually significantly lower with bed rail use than without.

Engineering Assessment

The CPSC staff comment includes *"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."*

Whether modular furniture, power tools, appliances, consumer medical devices or toys most consumer products require some amount of assembly on behalf of the consumer. When not properly assembled, maintained or used such products can pose a greater risk of injury than bedrails. However, no other CPSC or ASTM safety regulation attempts to create a dynamic performance test for products in a misassembled state. Various industries have gradually evolved to become proficient in communicating proper assembly to consumers while limiting the number of complex steps necessary for assembly.

JPMA believes the option for consumer assembly should remain for bedrails and notes that the injury data for bedrails as regards severity and number versus units on the market as a general means of comparison remains relatively low. CPSC has abandoned risk hazard analysis in regards to the proposed regulations. Also significant, is the fact that CPSC staff has not adequately adhered to the Congressional mandate to consider and adopt ASTM requirements as mandatory requirements as appropriate. Bedrail incidents for the intended user population remain extremely low when compared to almost any other consumer product and are extremely safe products.

ASTM standards have evolved with the intent of including performance testing and product warnings as evidenced by 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."

At this time no voluntary or mandatory standard exists which requires testing for all possible misassembly options. Furthermore the proposed added language is vague, arbitrary and invites unacceptably variability in test conditions.[1] JPMA urges the adhere to precedent and adopt the existing ASTM F 2085 -10a consensus, hazard based Safety

[1] This can be simply verified by interested Commissioners. Addition of the proposed language to any existing mandatory CPSC regulation results in confusion and arbitrary test determinations. This approach undermines the doctrine of contributory or comparative negligence, which presumes that reasonable persons will follow reasonable instructions and warnings.

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Standards for Portable Bed Rails, with suitable added warning language as a mandatory regulation.

There is a level of ambiguity to the proposal that leaves many areas of it open to arbitrary and capricious interpretation. Especially troublesome is the terminology, performance requirements, and testing sections with regard to the supposed determination of misassembly or misinstallation of a portable bed rail. As such, the language should be considered as void for vagueness[2].

Critical Assembly Components

The NPR defines 3.1.12 *Critical Assembly Component* as –"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 Bedrails Displacement of adjacent Style Portable Bedrails, 6.5 Openings Created by Displacement of Mattress-Top Portable Bedrails, and 6.6, Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers Beds of ASTMF2085-10A. As referenced in Appendix B of the NPR the concerns outlined in the task group proposal remain the same. All the products on the market now require that most all components be assembled in order to meet section 6.4, essentially making all components critical and consequently diluting the importance of calling out these components. The definition of a critical assembly component 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.

The NPR defines a *Misassembled / functional bed rail* as -
Section 3.1.14 – "A bed rail that has been assembled incorrectly but appears to function as a bed rail. Misassembly / functionality are determined by meeting one of the criteria listed in 6.9 Determining Misassembled/functional Portable Bed Rail The product would be considered misassembled if one of the following were met:

- *The portable bed rail can be assembled without any critical assembly component*
- *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.*

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[2] In the case of vagueness, a regulation might be considered void on constitutional grounds, since vague laws deprive citizens of their rights without fair process, thus violating due process. See *Connally v. General Construction Co.*, 269 U.S. 385 (1926)

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- *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.*
- *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.*

The proposed added language is vague. There have been no guidelines set against which third party laboratories can evaluate to this criteria without testing all permutations as arbitrarily established by the tester. The question that arises is whether the testing laboratories are expected to test every possible configuration to determine which parts of the bed rail are critical assembly components. The two laboratories that JPMA has certified to test durable infant products such as bedrails for the JPMA Certification Program have expressed their strong concern regarding this point. They have stated that the subjective nature of this requirement could lead to a profusion of additional testing and significantly increase their liability associated with claiming conformance to a potential configuration that was missed. The requirement itself invites arbitrary and capricious determinations. Additionally, it has been noted that no other Juvenile Products standard to date calls for the testing of products in such an ill defined manner. ASTM standards and CPSC regulations always set forth the specific performance criteria to which products must comply.

To exemplify the complexity of testing referenced in the NPR, the number of bedrail assembly components range from 12 to 40 as indicated in Figure 8 of the NPR. The permutations for this example would include 12 to 40 choices with component A in position 1, 11 to 39 choices for component B in position 2 and so forth. Thus conservatively taking a 12 piece product would result in a potential factorial of 12 mathematically equating to 479,001,600 possible configurations followed by removal of one component without replacement and evaluation of said component to determine if it is a critical assembly component. In order to make this determination, each unique permutation must be tested to 6.1, 6.3, 6.4, 6.5/6.6 or 4 tests. Thus the total number of tests required for the most conservative approach and fewest number of components listed in figure 8 would result in 4 x 479,001,600 = 1,916,006,400 tests for one bedrail.

JPMA certainly believes that this burdensome testing is not the intent of the CPSC; however the proposed added language does not provide the necessary direction for laboratories to even begin an adequate and reasonable evaluation thus leaving an uncomfortable level of interpretation necessary on the evaluator's part.

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.

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.

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

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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.

A leading example of this concern can also be seen in section 6.10.2 referenced above and listed in section 3. It has proven difficult to determine sag in material when incorporating a zipper in the design of the bed rail. During the CPSC staff's presentation of the briefing packet to the Commission, the staff presented a "prototype sample" of a bed rail with a zipper used to close the fabric once it has been fitted over the bed rail. The acceptable sagging of the fabric material when tested to 8.8 can only be achieved if the zipper is closed only so far to allow the minimum 3 inch sag. How far should the product be zipped? Should the lab measure sag one zipper tooth at a time? In this scenario the product would never meet the criteria since the opening, when zipped, will always achieve less than 3 inches of sag. Complicating matters the aforementioned permutation would have to be tested by the number of zipper teeth contained in the product raising the level of testing into the hundreds of millions.

The sample presented by the staff and included in Figure 10 was described as meeting the proposed requirements of the NPR. However after further review the prototype would not meet the requirement and has not been tested by an independent lab. During the April, 2011 subcommittee session the group discovered that when the center T-Bar illustrated in step 1 of figure 10, was inverted the bedrail would not meet the requirement as the CPSC had originally thought. The CPSC has had subsequent communication that, after further review, the prototype sample may be modified to meet the intent by "keying" one side of the T-bar to fit in only one direction. However it is imperative to note that this experience only confirms the certifying test labs concern of capturing every possible configuration based on the proposed language. Consequently, this proves that the reproducibility is unacceptable. Testing laboratories have expressed their concern over repeatability between test technicians as well. What is the probability that two technicians will execute all 1,916,006,400 permutations exactly the same with interchangeable results?

JPMA requests that the CPSC review the complexity of testing and consider performing a repeatability and reproducibility study using several labs in order to validate any requirement sought to be added to ASTM requirements so as to assure that testing variability is acceptable such that manufactures and laboratories can feel confident that a product, when tested at one lab will obtain the same result within the lab and between different labs. JPMA is in agreement with the expressed concerns of participating labs. These concerns have been well documented in previous bedrail subcommittee minutes.

Critical Installation Components

The NPR includes definitions and requirements for critical installation components as follows:

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3.1.13 *critical installation component, n* - any component of the bedrail that is used to attach the bedrail onto the bed.

5.6 *Critical Installation Components* used to attach the bed rails onto the bed shall be permanently affixed to a structural component(s) of the bedrail.

There appears to be some confusion between assembly components, installation components and "adjustments". Presently manufactures communicate components in terms of assembly in the instructional manual. Thus one would reasonably classify all components as assembly and not installation. Take the example of a bedrail being able to fit a twin, full and queen size mattress. Components necessary to achieve proper installation may be considered by test laboratories to be assembly components and consequently these labs may inadvertently fail such an adjustable product. Various installation systems such as telescoping bars or adjustable straps may be mistakenly considered to be assembly components and evaluated to the misassembly criteria in section 6.9. Figure 1, illustrates an installation assembly where the CPSC felt adjustment of the strap and clip would be acceptable, however, test labs may have inadvertently considered such an adjustment as an assembly exercise. The same logic and confusion may reside in adjusting strap systems, telescoping actions required to "lengthen" the bedrail from the in retail carton mode to complete install mode, etc.

ASTM suggests further clarity be added to such a definition in order to prevent misinterpretation between assembly, installation and adjustment components. Including more descriptive language and images of acceptable and unacceptable conditions would add more clarity to the requirement.

Impact on Business both Large and Small

The NPR suggests that the impact on the five firms that are compliant to the present ASTM standard as being less significant because they already comply with the voluntary standard. Preassembled products may require larger shipping boxes, and there may be higher shipping costs associated with shipping larger boxes. JPMA would like to highlight that shipping costs for the majority of these items are a significant portion of the product's total cost and thus increasing the box size to contain a preassembled product could potentially increasing cost to ship the product by 50%. In addition such approach is contrary to environmental sustainability efforts which aim to reduce packaging volume and material. This added expense would have a trickledown effect and may result in an adverse retail response to stocking bulkier packages on shelves or in inventory and consumer decisions not to buy the bulkier packaged product, thus resulting in an unintended consequence of placing children in adult beds without any such bedrails and an increased risk to the intended user population. Other risks include retailer dropping products or refusing to accept price increase thus placing the cost burden on manufacturers.

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Implementation

The NPR indicates that the intention of the Commission is to implement an effective date for compliance six months after publication of the final rule. The JPMA and our members feel that should a CPSC mandatory regulation vary from the ASTM standard that a minimum of one year is appropriate to allow adequate time for manufacturers to bring product into compliance with the new requirements. However this can only be accomplished one year after a final rule, clearly written and easily understood by its terms is published. The, arbitrary vague language and underlying misplaced assumptions in the proposed added test method causes unnecessary confusion and delay in the congressionally mandated rulemaking. Experience reported by testing laboratories already demonstrates that such additions are impractical and untenable. The Commission should adopt the ASTM F 2085 -10a consensus, hazard based Safety Standards for Portable Bed Rails as previously developed with extensive involvement and approval of its own staff. The fact that CPSC personnel has changed should not diminish the integrity accorded to the work of previous CPSC staff in conjunction with other engineers and experts that already developed an effective ASTM standard for the product category.

Figure 1

Conclusion

We encourage the CPSC to work with all stakeholders to assure an efficient, effective rule is finalized. We are committed to working with the CPSC, but feel at this time the proposal is so vague and arbitrary that it has lead to untenable confusion in the test labs and will needlessly delay congressionally mandated adoption of suitable ASTM standards

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as mandatory regulations. CPSC, working should adopt ASTM F 2085-10a as the final rule. Further, JPMA is dedicated to education on the proper use of bed rails to aid in the protection of those the product is reasonably intended to safeguard.

Sincerely,
Robert B. Waller

President

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Tracking No. 80eb4f52
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Document: CPSC-2011-0019-0014
Comment from Nancy Cowles

Submitter Information

Name: Nancy Cowles
Organization: Kids in Danger

General Comment

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KID
KIDS IN DANGER
IMPROVING CHILDREN'S PRODUCT SAFETY

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June 27, 2011

Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway, Room 502
Bethesda, Maryland 20814

Via: www.regulations.gov
Docket No. CPSC-2011-0019

Comments of Kids In Danger (KID) to the U.S. Consumer Product Safety Commission on "Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking"

Introduction

On April 11, 2011, CPSC published this notice of proposed rulemaking in the Federal Register, soliciting comments by June 27, 2011. KID has been participating in voluntary standard setting on this issue at ASTM International since 2001.

Background

Portable bed rails are used on adult size beds to prevent falls or entrapment for young children using the bed. These are different from toddler beds or youth beds that come with side rails either already affixed or designed solely for the bed on which they are used. The portable nature of these bed rails, as well as their use on a variety of beds leads to significant safety concerns. It is KID's view that it is better to use toddler or youth beds or to simply place a mattress on the floor. The risk of entrapment is a much bigger danger than a fall from an average height adult bed, assuming the area around the bed is clear.

Recommendations

KID commends CPSC for their efforts to reduce the risk of misassembly through performance standards and test methods. We hope that with the input of the ASTM Sub-committee on Portable Bed Rails, CPSC will develop means to reduce the likelihood of misassembly or use on inappropriate bed surfaces.

We also support extending the scope of the standard to cover newer designs that are inflatable or nonrigid materials. Parents will use

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many of the options available in the marketplace, we should make sure as many as possible are tested adequately for safety.

In addition, KID recommends an additional requirement. We believe that portable bed rails should be sold in sets of two. While many parents use the product to secure the open side of the bed to prevent falls, they rely on the wall or other furniture to provide the barrier on the other side of the bed. This can lead to entrapment scenarios between the bed and the wall, a cause of much more serious injury or death than a fall.

Conclusion

KID supports CPSC's effort to strengthen the Portable Bed Rail Standard by adding more testing for misassembly. We also support the addition of a requirement that bed rails be sold as pairs to encourage consumers to use one on both sides of the bed. We look forward to continuing to work with CPSC and ASTM International on this issue.

Respectfully submitted,

Nancy A. Cowles

Nancy Cowles
Executive Director

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PUBLIC SUBMISSION

Tracking No. 80eb7da
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0015
Comment from Donald Mays

Submitter Information

Name: Donald Mays
Organization: Consumers Union

General Comment

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June 27, 2011

Office of the Secretary
Consumer Product Safety Commission
Room 502
4330 East-West Highway
Bethesda, Maryland 20814
Via: www.regulations.gov

Comments of Consumers Union to the U.S. Consumer Product Safety Commission
on
"Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking"

Docket No. CPSC– 2011–0019

Introduction

Consumers Union (CU),[1] the non-profit publisher of *Consumer Reports*®, submits the following comments to the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") in the above-referenced matter.[2]

[1] Consumers Union of United States, Inc., publisher of *Consumer Reports*©, is a nonprofit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health and personal finance. Consumers Union's publications and services have a combined paid circulation of approximately 8.3 million. These publications regularly carry articles on Consumers Union's own product testing; on health, product safety, and market place economics; and on legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Union's income is solely derived from the sale of *Consumer Reports*©, its other publications and services, fees, noncommercial contributions and grants. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

[2] "Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking," Federal Register, Vol. 76, No. 69, 19914 (April 11, 2011).

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Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (''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 standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

In the above-referenced notice, the Commission proposes safety standards for portable bed rails which are substantially the same as the voluntary standards developed by ASTM International (formerly known as the American Society for Testing and Materials), but which include several modifications that will strengthen the standard. These more stringent requirements are intended to further reduce the risk of injury associated with portable bed rails.

While Consumers Union supports the ASTM standards-development process, we agree with the Commission that the mandatory standard for bed rails should be more stringent than the current ASTM standard. Certain design hazards involving this product currently exist or could exist and have not yet been adequately addressed by ASTM - International. There are several ways in which the standard could be strengthened – specifically, to further eliminate hazards associated with misassembly and misinstallation.

First, we support the Commission's conclusion that at least certain portions of the standard should also include bed rails constructed from non-rigid materials, such as foam or inflatable materials, in addition to traditional, rigid portable bed rails and. As noted in the NPR, the scope of the current ASTM standard does not currently cover these products at all.

Secondly, we completely agree with the CPSC that improper use and misassembly are some of the major contributors to bed rail-related hazards. In our experience, if a product can be misassembled by the consumer, it probably will be. In addition, bed rails are not typically long-term installations – they are subject to frequent disassembly and reassembly. Manufacturers' instructions are not likely to be used after the first assembly of the product. As a result, we are pleased that the proposed rule establishes some new performance requirements and associated test methods to address misassembly of portable bed rails. For example, we support the new

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section included in the mandatory standard that addresses critical installation components that are also critical assembly components and which could result in a misassembled/functional portable bed rail. We believe the requirements for these components will reduce the likelihood that consumers will misassemble the bed rail, because the product would not be functional in its misassembled state.

Consumers Union also supports the Commission's proposed test methods for determining the acceptability of the vertical structure of a misassembled/function portable bed rail, as well as the test method for determining fabric sag acceptability of a misassembled/functional portable bed rail. We agree that 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.

In addition, we are pleased with the proposed rule's requirements for clear, permanently affixed labeling or graphics in order to address potential consumer misassembly of the product. As noted in the CPSC notice, 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. As a result, Consumers Union agrees that the proposed new warning label for critical installation components would help consumers understand the importance of using the installation components when installing portable bed rails onto the bed and thus reduce the likelihood of misinstallation.

Consumers Union re-iterates its support for a captive hardware requirement, so that hardware cannot be lost or substituted in subsequent reassemblies, potentially increasing the risk of a misassembled final product.

In conclusion, Consumers Union strongly supports the adoption of the Commission's proposed mandatory standards for portable bed rails. We believe these stringent standards, coupled with rigorous and independent third party testing, will provide the market with safer products. Consumers Union looks forward to helping the Commission with these efforts.

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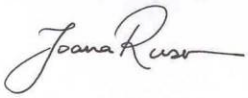
Respectfully submitted,

Donald L. Mays
Senior Director, Product Safety / Technical Policy
Consumers Union



Ioana Rusu
Staff Policy Assistant
Consumers Union

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PUBLIC SUBMISSION

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Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0016
Comment from Rachel Weintraub

Submitter Information

Name: Rachel Weintraub
Organization: Consumer Federation of America

General Comment

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CPSC-2011-0019-0016

Consumer Federation of America

1620 I Street, N.W., Suite 200 * Washington, DC 20006

June 30, 2011

Office of the Secretary
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4330 East-West Highway
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Via: tstevenson@cpsc.gov

Comments of Consumer Federation of America to the U.S. Consumer Product Safety Commission on "Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking"

Docket No. CPSC– 2011–0019

Consumer Federation of America[1] submits the following comments to the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") in the above-referenced matter.[2]

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (''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 standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

In the above-referenced notice, the Commission proposes safety standards for portable bed rails which are substantially the same as the voluntary standards developed by ASTM International (formerly known as the American Society for Testing and Materials), but which include several modifications that will strengthen the standard. These more stringent requirements are intended to further reduce the risk of injury associated with portable bed rails.

While Consumer Federation of America supports the ASTM standards-development process, we also support the Commission's position that the mandatory standard for bed rails should be made more stringent than the current ASTM standard. Certain design hazards involving this product currently exist or could exist and have not yet been adequately addressed by ASTM -

[1] Consumer Federation of America is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education.
[2] "Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking," Federal Register, Vol. 76, No. 69, 19914 (April 11, 2011).

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International. There are several ways in which the standard could be strengthened – specifically, to further eliminate hazards associated with misassembly and misinstallation.

First, we support the Commission's conclusion that at least certain portions of the standard should also include bed rails constructed from non-rigid materials, such as foam or inflatable materials, in addition to traditional, rigid portable bed rails. As noted in the NPR, the scope of the current ASTM standard does not currently cover these products.

Second, we agree with the CPSC's position that improper use and misassembly are some of the major contributors to bed rail-related hazards. If a product can be misassembled by the consumer, the misassembly is not at all clear to the consumer, and the product appears to function as intended, then it probably will be misassembled. Further, bed rails are not typically long-term installations – they are subject to frequent disassembly and reassembly, making the misassembly potential even greater. Manufacturers' instructions are not likely to be used after the first assembly of the product. As a result, we are pleased that the proposed rule establishes some new performance requirements and associated test methods to address misassembly of portable bed rails. For example, we support the new section included in the mandatory standard that addresses critical installation components that are also critical assembly components and which could result in a misassembled/functional portable bed rail. The requirements for these components will reduce the likelihood that consumers will misassemble the bed rail, because the product would not be functional in its misassembled state.

Third, Consumer Federation of America also supports the Commission's proposed test methods for determining the acceptability of the vertical structure of a misassembled/function portable bed rail, as well as the test method for determining fabric sag acceptability of a misassembled/functional portable bed rail. We agree that 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.

Fourth, we are also supportive of the proposed rule's requirements for clear, permanently affixed labeling or graphics in order to address potential consumer misassembly of the product. As noted in the CPSC notice, 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. As a result, Consumer Federation of America agrees that the proposed new warning label for critical installation components would help consumers understand the importance of using the installation components when installing portable bed rails onto the bed and thus reduce the likelihood of misinstallation.

In addition, Consumer Federation of America urges the Commission to include an additional requirement in this NPR. We recommend that portable bed rails be sold in pairs of two. Parents often purchase one bed rail to place on the open side of the bed to prevent a child from falling. However, a potential gap between the bed and the wall could pose a serious entrapment hazard to children that is often unanticipated. Selling portable bed rails in pairs will enable parents to prevent falls and entrapment on both sides of the bed.

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Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0017
Comment from Gloria Black

Submitter Information

Name: Gloria Black

General Comment

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U.S. Consumer Product Safety Commission
Room 502
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June 2, 2011

COMMENTS

RE: CPSC Docket No. CPSC-2011-0019
16 CFR Part 1224
Safety Standard for Portable Bed Rails: Proposed Rulemaking
AGENCY: Consumer Product Safety Commission

To Whom It May Concern:

In attempting to provide the Commission with my comments on the docket, I wish to acknowledge upfront that I am confused by your intended purpose. If your motivation is to end the high numbers of deaths in bed rails, portable or otherwise, involving children and/or involving adults, then I do not think the docket deals sufficiently with that at all. Much of the language in the docket revolves around speculation about reduction in risk of injury. It is proposing only slight improvements. These don't go to the heart of the problem.

In what follows I will provide comments to the docket, but also try to explain why the problems with portable bed rails (and other types of rails) are more serious than what one would be led to believe. Further, *I believe the CPSC already has the tools by which the problem can be resolved. It can ban dangerous bed rails, and it can recall them.* These options will be presented in a further section.

As I see it, the problem with bed rails is that people become entrapped and/or entangled in them, leading to injury or suffocation to death. In some cases individuals attempt to climb over the bed rail that is attached to their bed, and they may die from the fall that, due to the added height of the rail, is now at a greater distance than would have been had there been no bed rail at all. Especially (but not exclusively) with portable bed rails, there is a serious risk of strangulation as the rail, whether through faulty assembly, faulty installation, daily use, or simply through faulty and ineffective design, moves away from the bed, creating a gap between the mattress and the rail leaving an exposed bar on which the victim chokes to death. The nature of the deaths by bed rails is the same for adults as it is for children. These types of death take place not only in portable bed rails, but

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hospital bed rails and other types of rails as well. The proposed improved ruling is addressing portable bed rails only.

There is some question of jurisdiction between the CPSC and the FDA regarding 'consumer products' and 'medical devices.' (Perhaps this fine line has contributed to the failure to adequately regulate bed rails over the past 20 years.) Prior CPSC comment (Endnote 1) indicates that some adult bed rails may fall under CPSC jurisdiction, (e.g., possibly when the CPSC itself has done an Investigative Report into an incident). Since, in the eyes of consumers, there is no distinction between the two classifications (medical device or consumer product), it is in the greater good that we lean towards more stringent regulation when in doubt. Towards fulfillment of the CPSC's stated mission "...to protect the public against unreasonable risks of injury associated with consumer products" (Endnote2), and since this is not addressed in the docket, I pose the question, *What regulations are you proposing or will you propose for adult portable bed rails?* Why not include adult portable bed rails in these standards you propose? In my opinion, the inherent risks of asphyxiation to children using bed rails are the same as the risks posed to adults.

The docket proposes more stringent regulations to reduce the deaths and injuries in portable bed rails for children. In what follows I will explain why *I believe that such strengthened regulations, although welcome, will be insufficient to eliminate deaths and injuries in bed rails.*

THE EXTENSIVE REPORTS ON DEATHS BY BEDRAILS

Under 'Incident Reports' in the CPSC docket, the following appears:

"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 olds; and two children, both physically handicapped, were 6 years old. ..... A total of 40 nonfatal incidents associated with the use of a portable bed rail involved injury to a child..."

Data which the CPSC has gathered prior to the year 2000 was not included. Yet there is a CPSC Memorandum on 'Portable Youth Bed Rail Entrapments and Hangings,'dating back to June 7, 2010 (attached), which refers to 36 incidents the CPSC is aware of from 1/1/90 to 3/14/00. Twelve of those incidents resulted in deaths. Stated in the same memorandum is also the following:

"These deaths and incidents are neither a complete count of all that occurred during this time period nor a sample of known probability of selection. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in these entrapment or hanging incidents involving portable youth bed rails."

In its December 7, 2010, letter the CPSC provides statistics for bed rail incidents dating back to 1985:

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"CPSC staff is aware of 203 incidents between 1985 and 2009 that involved entrapments, entanglements, or strangulations in bedrails. ... Of the 203 reported incidents, 155 resulted in fatalities; 18 resulted in non-fatal injuries; and 30 reports did not mention any injury. The number of incidents and fatalities of which CPSC staff is aware does not likely represent all incidents that occurred in the time period because not all incidents are reported, and the reports are not projected nationally. It is possible some of these incidents may be reported directly to the FDA. Of the 203 incidents reported to the CPSC, 4 mentioned a hospital bed, 13 mentioned a bed in a nursing home, and 37 mentioned a twin/full/queen/king size bed. The remaining 149 reports did not mention either the bed rail type or the bed. Of the 203 incidents reported to the CPSC between 1985 and 2009, 123 incidents involved individuals older than 60 years of age; 40 incidents involved children younger than 5 years of age; and 31 involved individuals between the ages of 5 and 60. Victim's age was not mentioned in 9 of the incidents reported to the CPSC."

Perhaps it is the case that most of the bed rail reports on death which are sent to the FDA are not necessarily under CPSC jurisdiction. Due to the scope of the bed rail injuries and deaths for which we do know about, I believe it remains relevant and important to mention that the FDA has received reports of over 500 deaths allegedly involving bed rails (Endnote 3.) While it is largely an adult population of seniors with dementia who allegedly fall victim to asphyxiation deaths in bed rails, the FDA reports do also include children. Additionally, the FDA has reports of injuries (numbering in the hundreds) associated with bed rails, but for the intended purpose here, I focus on statistics for the deaths only.

"The CPSC's mission is to protect the public against unreasonable risks of injury associated with consumer products." (Endnote 2.) If we consider the scenario, that a bed rail might be sold in a medical supply store, and as such might be more likely to be considered under FDA jurisdiction, we must also take into account that that identical rail might also be sold on the Internet. It might also be sold directly by the manufacturer, from, say, his home. It can also be sold through a chain department store. So, given the variety of situations under which bed rails are sold, can it be conclusively stated that many bed rails for adults (or children) are not 'products'? Anyone can buy a bed rail, and at no point do the sales personnel need to ask for what purpose it is being used.

Finally, lest one be lured into the false belief that re-labeling all bedrails as medical devices (thus throwing them into FDA domain solely) and requiring them to be purchased only with a prescription from a doctor is the solution to keeping children (and adults) from dying in bed rails, I will note that several deaths, including of children, have occurred even when doctors did supply families with a prescription or recommendation to purchase a bed rail.

DO BED RAILS MAKE PEOPLE 'SAFER'?

Nowhere in the docket is this question asked. *It is the most important question that begs answering.* Risk assessment I assume typically asks questions such as, How many people have died versus how many products have sold? One can determine how many bed rail type products have been sold, but, as has already been established, the upper bounds of how many have died cannot be determined. (Endnote 4).

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The already high numbers of death we do know about (not to mention the additional statistics pertaining to injuries), I believe is evidence of a fundamental problem which is not necessarily going to be resolved through changes in standards alone. (Endnote 5.)

In their article, (attached), 'Myths and Facts About Side Rails,' [1]Karen Talerico and Elizabeth Capezuti present the following:

"MYTH: Side rails serve as a safe and effective means of preventing patients from falling out of bed.
FACTS: No research study has demonstrated the efficacy of side rails in the prevention of injuries resulting from falling out of bed. In fact, several studies have shown that raised side rails do not deter older patients from getting out of bed unassisted, and may even lead to more serious falls and injuries..."

"MYTH: Safe alternatives to side rails do not exist.
FACTS: Alternatives that may not pose the serious physical and psychological threats that the use of side rails does include: the low-height bed, floor mats placed at the sides of the bed, ..."[2]

It is worth repeating what is written in their researched report: **"No research study has demonstrated the efficacy of side rails in the prevention of injuries resulting from falling out of bed."**

In The New York Times article, 'Safe in Bed?' by Paula Span, (March 10, 2010), Dr. Steven Miles, Bio-ethicist, medical doctor, Professor at the University of Minnesota, expert witness in deaths involving bed rails, and author of several publications on bed rail deaths, states: "Rails decrease your risk of falling by 10 to 15 percent, but they increase the risk of injury by about 20 percent because they change the geometry of the fall."

CLAIMS MADE BY THE CPSC REGARDING THE VALUE OF PROPOSED RULE-MAKING CHANGES.

Statements such as the following are made in the docket:

"...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. ..."

" The proposed modifications, if finalized, will further reduce the risk of death and injury associated with portable bed rails."

There is, in my opinion, no statistical evidence provided to demonstrate that any of the changes you propose will definitely make bed rails sufficiently safe to cease posing an unnecessary risk to the public. What is provided is conjecture.

"...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 requirement would further reduce the risk of injury associated with the product. ... "

---

[1] [1] (American Journal of Nursing, July 2001, Vol. 101, Issue 7, 43-48)
[2] Further solutions are offered, but these would be geared more to use by older patients rather than children, so I do not mention those here.

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The very key word here is 'if.' **If** the Commission concludes that more stringent requirement would further reduce the risk of injury associated with the product... My question is: on what basis can you draw that conclusion?

"...if a portable bed rail is misassembled or misinstalled on the bed, it could present an entrapment hazard."

That is a true statement. **It is also true that if a portable bed rail is properly assembled or properly installed on the bed, it STILL presents an entrapment hazard.**

Nowhere do you address other issues, such as, what happens to these rails when something like daily changing of sheets, or other routine use, for example, inevitably result in some further movement or possible stress on the product itself?

THE NEED FOR RECALLS AND/OR BANS

There is nothing I could find in your proposal that removes dangerous bed rails that children (or adults) use. Why not? Why not recall all of those rails that are known to be associated with injuries and deaths, as well as those that do not meet your proposed new standards? You openly acknowledge that the standards need improvement. Improper assembly is listed as one of the problems contributing to deaths in bed rails:

"...current portable bed rail designs do not meet the proposed misassembly requirements."

Why would you leave on the market all those inferior perhaps failed models that clearly run the risk of causing children to die, both through proper use and/or improper use?

"The proposed modifications and additions to the standard would reduce further the risk of injury associated with portable bed rails."

By how much? Where is the math in these assertions? I find words like 'reduce,' but nowhere do I find the key word '*eliminate*.' You may claim that recalls or bans are outside the scope of the docket. Why? **We need to address the fundamental problems inherent in the designs of this problem, not just 'reduce' by an unknown factor the numbers of injuries and deaths by proposed changes.**

"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."

Really? My interpretation of this statement is that the Commission therefore actually must believe that the cause of multiple hundreds of deaths known of through reports to the CPSC and FDA collectively is due to assembly and installation. I would sooner assert that evidence shows that if a portable bed rail is misassembled or misinstalled on the bed, it could present an entrapment hazard, **AND if a portable bed rail is assembled or installed properly on the bed, it could also present an entrapment hazard.**

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In the attached article 'Bed-rail entrapments still a serious problem,"[3] published July 24, 2008, by Prof. Hyman (Endnote 6), he provides a detailed analysis of the multiple design factors that contribute toward making these products left on the market to be potentially dangerous. It is well worth studying that work.

The very nature of portable bed rails means that different mattress systems are going to be used along with the portable rail. I do not find this fundamental problem mentioned or addressed in the docket itself. An entire set of problems emerges, resulting from the various types of mattresses a portable rail might be used with. And there is in fact no way I can think of that would ensure that users would use only specified bedding/mattress systems were that to be provided as part of the labeling. We just do not have control over what people are going to do in their own homes or even in many nursing facility situations.

"The time to end lethal bed-rail entrapments is now, and the way to do it is to remove from the inventory those bed-rail systems that are unreasonably dangerous..." These words, excerpted from Prof. Hyman's. 2008 article, were true 3 years ago, and they shall remain true until action is finally taken to remove dangerous bed rail systems from the market.

Further questions remain. Perhaps these questions are deemed to be outside the scope of the docket, but in the public interest and because I believe it is your responsibility to consider these, I will ask them.

1. What consequences do you impose on manufacturers when you have/know of not just one report on file of a death that has allegedly ensued, but multiple reports?

2. What numbers of deaths of children do you consider acceptable before you take action such as banning a product and/or demanding a recall?

3. For the past 20 years CPSC has known of the existence of this problem. Why are families still dealing with the end results of failure of government oversight when it comes to bed rails, portable or otherwise?

RECOMMENDATIONS REGARDING WARNINGS OF RISK OF ASPHYXIATION

Warnings of risk of asphyxiation on Internet advertisements are entirely absent. This needs to be changed. Why can't the CPSC mandate these warnings? It is critical that if you deem these bed rail products safe enough to be on the market, then warnings need to accompany any advertisement on the Internet as well. This courtesy should be extended to bed rails advertised for adults too.

I fully support your proposal to place warnings on the products themselves, in large, always visible letters, but why on rails for children only? Why not for adults too?

---

[3] http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/

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"The proposed warning would state 'Children who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate'."

I believe this warning provides a false sense of security for those with children who can get in and out of an adult bed without help.

"Incorrect installation can allow the portable bed rail to move away from mattress, which can lead to entrapment and death."

Again, this statement is misleading. Correct installation can also achieve the same tragic results.

Last, the docket contains a gracious gesture in proposing to allow additional time for manufacturers to come into compliance if proposed new ruling is approved. But the lives of children are in jeopardy here. Would you want your child to be the victim caused in part by such a delay in administrative enforcement?

SUMMARY OF PROPOSED SOLUTIONS

To address the causes of the real problems, as I perceive them, I propose the following:

1. All bed rail type products that have been involved in an injury or a death should be removed from the market unless and until the manufacturer can demonstrate that his/her product had no role whatsoever in the injury or death that occurred.

2. New bed rails should have warnings of risk of asphyxiation printed in large letters, and in a place where it is always visible (to help caregivers be alerted to the risks. As explained above, warnings that become too specific can lead to false senses of security.

3. All bed rails currently on the market should have warnings of risk of asphyxiation.

Thank you very much for the opportunity to provide these comments. All statements expressed by me and contained herein are my opinion. I apologize in advance for any mistakes I may have inadvertently made in my analysis presented here, in any misinterpretations I may have made of material you presented. All of my comments refer to all bed rails in general, and nothing herein is suggested to single out any specific manufacturer, medical device or consumer product. The numbers of deaths speak for themselves. With each passing month, we learn of approximately two more deaths involving bed rails. It's time to halt the tragedy.

Respectfully,

Gloria Black

Gloria Black

(cont. on next page)

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Enc.
1. CPSC letter, dated December 7, 2010
2. "Bed-rail entrapments still a serious problem," William A. Hyman, [1]
http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/
3. "Safe in Bed?', Paula Span, The New York Times
4. "Myths and Facts about Side Rails," Karen A. Talerico, Elizabeth Capezuti
5. CPSC Memo, dated June 7, 2000, "Portable Youth Bed Rail Entrapments and Hangings."

ENDNOTES

1. Responding to the question, "If the CPSC has done an Investigative Report into an item allegedly involved in a death, does that fact (i.e., the existence of your report) signify that the item in question is in your jurisdiction, and therefore could be reported here?" the CPSC response, through their saferproducts website, was "... If the CPSC investigates a product, it would most likely be in our jurisdiction." The CPSC conducted an Investigative Report into the alleged entrapment death of an adult, date of report initiated March 28, 2007.

2. CPSC letter addressed to me, dated Dec. 7, 2010. (Letter attached.)

3. Please see FDA website www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/TextSearch.cfm. Click on 'Go to Simple Search and input Bed rail deaths.

4. The lack of requirement for medical examiners to report to a central location on suspected bed rail deaths, the failure of certain institutions to report bed rail deaths to families (perhaps for fear of lawsuit reprisals, etc.,) - these are just a few causes that would result in a suppressed recording of the actual number of incidents.

5. Public Citizen, on May 4, 2011, submitted a Citizen's Petition to the FDA in which they call for a ban and a recall of certain types of bed rails. The Petition has to date not been assigned a docket number, but is available on the Public Citizen website. There is reference to CPSC in this Petition.

6. Prof. Hyman is a Professor in the Department of Biomedical Engineering at Texas A&M University, and also serves as an expert witness in bed rail cases involving death or injury.

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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

December 7, 2010

Ms. Gloria Black
17788 NW Gilbert Lane
Portland, Oregon 97229

Re: Inquiry on Bed Rail Type Products

Dear Ms. Black:

Thank you for your letter to Chairman Tenenbaum regarding bed rail type products. Your letter was forwarded to me for response.[1] Because you had a number of questions ranging from general U.S. Consumer Product Safety Commission (CPSC) operations/procedures, to specific bed rail-related questions, I grouped your questions into categories and provided responses below.

CPSC Mission/Recall Authority/Procedures for Analyzing Death Reports

The CPSC's mission is to protect the public against unreasonable risks of injury associated with consumer products. The CPSC has the legal authority to recall products whether or not deaths can result from their use. If CPSC staff concludes that a product has a defect that may be serious enough to create a substantial product hazard, a recall can be ordered. Several factors are considered by staff in this determination, including the pattern of defect, number of defective products distributed in commerce, severity of the risk, likelihood of injury, and other appropriate data.

CPSC statisticians review all product-related death and injury reports that come into the Commission via hotline or Internet on a daily basis. Our analysts screen the reports to identify the product involved and whether an injury or fatality is reported. The analysts then forward the reports to the appropriate technical and enforcement staff, who may request additional information about the report or request that an in-depth investigation be conducted by CPSC field investigators to collect more details about the hazard scenario. These in-depth investigations are assigned based on established criteria that align with the CPSC's mission and product studies. In-depth investigations completed by CPSC field staff are uploaded to an internal database and are transmitted electronically to subject matter experts. Analysts apply data mining algorithms across newly received reports, on a weekly basis, to characterize the frequency of fatality reports received by product type and to characterize the number of reports received on that specific product over the last five years. The frequency of historic reports received on the product is characterized by severity (i.e., no injury, injury, fatality). These reports are used to suggest emerging trends and guide CPSC staff actions to remove unsafe consumer products from the market.

[1] These comments are those of CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

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CPSC Strategies/Decision Making Policy

The CPSC employs a number of strategies to reduce risks associated with hazardous consumer products. These strategies include: (1) completing new regulations in accordance with the Consumer Product Safety Improvement Act; (2) conducting enforcement activities to ensure compliance with the new requirements resulting from the CPSIA; (3) conducting activities to ensure the safety of imported products; (4) participating in the voluntary standards process or developing mandatory safety standards/warning labels; (5) conducting compliance actions, such as recalls, corrective actions, and enforcement of existing regulations; and (6) alerting the public to safety hazards and informing them about safe practices. The Commission bases its actions on staff's recommendations, which are formulated from the information contained in its extensive data collection systems, which can be used to assess the causes and scope of product-related injuries, and, as needed, the peer-reviewed scientific literature.

The Commission uses risk- based decision making in prioritizing hazard reduction activities by evaluating: (1) the severity of the hazard and risk factors posed for the populations exposed to the hazard; (2) when appropriate, the susceptibility of the hazard to remedial action; and (3) the costs associated with investigating the hazard and achieving appropriate remedial action. The important factors considered are severity, frequency, exposure, foreseeability of the hazard, and the vulnerability of the population. Seniors and children are considered vulnerable populations.

Manufacturer/Importer/Distributor/ Retailer Reporting Obligations

A company has a reporting obligation to the CPSC once they have information that would reasonably support the conclusion that their product fails to comply with a mandatory or voluntary standard, or that it contains a defect which creates a substantial product hazard or creates an unreasonable risk of injury or death. If the product is involved in a death, it must be reported immediately. Failure to report may result in civil penalties. Manufacturers, importers, distributors, and retailers of consumer products must notify the Commission immediately if they have information about possible defects involving consumer products that may pose safety risks to consumers. CPSC staff evaluates this information and notifies the public and any other appropriate stakeholders.

Medical Examiner Reporting Obligations

Medical examiners are not obligated to report product-related deaths to the CPSC or the Food and Drug Administration (FDA). The CPSC has annual contracts with between 50 and 100 medical examiners' offices to provide reports on consumer product-related deaths. The CPSC also has a web-based form that medical examiners may use to voluntarily submit reports of consumer product-related deaths to the agency. Several times each year, CPSC staff provides a newsletter to medical examiners and coroners highlighting cases of interest and describing how medical examiners and coroners can submit a report to the agency. The CPSC receives about 4,500 reports annually of consumer product-related deaths from medical examiners and coroners.

CPSC/FDA Bed Rail Jurisdictional Questions

Products are under the jurisdiction of the CPSC if they meet the definition in the Consumer Product Safety Act (CPSA) of a "consumer product," which is defined in part, as:

> any article, or component part thereof, produced or distributed
> (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or
> (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.

This definition excludes "drugs, devices, or cosmetics (as such terms are defined in sections 201(g), (h), and (i) of the Federal Food, Drug, and Cosmetic Act)."

Products are considered medical devices if they meet the definition of a "device" regulated by the FDA under the

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Federal Food, Drug, and Cosmetic Act. Section 201(h) of the Federal Food, Drug, and Cosmetic Act defines a device, in part, as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is–
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Thus, in many cases, the jurisdictional determination will depend on the claims made for the product (e.g. to examine whether it is "intended for use in the diagnosis of disease or other conditions").

It is possible that a product may be regulated by several agencies for different purposes. For example, cell phones are subject to regulation by several agencies. The FDA may regulate the radiation-emitting aspects of the product; the Federal Communications Commission (FCC) certifies wireless devices, and all phones that are sold in the United States must comply with FCC guidelines on radio frequency exposure. The FCC also regulates cell phone base stations. The CPSC may take action if the phone exhibits product performance issues, such as overheating or exploding batteries, or if it causes a fire or shock incident.

Bed rails that are intended to keep a young child from inadvertently falling from a bed have been determined to be consumer products by the CPSC. With respect to your questions regarding whether the products are medical devices regulated by FDA, the answer depends on whether the product meets the definition of "device" in section 201(h) of the Federal Food, Drug, and Cosmetic Act. We suggest that you contact FDA for more detail as to the regulation of devices.

CPSC Bed Rail Death and Injury Statistics/Agency Coordination

CPSC staff is aware of 203 incidents between 1985 and 2009 that involved entrapments, entanglements, or strangulations in bedrails. The sources of these incident reports include consumers reporting via the Internet or hotline, death certificates provided by states, newspaper clippings, medical examiner reports, and reports from a probability sample of hospitals with emergency departments. Of the 203 reported incidents, 155 resulted in fatalities; 18 resulted in non-fatal injuries; and 30 reports did not mention any injury. The number of incidents and fatalities of which CPSC staff is aware does not likely represent all incidents that occurred in the time period because not all incidents are reported, and the reports are not projected nationally. It is possible some of these incidents may be reported directly to the FDA. Of the 203 incidents reported to the CPSC, 4 mentioned a hospital bed, 13 mentioned a bed in a nursing home, and 37 mentioned a twin/full/queen/king size bed. The remaining 149 reports did not mention either the bed rail type or the bed.

Of the 203 incidents reported to the CPSC between 1985 and 2009, 123 incidents involved individuals older than 60 years of age; 40 incidents involved children younger than 5 years of age; and 31 involved individuals between the ages of 5 and 60. Victim age was not mentioned in 9 of the incidents reported to the CPSC.

As part of an annual interagency agreement with the FDA, the CPSC collects data on injuries treated in hospital emergency departments related to medical devices. Hospital beds have a specific product code. The data are provided to the FDA, and this communication has been ongoing for 10 years. However, CPSC staff is not aware of other sources that the FDA may use in collecting data on incidents involving bed rails in hospital settings.

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Activities on Bed Rail Entrapments to Adults

Bed rails used by adults for medical purposes are not under the jurisdiction of the CPSC. The FDA, working with the then-Veterans Administration (now called the Department of Veterans Affairs), Health Canada's Medical Devices Bureau, representatives from national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers, formed the Hospital Bed Safety Workgroup in 1999. The workgroup cooperated with other federal agencies, including the Center for Medicare and Medicaid Services and the CPCS, to improve patient safety associated with the use of hospital beds, including bed rails. In October 2000, the FDA issued a brochure titled, "A Guide to Bed Safety." The brochure contained information on bed rails, how to meet patients' need for safety, the risks and benefits of bed rails, and other topics. The FDA has also issued other documents pertaining to hospital beds. The information is available on the FDA's website at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/default.htm.

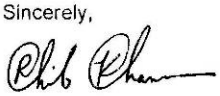
The American Medical Association/National Patient Safety Foundation is aware of the potential dangers of bed rail products. They have participated in Hospital Bed Safety Workgroups involving this hazard, and CPSC staff has provided information on the hazards to children associated with portable bed rails.

CPSC Activities on Bed Rail Entrapment Hazards to Children

CPSC staff developed performance requirements to address the hazards associated with most of the reported deaths and injuries to children involving portable bed rails. The Commission voted to begin a rulemaking proceeding for a mandatory standard on portable bed rails. In response to this action, the voluntary standard developer, ASTM International, adopted the performance requirements that were developed for the proposed mandatory standard. As a result, most manufacturers of portable bed rails upgraded their designs to meet these new requirements. Under the requirements of the Consumer Product Safety Improvement Act of 2008, staff plans to present a draft mandatory standard to the Commission for its consideration in 2011.

If you would like any additional information or need further clarification on these issues, please feel free to contact me at (301) 504-7546 or at rkhanna@cpsc.gov.

Sincerely,



Rohit Khanna

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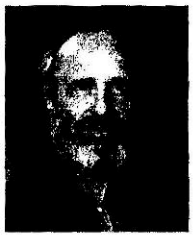
Penner Manufacturing is changing the face of bathing by creating the ultimate bathing experience and homelike atmosphere.

Bed-rail entrapments still a serious problem

William A. Hyman
July 24, 2008



More In Guest columns

- Demystify risk management in nursing homes
- The federal government should invest more in home care
- Strive to integrate assisted living into care continuum at retirement communities
- Every day is an opportunity to forge relationships
- Let's build better boards of directors

Bed-rail entrapments and deaths continue to occur in nursing homes, other facilities and in the home because rail and bed designs that are clearly dangerous continue to be used. Such rails may be in your inventory, or in the inventory of your rental supplier.

The U.S. Food and Drug Administration has recognized and reported on the problem of lethal entrapments for over 10 years, but it has not ordered recalls. Some manufacturers have designed safer rails yet not replaced those already in use. And despite the publicity efforts of the FDA, The Joint Commission published articles and others, there continues to be a lack of practical understanding of the nature of this hazard and how to recognize a dangerous bed.

The time to end lethal bed-rail entrapments is now, and the way to do it is to remove from the inventory those bed-rail

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systems that are unreasonably dangerous, and to insist that suppliers provide beds that at least meet current guidelines.

It is now 13 years since the FDA's Safety Alert on the dangers of entrapment in bed rails, and other parts of hospital and nursing home beds (1). This alert was directed to Home Healthcare Agencies, Hospices, and Nursing Homes, among others. It was based, in part, on already published work and reports to the FDA of deaths and injuries associated with beds and bed rails, the latter going back to publicly available data since 1985. The FDA alert triggered a number of related reports and announcements in the clinical literature (2- 4).

The entrapment issues stimulated the creation of the Hospital Bed Safety Workgroup (HBSW) (5) in 1999. The work group is a partnership among FDA, the medical bed industry, national healthcare organizations, patient advocacy groups and other federal agencies. This group labored for many years to reconcile the diverse interests of its members, and to balance safety and economic concerns. The HBSW ultimately produced a brochure, which currently has a 2006 update date, along with guidance documents and a gap measurement methodology. Earlier drafts of the guidelines also were publicly available, but are no longer posted at the FDA/HBSW Web site. The guidance is not applicable to all beds. For example, air-fluidized beds, bariatric beds, pediatric beds, infant cribs, and pressure-reduction products such as air mattresses are fully or partially excluded. Air mattresses that replace the regular mattress may present particular risk for under the side rail entrapment because of the high compressibility of the air mattress at the edge (6). It is notable that air mattresses in particular are excluded—not because of any lack of risk, but because of "technically difficulties with measuring certain dimensional gaps."

Articles and other material on bed and bed rail entrapment hazards have continued to appear in announcements from the FDA (7), The Joint Commission (8), the Veteran's Administration (9), on National Public Radio (10), and in the pages of Nursing Homes (11). The latter article addresses the March 10, 2006, FDA guidance (12).

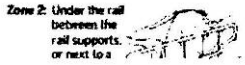
Regrettably, none of the FDA's efforts have resulted in recalls or other manufacturer formal actions to remove dangerous bed-rail systems from use. In fact, the guidance notes that the "FDA does not intend to take enforcement actions for failure to submit reports of corrections and removals under 21 CFR Part 806 for actions taken in response to this guidance that correct or improve hospital beds currently in use or held as inventory" (12). Thus, the manufacturers achieved protection from the "recall" label, if they took any action at all. Individual nursing homes or equipment dealers may have removed from inventory certain bed systems, but their disposition is unknown. At least some design improvements for new equipment have become available. While the latter may increase the safety of newly purchased beds, it does not protect either patients or providers from the use of older equipment. In fact, the open availability of better products, along with the extensive literature on the hazard, most likely increases the liability exposure of the nursing home, particularly with respect to the possible assertion that they didn't know about the risk.

Although the effort to inform the user community about bed-rail entrapment hazards has been ongoing, there continue to be deaths in nursing homes resulting from such entrapments. Some individual nursing homes have had more than one such death, and some corporate chains have had deaths in more than one facility. In some cases, corporate level expertise has generated warnings and or guidance documents to their individual facilities, but whether there has been decisive or ongoing vigilance with respect to these issues is not clear.

What is the problem?

The basic bed-rail entrapment problem is that the design of the bed frame, the bed rail and the mattress may create gaps into which body parts can become trapped. These components together are called the bed system. When the body part is the neck or chest, this can lead to death. Seven particular entrapment zones have been clearly identified and graphically illustrated. These are:

Zone 1: Within (between) the bars of the rails



Zone 2: Under the bottom rail, between the rail and the mattress or bed frame

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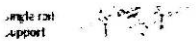
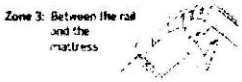
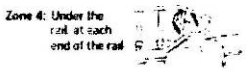


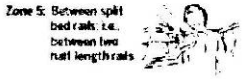
Zone 3: In the gap between the rails and the mattress



Zone 4: Under the rail and between the rail and the mattress at the outside edge of the rail



Zone 5: Between split rails



Zone 6: Between the end of the rail and the head or foot board

Zone 7: Between the end of the mattress and the head or foot board

The FDA guidance, which is voluntary, only contains test protocols for Zones 1-4. Thus, a bed that asserts it is compliant with the guidance may not adequately address all of the zones. It should also be noted that the situations illustrated are not the only relevant risks. For example, in Zone 2 the illustration shows the head having entered the gap. Alternatively, the body can slide through this gap while the head might not, leading to strangulation aided by body weight. Such a situation is shown in the Zone 4 and Zone 5 graphics, but those graphics do not in turn show headfirst entry. Also, Zones 2 and 3 are highly interactive. The space between the bottom rail and the top of the mattress relevant to Zone 2 is a function of both the horizontal distance between the inner face of the bed rails and the edge of the mattress and the vertical space between the bottom of the lowest rail and the top of the mattress. The resulting oblique distance can be substantially increased as body weight compresses the edge of the mattress.

The "gap" in Zone 3 is a function of the horizontal distance between the edge of the mattress and the inside face of the bed rail, but the risk is also a function of where the bottom rails are as well as the compressibility of the mattress. In addition, whether the mattress is centered or not affects the Zone 2 and 3 gaps and assessment should be made with the mattress pushed all the way to one side, even if no-slip pads or physical mattress retention systems are supposed to be used. In many designs, this horizontal gap seems to have been intentionally increased by the bed or bed rail manufacturer by making the structure that holds the bed rail stand out from the bed frame that supports the mattress. This may be to facilitate raising and lowering the bed rail, or being able to change the bedding, without interference from contact between the mattress and the rails.

However, this convenience feature increases the risk of entrapment and is therefore a poor trade-off. Some newer designs move the side rails closer to the mattress, and add one or more bars to the bottom of the side rails in order to reduce or eliminate the vertical component of the Zone 2 gap. It must also be noted that articulating the bed can significantly increase the Zone 2 gap in a full rail. In turn, readjusting the rail, if there are adjustment points between fully up and fully down, can reduce this gap increase, but this requires specific knowledge and consistent action by staff.

The challenge of bed assessment is increased by the mix of products that may become in use even at a single facility. For example, any two or all three of the bed, bed rails, and mattress may come from different manufactures. Thus, a bed system that was reasonably safe today may become relatively unsafe if any component is changed tomorrow. The mismatch is facilitated by many components being more-or-less mechanically interchangeable, even though they may be functionally different. This mismatch can be a particular challenge when rental equipment is used since the rental supplier may have a variety of bed components in its inventory such that one day's delivery is relatively safe while the next bed delivered is relatively unsafe.

In addition, not all patients are of equal risk. In particular, small, lightweight patients are generally at the greatest risk given that their small physical dimensions may enhance their ability to fit into a gap, in whole or in part. Of course, such

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relatively small people are a common element in many nursing home settings. Another patient consideration is mobility, agitation and temporary or chronic reduced mental capacity. In this regard it must be understood that a major critical use situation of the bed rail will be when the bed occupant moves or rolls into contact with the rails. Often, this occupant will not be in full use of normal physical or mental faculties. Pretending that a bed rail is only to "remind" the occupant that they have come to the edge, or that it is only an aid to turning or bed egress (half-rails), is a fantasy that does not address actually use and risk. This fantasy is partially driven by the need to reduce restraints, as well as by manufacturer's liability "risk management" by disclaimer.

What are the real solutions?

When bed rails are indicated and specifically ordered, the ideal solution is to not have any beds or bed systems that present unreasonable risks of entrapment. This is the only solution that eliminates the problem, and elimination is always the first choice in hazard reduction. In addition, elimination of hazardous bed systems by manufacturers addresses the problem where the solution can be most effectively implemented, rather than relying on the far more numerous users to address the problem. This has been called solving the problem at the blunt end, rather than at the sharp end where the hazard actually manifests itself. At the blunt end the manufacturer also has more technical expertise and is not under short time constraints.

Addressing elimination at the local or facility corporate level requires an assessment of current bed systems and combinations, and a replacement strategy using manufacturer certified compliant beds. To aid in this process, the manufacturer of a single sourced existing bed system should in principle be a good source of information as to whether that bed system is compliant if properly maintained. An answer that is not meaningful is a bad sign. A rental supplier should be similarly asked what their own assessment of their equipment has revealed. If either the bed manufacturer or rental supplier hasn't done an assessment, doesn't understand the question, or asserts that the guidance is only a guidance and/or that it doesn't apply to older beds, it may be time to find new sources.

When replacing or adding beds, it is not logical to buy a new bed system and then take on the primary responsibility of measuring it for compliance. Contracts with suppliers must specify that only bed systems that are compliant may be delivered to the facility or its patients, and actual compliance with this contract provision must be assured. However, even here it must be remembered that the FDA guidance does not address all hazards, e.g. most measurements are made with the bed flat or with an assumed direction of into the entrapment Zone. Thus, it is equally appropriate to ask manufacturers what they themselves have done to address entrapment risks, aside from or in addition to the FDA guidance.

In addition, active policies must be in place with respect to maintaining system integrity with respect to replacement parts including mattresses. Similarly, separate or add-on products such as air mattresses must be certified by their manufacturer, or physically tested within the facility, to assure that their use does not increases the entrapment risk. Such testing must use specific and meaningful criteria. Associated product demonstrations must consist of a full system of mattress, bed and bed rails. Demonstrating an air mattress on a cafeteria table will not adequately address entrapment risks. If the product does increase the entrapment risk, but is desirable none-the-less, explicit and realistic measures to mitigate the risk must be identified and consistently implemented. It is not appropriate to simply "accept" the risk without mitigation.

A less-than-ideal solution is to identify bed, bed rail, mattress combinations that are of greater risk than some other combinations, and to create a system that assures that the undesirable combinations are never used. As above, a similar requirement must be placed on rental suppliers. Another less-than-ideal approach is to identify bed, bed rail, mattress combinations that present increased risk to certain segments of the patient population (e.g. patient's below a certain weight), and to have a functional and realistic plan to assure that such patients are not put in high risk beds. For a bed system from a single manufacturer, if there is a population for which the product is not suitable, that population should be identified by the manufacturer as a contraindication. On the other hand, broad warnings that seek in effect to shift the burden to the end user should be recognized and the product avoided.

The challenge in implementing either a product- intensive or patient-intensive plan is that each requires ongoing vigilance by trained and knowledgeable people. The associated challenge is training relevant personnel so that they can and will make informed judgments about the suitability of a bed system for a particular patient or type of patient. Such training must include specific and measurable criteria. For example, an instruction to "make sure the gap is not too big" is basically meaningless since it does not adequately address whether the gap in question is viewed from the side or above or at an

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angle, whether it is actually measured or just eyeballed, and what in fact makes a gap "too big." Similarly, entrapment risk warning labels on inherently dangerous products that do not provide any clear guidance as to how to assess the bed or the patient cannot be effective, unless used as a guide to not purchase such a product in the first place.

Another facility-based work-around for excessive gaps, besides realistic bed and patient assessment, is attempts to fill such gaps with dedicated or ad hoc products. Such solutions must be carefully assessed for their actual suitability and effectiveness. They also must be routinely practiced or the situation could end up that a risk was identified and a solution was identified, but the solution was not implemented, thereby leading to death. Furthermore, such work-arounds are inherently an attempt to locally fix a situation that should not exist in the first place.

Explaining the death that occurs

When an entrapment death occurs, there will often be a common set of facts that must be addressed. One is that the death itself demonstrates the hazard, and that the general hazards are "well known," and have been for well over a decade. The issue may also be compounded by a state level facility investigation and sanctions. This makes a claim of not knowing about the hazard hard to justify for both the facility and equipment suppliers, yet such a defense is often made. In this regard it should be noted that there are few other patient deaths for which graphic illustrations already exist, and even more graphic photographs may be taken.

Second, it may be the case that the hazard is "obvious" to a knowledgeable observer, and can be readily demonstrated. For example, a test device such as that recommended by the FDA may freely fall through an oversize gap, even without pressure on the mattress or simple hand pressure on the mattress may open a clearly dangerous gap. The manufacturer may use this fact to assert that it should then have been obvious to the users at the facility, and that they had provided various warnings. However, in the absence of specific training about the hazard and its meaningful assessment, such obviousness will likely not actually be within the working knowledge of the caregivers.

The current situation

The current situation with respect to bed-rail dangers is that (a) entrapment hazards have been clearly identified, (b) bed systems that embody those hazards continue to exist in nursing home and rental agency inventories, (c) bed system or bed components that do not adequately address these hazards are still on the market, (d) too many nursing homes and equipment suppliers either remain uninformed or do not have an effective action plan to mitigate the risks, and (e) bed users continue to die.

The FDA's action to address this situation has been limited to safety alerts, brochures and guidance documents, and seemingly protecting manufacturers from recalls. In addition, many bed rails receive relatively little regulatory review before being marketed because of the FDA classification of hospital beds. The responsible nursing home should act now to assess its, and its supplier's inventory, and to institute a clear and effective plan to eliminate or actively and effectively manage the entrapment hazard.

While it is true that some bed systems may be safe for some patients yet unsafe for others, the continued presence and deployment of bed rails and beds that are known to be hazardous to at least a common class of patients presents excessive opportunity for these bed rails to be used for inappropriate patients.

A patient dying from strangulation in a bed rail is clearly an event that is intolerable when it occurs because of well-known bad bed rail design, or a bad bed rail/bed/mattress system. The often-associated lack of continuous observation is hardly surprising and is in fact what can be reasonably expected in most care settings.

When entrapment and strangulation occurs with older designs that should have been recalled or replaced, the situation is even more offensive. And when those same bed rails have contributed to prior deaths, and continue to be used, the offensive is magnified. The time to retire dangerous bed rails is now!

William A. Hyman is a professor in the Department of Biomedical Engineering at Texas A & M University in College Station, TX. You can e-mail him at w-hyman@tamu.edu or call him at 979-845-5593. For more, go to http://biomed.tamu.edu.

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DuWayne E Kramer, Jr 0

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Professor Hyman's article is very informative and timely. However, the article does not discuss the regulatory standards requirements for electric hospital beds used in public facilities.
The IEC60601-2-38 is OSHA's and the FDA's recognized consensus standard for Electric Hospital Beds. Federal regulations require testing to the 2-38 by a nationally recognized testing lab, NRTL, before a bed can be placed in a public facility. Further information about the 2-38 is available at www.BurkeBariatric.com Click on safety. You will find:
1). A Safety and Regulatory information letter.
2). A Bed Standards educational article that explains in more detail the correct 2-38 standard usage and other confusing, inappropriate standards currently being referenced by some bed manufacturers.
3). A list of NRTL tested electric hospital beds that can be used in public facilities.
Before you place any electric hospital bed in a public facility you should understand the 2-38 regulatory requirements for quality and safety

Reply

William A Hyman 2 weeks ago 0

IEC 60601-2-38 is, as stated, an FDA Recognized Consensus Standard--but subject to modifications to the dimension tables in favor of the FDA Hospital Bed Guidance. (Search for 60601-2-38 from the FDA Standards Database.) However conformance to all FDA Consensus Standards is "strictly voluntary", as is conformance to the Guidance. Such conformance even if present would only be brought to the FDA's attention as part of a 510(k) premarket notification, but "AC-powered adjustable hospital beds" are 510(k) exempt per regulation (880.5100) and thus there is no opportunityto demonstrate or need to demonstrate compliance with 60601-2-38 (as modified), or with the Guidance. Thus it is not corretc FDA that "regulations require testing to the 2-38", and there is no FDA requirement that it be done by an NRTL.

As for OSHA, I couldn't such a regulation. An actual citation would be helpful.

An actual mandatory and retroactive bed rail entrapment regulation would be a good thing, but unfortunately for those who still die from bed rail entrapments, one currently exist.

Reply

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The New York Times
The New Old Age
Caring and Coping

MARCH 10, 2010, 12:29 PM

Safe in Bed?

By PAULA SPAN

Ron Koeberer/Getty Images Despite potential hazards, bed rails are still used in many nursing homes and assisted living facilities.

Early on Christmas morning in 2004, a staff member walked into Harry Griph Sr.'s room at the New Perspective assisted living facility in Brookfield, Wis., and found that Mr. Griph had died.

This was probably not a shocking development in itself. Mr. Griph, who was 75 and a retired phone company worker, was a hospice patient, given a diagnosis geriatricians call failure to thrive, a multifaceted decline that most commonly occurs toward the end of life. He had a do-not-resuscitate order.

But the way he died was unexpected. "He was found with his neck entrapped between the mattress or bed frame and the rail," said Jeffrey Pitman, a lawyer in Milwaukee who represents Mr. Griph's three children and his estate. "He was asphyxiated."

The family's lawsuit initially included the hospice organization, the manufacturer of the bed and the medical equipment vendor that supplied it; those three parties have settled with no admission of liability. The negligence suit against the facility continues, however, with a trial scheduled for August.

"New Perspective believes that it provided proper care to Mr. Griph," said its lawyer, Marilyn Carroll, who said she was constrained from commenting further.

Mr. Pitman disagrees, of course. "Almost all health care providers as of 2004 were aware of the entrapment danger posed by bed rails, because an F.D.A. warning came out in 1995," he said. "And the state of Wisconsin put out an alert about the dangers of bed rails in September 1999."

True, Mr. Griph was already near death, he acknowledged. "But nobody at the end of life should have to die in this manner."

Like a lot of people, I supposed that bed rails were a safety device, analogous to a seat belt in a car, meant to keep sick, drugged, confused or restless people from falling or climbing out of beds in hospitals and nursing homes. But as the geriatrician and bioethicist Steven Miles of the University of Minnesota has found — after years of reviewing cases of elderly

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people being injured or killed in bed rail accidents — the reality is different.

"Rails decrease your risk of falling by 10 to 15 percent, but they increase the risk of injury by about 20 percent because they change the geometry of the fall," he explained in an interview. Confused or demented patients who try to climb over the rails, instead of falling from a lower level and landing on their knees or legs, are apt to fall farther and strike their heads.

But the greater danger is entrapment — patients getting stuck within the rails or between the rail and the mattress. By last year, the Food and Drug Administration had tallied 480 deaths, 138 injuries and 185 close calls involving hospital beds over a 24-year period; Dr. Miles believes those statistics represent only a small fraction of the total accidents, which often go unreported.

In a typical case, Dr. Miles explained: "A person will roll into the slot next to the rail, and the mattress slides to the opposite side. That doubles the size of the gap. The patient drops into the gap, the mattress presses against his chest and he can't breathe." Asphyxiation can follow in minutes.

The F.D.A., bed manufacturers and hospital and nursing home administrators have known of such potential hazards for years, and in 2006 the F.D.A. issued guidelines to reduce them. In fact, bed rail use has dropped substantially, partly because of those guidelines but also because research has shown that they don't benefit patients — and because of lawsuits by family members.

"Government sanctions cost a couple of thousand bucks," Dr. Miles pointed out. "A lawsuit can cost $500,000 to a million; it gets much more attention." (He's scheduled to testify as an expert witness in the Griph case.)

At this point, based on Medicare surveys, he estimates that fewer than 10 percent of nursing home residents occupy beds with rails in use. But Ms. Carroll, the lawyer, said, "Bed rails are still used extensively today." Either way, with roughly 1.4 million older people in nursing homes and rehabilitation centers, plus those in hospitals or using hospital-style beds at home, hundreds of thousands may still be at risk.

The ultimate solution would be to establish manufacturing standards so that no bed has a dangerous gap between mattress and rail, just as one can no longer buy a crib that could entrap an infant. "We value babies more than elderly nursing home patients," Dr. Miles observed.

Meanwhile, here's his straightforward counsel about how to distinguish a quality rehab facility or nursing home from an unsafe one: "Count off 10 beds. See how many have rails in use. If more than one or two in 10 beds have rails up, walk out of the facility."

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By Karen A. Talerico, PhD, RN, CS, and Elizabeth Capezuti, PhD, RN, FAAN

Myths and Facts About Side Rails

Despite ongoing debates about safety and efficacy, side rails are still a standard component of care in many hospitals. So how do you determine their safe use?

For decades, the use of side rails has been as integral to the nurse's daily work as that of stethoscopes and alcohol swabs. Now nurses in both acute care and long-term care settings face new mandates from the Health Care Financing Administration (HCFA) to decrease the routine use of them.[1] Nurses are responding by developing and using alternative interventions to minimize falls and consequent injury. Nevertheless, fallacies about the safety of side rails persist. Whether used as restrictive or assistive devices, the risk of entrapment can eclipse potential benefits, particularly to older patients and those with altered mental status.

Despite findings that patients frequently climb over them, side rails have been used to prevent falls for about 70 years.[2] Their use in U.S. hospitals and nursing homes appears to be closely linked to institutional concerns with liability. In a landmark 1957 article in this journal, Ludlam, serving as legal counsel to the California Hospital Association, noted that between January 1954 and mid-1957 there were 7,819 "out-of-bed" incidents in California hospitals alone.[3] Although about 62% (4,893) of these incidents resulted because side rails had been raised, the number of claims paid

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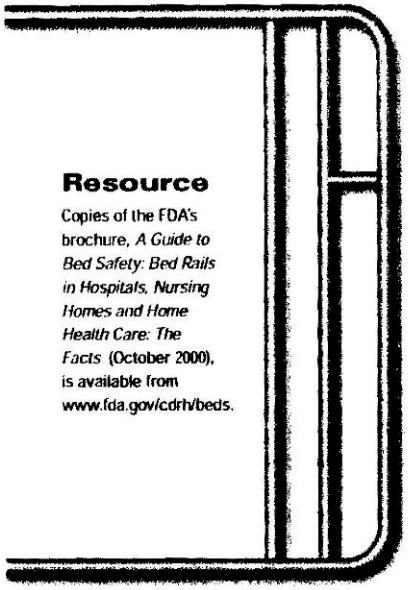

Resource

Copies of the FDA's brochure, *A Guide to Bed Safety: Bed Rails in Hospitals, Nursing Homes and Home Health Care: The Facts* (October 2000), is available from www.fda.gov/cdrh/beds.

by insurance companies nearly tripled when falls occurred from beds without side rails. Ludlam attributed the disproportionate number of claims awards to the perception that raising side rails demonstrated an effort to protect the patient, although the actual efficacy of this intervention had not been proven. Because most of these early cases were settled out of court, only a limited number of court opinions were used in establishing a standard of care.[3,4]

Nurses and hospitals began to accept the use of side rails. Despite a lack of appropriate data, Ludlam recommended that institutions implement standing orders and policies requiring their use with certain types of patients, including those under sedation, those in labor, those with impaired vision, and "elderly patients in a confused or in a known senile condition."[3] By the mid-1970s, this recommendation had been instituted as routine practice in U.S. hospitals and nursing homes.

But such policies have deterred nurses from formulating individualized clinical judgments concerning side rail use and from using other interventions to reduce the risks of falling from bed and consequent serious injury. In fact, side rail use has been determined according to several myths.

MYTH: Side rails are not restraints.

FACTS: Side rails have many purposes; they can serve as either a restraint or an aid to independence. However, even when side rails are not used to restrain patients, efforts to lessen the risk of entrapment must be made.

HCFA offers a functional definition of restraints for both nursing homes and hospitals: any device that restricts a patient's voluntary movement or access to his body and that can't easily be removed by the patient constitutes a restraint.[2,5] The Food and Drug Administration (FDA) offers a narrower definition; it considers restraints to be devices that attach to a patient's body and that are intended for such use by the manufacturer, according to labeling or promotional materials.[6] Neither does the Joint Commission on Accreditation of Healthcare Organizations consider side rails to be restraints.[7] Because side rail use is associated with significant risks to patients, and because facilities rely on federal monies through the Medicare and Medicaid programs, we believe it wisest to practice in accordance with HCFA's definition.

Thereby, a half- or quarter-length upper side rail is not considered a restraint if the patient uses it as an aid in getting into or out of bed. Similarly, two full-length or four half-length (also known as split) rails aren't considered restraints if a patient requests them in order to feel more secure, and if he is able to lower them by himself before getting into or out of bed. And family members often request side rails, believing them to be proven protective devices. It's important for nurses to assess the appropriateness of side rail use for each patient and to inform both the patient and his family of both the potential benefits and associated risks. Further, side rail use must be reevaluated periodically to make sure it doesn't increase the patient's risk of injury.

MYTH: Side rails serve as a safe and effective means of preventing patients from falling out of bed.

FACTS: No research study has demonstrated the efficacy of side rails in the prevention of injuries resulting from falling out of bed. In fact, several studies have shown that raised side rails do not deter older patients from getting out of bed unassisted, and may even lead to more serious falls and injuries.[8-10] Si and colleagues studied the effects of a program to reduce side rail use among older residents (mean age, 83 years) on a short-term rehabilitation unit.[10] They found there were 15 falls in the control group and 15 falls in the study group of residents (N = 246) and that serious injuries rarely occurred. Similarly, Hanger and colleagues, studying the effects of a significant reduction in side rail use on an Australian rehabilitation unit, found that there was no significant change in rates of falling; they also found that significantly fewer serious injuries occurred.[9]

MYTH: The use of side rails poses no risk to the patient.

FACTS: Several hundred cases of side rail entrapment injuries and deaths have been described by researchers and the FDA.[11-13] Physical consequences of side rail use among older adults include

- increased incidence of incontinence.[14]
- increased likelihood of serious injury resulting from a fall from a height greater than that of the

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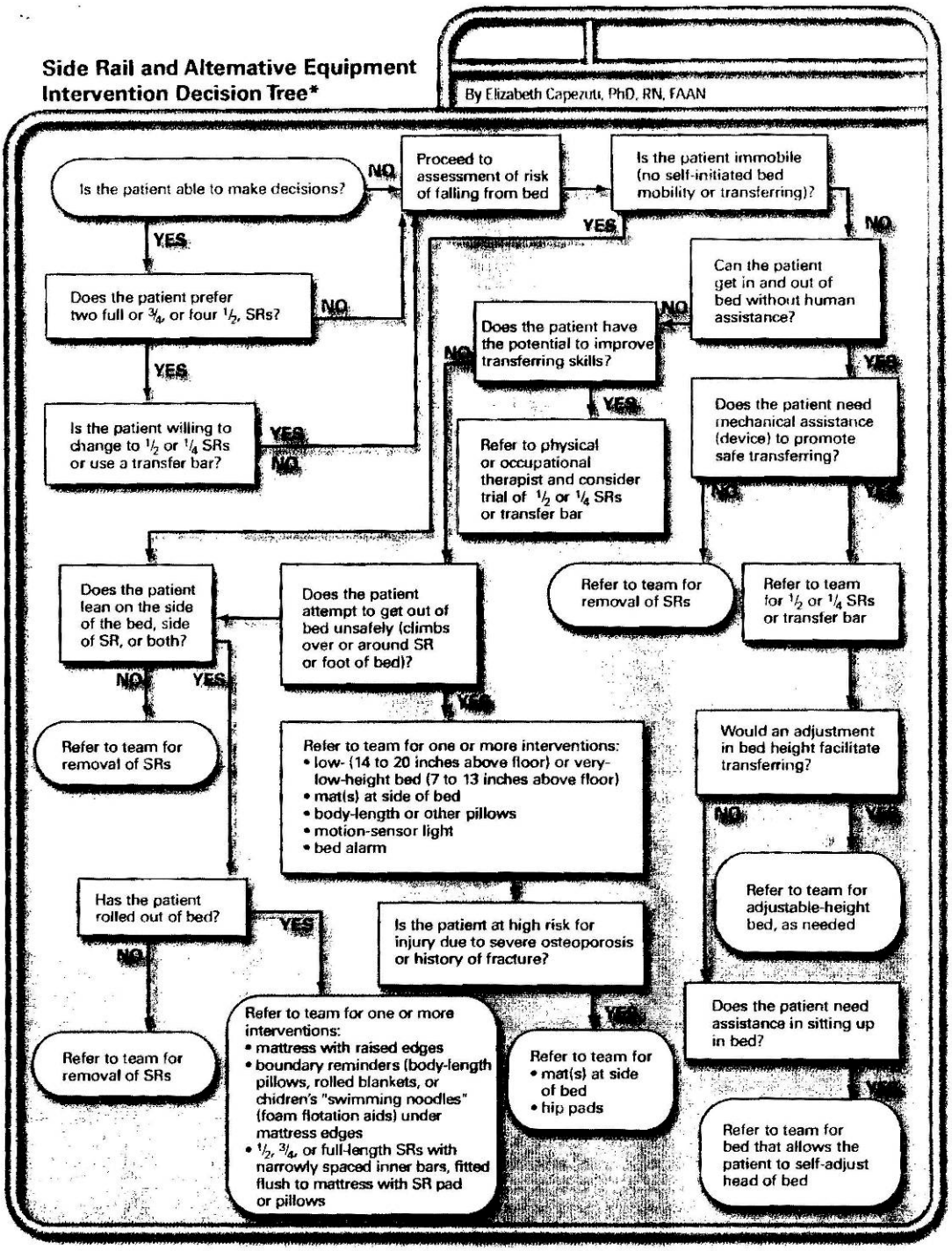
Side Rail and Alternative Equipment Intervention Decision Tree*

By Elizabeth Capezuti, PhD, RN, FAAN



* SR = side rail. "Team" refers to a decision-making person or group as specified by the institution: a multidisciplinary restraint-reduction team, a geriatric-consultation team, the rehabilitation department, a nurse manager or supervisor, or a gerontologic advanced practice nurse.

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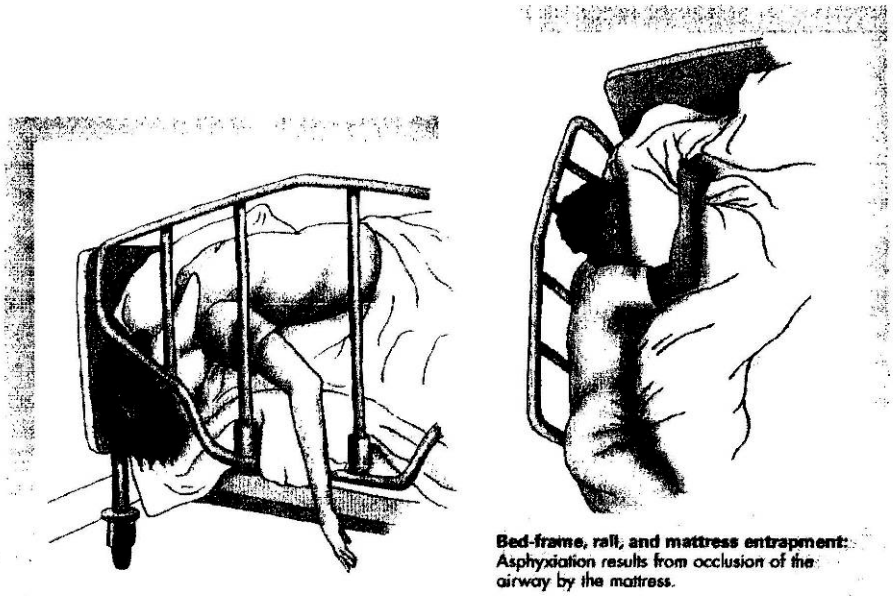

Bed-frame, rail, and mattress entrapment: Asphyxiation results from occlusion of the airway by the mattress.

mattress (in cases in which the patient goes over the rail)[15]; lacerations, bruises, and skin tears resulting from contact with the metal rails.

- dislodgment of tubes (feeding, IV, and urethral catheterization) when lowering or raising side rails.[16]
- decreased visual field.
- increased functional dependence resulting from reduced access to bedside items (because the rails can act as barriers).

Because side rail surfaces may serve as potential reservoirs for pathogens such as vancomycin-resistant enterococci and *Clostridium difficile*, they've been implicated in nosocomial transmission.[17, 18]

Deaths related to the use of side rails may occur even when the side rails are both installed and used as directed by the manufacturer. Parker and Miles studied 74 deaths reported to the U.S. Product Safety Commission between 1993 and 1996 and found that 69% of them occurred in people older than age 70.[12] Of these, 70% involved bed frame, rail, or mattress entrapment. Deaths from asphyxiation occurred when patients became wedged in gaps wider than 6 cm (about 2.5 in.), between the mattress or bed frame and a side rail. The authors have identified three types of deaths related to side rails: those resulting from bed-frame, rail, and mattress entrapment; from rail and in-bed entrapment; or from rail and off-bed entrapment. In another study, Todd and colleagues found that those at greatest risk of death related to side rail use are patients older than 65, patients who are confused or restless, and patients of low body weight (less than 150 lbs.),[11] although such deaths have also been reported among adults who did not fit this profile.

There are also psychological consequences to the use of side rails. Many older or cognitively impaired adults regard side rails as a barrier rather than as a reminder of their need of assistance with transferring.[19] Others have reported feeling "jailed" or "caged," especially those with a history of trauma (such as that induced by war, rape, or domestic violence).[20] To some, the use of side rails may engender fear and agitation, thereby increasing the likelihood that additional physical and pharmacologic restraints will be implemented.

Legal implications. In 1995, the FDA issued a Safety Alert concerning hazards associated with side rail use and informing clinicians that use of side rails may not be benign practice.[11] Elizabeth Capezuti (an author of this article) and colleagues are completing an ongoing study of legal cases involving side rails and falls from bed; preliminary findings indicate a significant increase in the number of hospitals and nursing homes sued for injuries and deaths related to side rail entrapment in the last five years. While many of these cases are still in litigation, the majority of them have involved suits against a facility rather than a nurse

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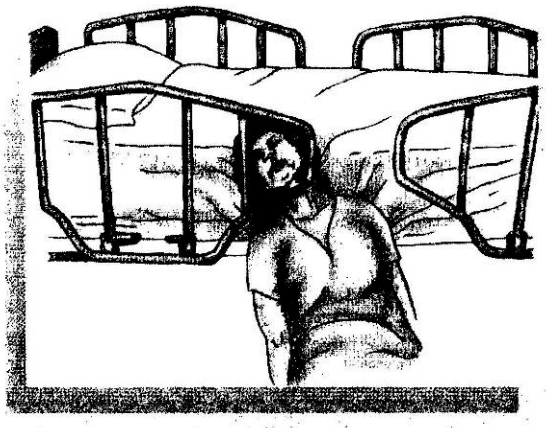
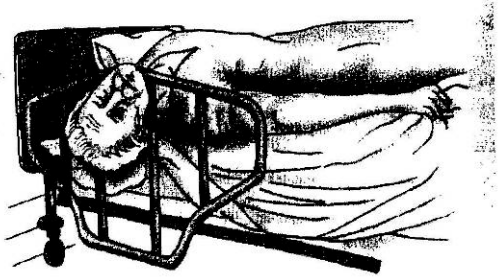
Rail and off-bed entrapment:
Most of the patient's body is off the bed, and asphyxiation results from occlusion of the airway by the rail.





Rail and in-bed entrapment:
Most of the patient's body is on the bed, and the airway is occluded by the rail as a result of side rail latch failure.

and have focused on the presence or absence of an individualized patient assessment that led to the judgment that side rails were appropriate for a particular patient. Providers should no longer assume that the use of side rails protects against liability.

MYTH: Safe alternatives to side rails do not exist.

FACTS: Alternatives that may not pose the serious physical and psychological threats that the use of side rails does include: the low-height bed, floor mats placed at the sides of the bed, motion sensors, hip pads, full-length body pillows, individualized nighttime toileting rounds, adequate nighttime pain control, bed alarms, treatment of depression and sleep disorders, and individualized sleep regimens.[8, 10, 15, 19, 21, 22] Choosing interventions to replace restrictive side rail use—that is, side rails used as restraints—while addressing the patient's risk of falling from bed requires a thorough assessment.

Decision trees may facilitate clinical decision making when considering alternatives (see *Side Rail and Alternative Equipment Intervention Decision Tree*, page 45). Although the one shown here is limited to equipment interventions, the risk of falling is also frequently associated with other factors, such as nocturia, incontinence, and sleep disturbance, that require additional nursing strategies.[10, 15, 19] Further, the availability of equipment is contingent on institutional resources and, particularly, on the ability of a health care team (including clinicians, administrators, and facility managers) to work together to curtail restrictive side rail use.

To Report a Problem

To report an adverse event or medical device problem, contact MedWatch: The FDA Safety Information and Adverse Event Reporting Program at (800) FDA-1088, or www.fda.gov/medwatch/how.htm.

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Alternatives to Side Rails

Low-height beds have been employed successfully at health care facilities during the last five years.[8] They usually have short (quarter-length) upper rails instead of full-length ones (that is, fully enclosing). Nonadjustable low-height or platform beds may cause injury to staff members as a result of the necessity of bending when assisting patients. We suggest the use of a bed which can be electronically adjusted from a maximum height of 26 to 30 in. to a minimum height of 7 to 15 in. as measured from floor to top of mattress with the patient on it. Manufacturers include*:

Carroll Healthcare, Inc. (Allto, Echo, and Solo Beds)
1881 Huron Street
London, Ontario
N5V 3A5
Phone: (519) 659-1395; (800) 668-BEDS (-2337)
Fax: (519) 659-4001
E-mail: info@carrollhealthcare.com
www.carrollhealthcare.com

Hill-Rom Company, Inc. (Resident Electric LTC Bed)
1069 State Route 46
Batesville, IN 47006
Phone: (800) 445-3730
www.hill-rom.com

Stryker Medical Corporation
(Acute Care and Skilled Nursing Beds)
6300 Sprinkle Road
Kalamazoo, MI 49001
Phone: (616) 329-2100; (800) STRYKER (787-9537)
www.strykermedical.com

Bedside mats can soften the impact of a fall and possibly reduce the likelihood of consequent injury. They are available from:

Fall-EZ Mats, LLP.
637 NW 13th Street
Gainesville, FL 32601
Phone: (352) 381-9522; (888) 532-0555
Fax: (352) 381-9525
E-mail: fr5656@aol.com

J. T. Posey Company (Floor Cushion)
5635 Peck Rd.
Arcadia, CA 91006-0020
Phone: (626) 443-3143; (800) 447-6739
www.posey.com

*This listing is not exhaustive and does not constitute endorsement of any product.

Most of the named equipment is inexpensive and may be purchased as part of a facility's routine capital improvements. (See *Alternatives to Side Rails*, above.) Costs can and should be considered as part of a risk-management strategy to decrease the occurrence of injuries related to side rail entrapment. ▼

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: June 7, 2000

TO : Patricia Hackett
Division of Mechnical Engineering
Directorate for Engineering Sciences

THROUGH: Susan Ahmed, Ph.D, AED
Directorate for Epidemiology

Russell Roegner, Ph.D., Director
Division of Hazard Analysis

FROM : Joyce McDonald
Program Analyst
Division of Hazard Analysis

SUBJECT : Portable Youth Bed Rail Entrapments and Hangings

This memorandum provides data on entrapment and hanging incidents involving portable youth bed rails.[1] Specifically, CPSC data files were searched to determine how many incidents occurred where the victim became entrapped or hung during the time period of January 1, 1990 to March 14, 2000.[2] The Office of Compliance has also received reports of entrapment and hanging incidents involving portable youth bed rails from manufacturers. Both data sources are discussed in this memorandum.

Table 1 shows a breakdown of the incidents by death, injury and no injury for both the CPSC data files and the incidents reported to Compliance by the manufacturing firms.

Table 1: Portable Youth Bed Rail Entrapment and Hanging Incidents

CPSC Data Files 1/1/90 to 3/14/00		Incidents Reported to Compliance by Firms		Total
Total	**36**	**Total[3]**	**16**	**52**
Deaths	12	Deaths	0	12
Incidents with Injury	5	Incidents with Injury	4	9
Incidents with No Injury	19	Incidents with No Injury or Not Reported	12	31

[1] These deaths and incidents are neither a complete count of all that occurred during this time period nor a sample of known probability of selection. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in these entrapment or hanging incidents involving portable youth bed rails.

[2] The databases searched were the Indepth Investigation file, the Injury or Potential Injury Incident file, the Death Certificate file and the National Electronic Injury Surveillance System file.

[3] These 16 incidents shown in Table I are the portion of the firm reports that could be identified as not duplicating cases in the CPSC data files.

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CPSC Reports

The following is a discussion of the fatal and non-fatal incidents found in the CPSC databases related to the entrapment and hanging hazards associated with the use of portable youth bed rails.

Deaths

The children involved in the 12 fatal incidents ranged in age from 3 months to 4 years of age. Eight of the fatalities were males and 4 were females. Three of the 12 children were disabled (a 2 year old female with brain deformities, a 2.5 year old female with cerebral palsy and a 4 year old male with mental retardation). The beds on which the bed rails were used were a full size bed, a king size bed, a bed described as an adult bed, 2 bunk beds, 3 toddler beds, 3 twin/single beds and a bed described as "youth size".

In 8 of the 12 cases, the child became entrapped in an area between the mattress on the bed and the attached bed rail, in one case the child slipped through the bars of the bed rail, in another a child was found hanging from a protrusion on the bed rail itself, and 2 children were entrapped in the space between the headboard/bedpost and the bed rail. The deaths were the result of asphyxia or strangulation, with the exception of one child who died of pnemonia due to the cervical injury sustained by hanging. Additional information on each of the 12 fatalities is detailed in Appendix A (attached to this memorandum).

Incidents with Injury

Five of the non-fatal incidents resulted in minor injuries: red marks on the head, a bruised back and swollen arm; a contusion to the neck; a red mark on the neck; a scraped nose and bruise to the back of the head; and a bruised right temple. These children were 6, 9, 14, 23 and 30 months old respectively. The beds involved were 3 twin beds, a king-size bed and an unspecified type of bed. In 4 of the cases, the children were found between the mattress and bed rail. The fifth case involved a bed rail which snapped together in the middle with plastic couplers. The victim became entrapped when the bed rail partially disengaged into a "V" shape where it snaps together. For further details on these cases, refer to Appendix A (attached).

Incidents with No Injury

The remaining 19 incidents of the 36 total did not involve an injury. The children ranged in age from 17 months to 3.5 years old. In 16 of the incidents, the child got a part of his/her body entrapped between the mattress of the bed and bed rail. Two incidents do not specify the exact location of the entrapment in relation to the bed/mattress and bed rail. In one incident the child partially slipped through a mesh net bed rail.

Comments

A number of cases contained comments about the role the youth bed rail played in causing the entrapment. The most common scenario was that the two rods/bars that go under the

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mattress slipped out creating a space. This was reported to have happened in some cases when the child rolled or pushed against the bed rail itself. There were some comments made about the flexibility of the bed rail allowing a child to become wedged between the bed rail and bed without the bed rail pulling out from under the mattress. Lastly, there was the case in which the design of the bed rail (coupling in the middle) allowed an entrapment space to be created.

Compliance Reports

In addition to the 36 incidents found in the CPSC data files, the Office of Compliance has received 30 reports of entrapment and hanging incidents (no deaths) from manufacturers of portable bed rails.[4] Appendix B (attached) gives the details of the individual reports from the firms.

Only 17 of these reports contained enough information to determine whether they were duplicates of cases that we have in the CPSC data files. Of those, one case was a duplicate of an incident in the CPSC data files, leaving 16 reports.

Of the 16 incidents reported, 4 involved an injury: a ring around the neck with breathing cut off; 2 bruised necks; and a case of choking and vomiting. Fourteen of the incidents involved either entrapment or hanging between the bed rail and the bed or mattress. Two incidents indicate the child was caught or stuck in the rail.

The youngest child was 7 months and the oldest was 5 years, but ages are only available for 9 of the 16 cases. The gender of the child is not available. Most of the 16 incidents do not report the type of bed involved. Two twin beds and 1 queen size were reported.

Deaths from Falls from Bed and Wall Side Incidents

CPSC staff also reviewed data[5] for children 0-5 years old involving falls from beds and incidents occurring on the wall side of the bed that resulted in fatalities.

Falls

There were 47 deaths involving children 1 month to 2 years old from January 1, 1990 to May 17, 2000 involving a fall from a bed[6]. The great majority (38) were under a year old. Most of the children died when they fell into or onto an object (a bucket or bag of clothes, for example). Incidents of death due to blunt force trauma from the fall were rare with only 2 cases reported. In another case a massive intracerebral hemorrhage resulted from the fall out of the bed and this may have been a death due to blunt force trauma also. About 70% of the children died from asphyxia/suffocation/drowning. (See Appendix C.)

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[4] The information in these reports is minimal. The dates of the actual incidents and the city and state in which they occurred were not available for inclusion in this memorandum.

[5] The databases searched were the Indepth Investigation file, the Injury or Potential Injury file, the Death Certificate file and NEISS from January 1, 1990 to May 17, 2000. The search was limited to children under 6 years of age.

[6] Bunk beds were not included in this data.

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Wall Side Incidents

There were 271 deaths involving children 1 month to 5 years old from January 1, 1990 to May 17, 2000 involving an incident on the wall side of the bed[7]. The deaths on the wall side included entrapments between the wall and bed/mattress; incidents between the wall and bed/mattress where entrapment was not indicated; and falls from the bed/mattress out of a window.[8] Table 2 shows a breakdown of these wall side deaths.

Table 2: Wall Side Deaths Involving Beds/Mattresses Involving Children 0-5 Years of Age 1/1/90 to 5/17/00

Total	**271**
Entrapments Between the Bed and Wall/Mattress	233
Incidents Between the Bed and Wall/Mattress with No Entrapment Indicated	30
Falls out of Windows	8

As with the fall deaths mentioned previously, a majority of these wall side incidents (232) involved children under 1 year of age. With the exception of the falls out of windows, almost all of the wall side deaths involved asphyxia. Where the type of bed was mentioned, most were adult beds of varying sizes.

[7] This data did not include bunk beds or incidents that happened at the headboard or footboard of a bed.
[8] Many incidents indicated an entrapment between a mattress and a wall or mentioned the mattress and not a bed specifically. Where it clearly stated that the mattress was on the floor, the case was not used in the count.

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PUBLIC SUBMISSION

Tracking No. 80f5cfb
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0018
Comment from Kenneth J. Walsh

Submitter Information

Name: Kenneth J. Walsh
Organization: Bureau Veritas

General Comment

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To Whom It May Concern

As a representative of a third party independent laboratory, I do have 2 concerns with the proposed language on the Notice of Proposed Rulemaking for the Safety Standard for Portable Bed Rails.

The first concern is with the test platform #2 as currently required within the ASTM F2085-10a. This test platform is extremely difficult to locate due to the strict physical characteristics of the platform. Currently, the platform must be of an innerspring design, must have a vertical dimension between 10.0 and 11.0 inches thick, must weigh 40-60 lbs, and any foam used within the construction of the test platform must have an Indentation Load Deflection (ILD) of between 28 and 33 (when tested accordingly). These 4 characteristics make it very difficult, if not impossible, for a test lab or even a manufacturer to locate and purchase one of these test mattresses. I would like to recommend that the ILD requirement be deleted as a characteristic for this piece of equipment.

The second concern is in regards to the standard twin size cotton fitted sheet and the ability to locate this piece of equipment as well. According to the standard, the sheet must be white, must be 50/50 cotton/polyester blend, must have 180 threads per square inch and must have a fabric weight of 3.5 oz/yd^2. I would like to recommend that the sheet color and the fabric weight be deleted as a characteristic of this piece of test equipment. I would also like to recommend that the threads per square inch characteristic be given a range (ie: 150-300).

These changes will make these two pieces of equipment more accessible for test laboratories and manufacturers.

Sincerely Yours,
Kenneth J. Walsh

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TAB B: Comparison of ASTM F2085-12, Standard Consumer Specification for Portable Bed Rails, with the Proposed Requirements in the NPR docket # CPSC-2011-0019

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

Memorandum

Date: January 4, 2012

TO : Rohit Khanna
Project Manager, Portable Bed Rails

THROUGH: George A. Borlase, Ph.D., P.E.
Associate Executive Director
Directorate for Engineering Sciences

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

SUBJECT : Comparison of ASTM F2085-12, *Standard Consumer Specification for Portable Bed Rails*, with the Proposed Requirements in the NPR docket # CPSC-2011-0019

I. BACKGROUND

The U.S. Consumer Product Safety Commission (CPSC) Directorate for Engineering Sciences' Mechanical Engineering Division (ESME) concluded[2] that ASTM F2085-10a did not sufficiently address the risk of entrapment hazards associated with portable bed rails. This conclusion was based on an evaluation of requirements in the 2010 ASTM F2085-10a standard, analysis of the incident data, and testing and evaluation of products currently in the market. Specifically, ASTM 2085-10a did not address hazard entrapment scenarios that can be present when a portable bed rail is misassembled or misinstalled onto a bed. Staff's notice of proposed rulemaking (NPR) briefing package recommended that portable bed rails meet additional requirements, as drafted in Appendix C of Tab C, of the 2011 Briefing Package [3] to address scope, misassembly, misinstallation, and warning labels.

II. DISCUSSION

A. ASTM Activity (November 2010–January 2012)

Following publication of the NPR, the ASTM Subcommittee for Bed Rails developed and balloted similar requirements to address CPSC staff's concerns of misassembly and misinstallation and the test equipment specification concerns submitted

[2] U.S. Consumer Product Safety Commission, Staff Briefing Package, Draft Proposed Rule for Portable Bed Rails, March 16, 2011 (http://www.cpsc.gov/library/foia/foia11/brief/bedrailNPR.pdf).
[3] Ibid.

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by commenters. These requirements were based on the NPR but were improved by simplifying the evaluation process, clarifying language, and providing graphics that illustrate acceptable and failing performance criteria and test configurations. In January 2012, a new standard, ASTM F2085-12, was approved for publication.

B. Summary of NPR Proposed Requirements Addressing Misassembled Bed Rail Hazard

The NPR contained performance requirements that were intended to address the risk of entrapment hazards associated with consumer misassembly of portable bed rails. In the NPR, a bed rail was considered to be misassembled if:

- The portable bed rail could be assembled without any critical assembly component;
- The portable bed rail could be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component like the frame;
- The portable bed rail's fabric cover or mesh could be placed over the rigid frame structure without engaging critical parts of the frame as intended in final assembly.
- The portable bed rail could be assembled by improper placement of any critical component, such as an inverted or an interchanged part, without permanent deformation or breakage.

The NPR contained test methods and performance criteria to determine if a misassembled bed rail (as defined by the 4 conditions above) provided sufficient visual cues so that a consumer could identify that the bed rail was misassembled. If the misassembled bed rail did not stay upright or the top rail collapsed after testing, the misassembly was considered to have a sufficient visual cue for the consumer to recognize that the product was not assembled correctly. This condition would be considered a passing result, because the bed rail only could be misassembled in a way that was obvious to the consumer. Bed rails that are preassembled or designed in such a way that minimizes the potential for consumer misassembly, without deforming or breaking parts, would also meet these requirements. CPSC staff developed two prototype bed rails to demonstrate that products could be redesigned to meet the proposed requirement.

C. Comparison of NPR Proposed Requirements to ASTM 2085-12 to Address Misassembly

ASTM 2085-12 addresses misassembly by identifying criteria similar to those in the NPR and contains additional figures and illustrations showing examples of passing and failing bed rails that have been misassembled. ASTM 2085-12 does not require that a misassembled bed rail be tested to determine if it falls over or collapses (as in 6.10.1 of the NPR) to give the consumer a visual cue that the bed rail is misassembled. Instead, performance requirements were clarified and examples of correct test configurations focusing on components involved in the incident data were added. This should reduce the number of tests needed to be performed to certify a bed rail. It should also reduce ambiguity between a passing or failing bed rail with the additional figures.

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ASTM 2085-12 section 6.9.1 *Determining Misassembled Bed Rail* specifies that if a bed rail ***"appears to be functional"*** after being misassembled in certain ways, the bed rail fails the misassembly requirements. Determination of whether a misassembled bed rail ***"appears to be functional"*** (failing the standard) or appears not to be functional (passing the standard) will require some professional judgment by the test laboratories. Figures 1–2 show examples of misassembled bed rails that appear to be functional, and Figure 3 is an example of a misassembled bed rail that is not functional. Figures 4 and 5 show misassembled bed rails with inverted or interchanged parts. If the orientation of the parts is critical to meet the entrapment requirements, the bed rail would fail; if the design allows for interchanging parts, then the bed rail would pass. Figures 1–5 are included in ASTM F2085-12 for guidance to the test lab.

FIG. 9 Example of Fail Condition – Center horizontal structural component is omitted consequently the fabric does not engage the center structural component.

Figure 1. Photo of incident bed rail with the middle horizontal bar missing (Ref. ASTM F2085-12, Fig 9)

Bedrail fabric with bottom zipper misassembled, fabric cover can be zipped up without engaging the bottom horizontal bar.

Bottom bar can be omitted from insertion into fabric sleeve or channel located at the base of the fabric component.

FIG. 10 Examples of Fail Conditions.

Figure 2. Examples of the fabric not engaging the bottom bar, but it still appears to be functional. (Ref. ASTM F2085-12, Fig 10)

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FIG. 11 Example of Condition Not To Be Tested- Bedrail fabric with a zipper that is not fully engaged. The zipper cannot be fully engaged due to interference with the middle bar.

Figure 3. Example of a misassembled bed rail because the fabric is not engaging the frame. However, because the zipper cannot be fastened fully, the bed rail is considered **not** to appear functional.

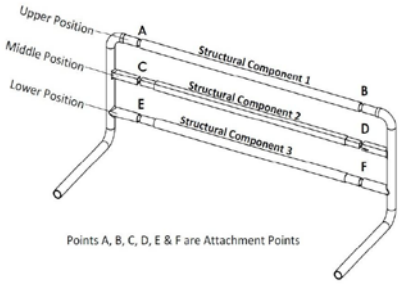

FIG. 12 Example of Tube Inverted or Interchanged

Figure 4. Example of inverted or interchanged parts

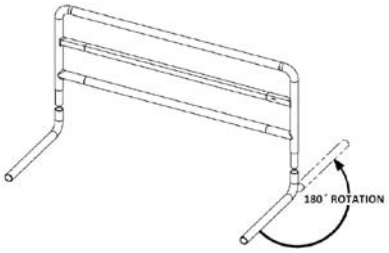

FIG. 13 Example of Test for Unidirectional Arm

Figure 5. Example of testing the arm orientation

Appendix A compares ASTM 2085-12 to the proposed requirements in the NPR. It is staff's opinion that ASTM 2085-12 section 6.9.1 simplifies the testing requirements in comparison to the NPR and addresses the comments that the NPR requirements for misassembled bed rail configurations would result in an unreasonable amount of testing.

III. Comparison of NPR Proposed Requirements and ASTM 2085-12 to Address Misinstallation

The performance requirements in the NPR were intended to address potential incidents involving consumer misinstallation of the bed rail onto the bed due to missing installation components, such as straps and anchor plates. The NPR would require installation components to be attached permanently to a structural component of the frame. The NPR also would require that these components be labeled to inform the consumer how to use the component properly.

ASTM 2085-12 is similar to the NPR requirements for misinstallation. Both require installation components to be attached permanently to the bed rail and labeling on the installation component. ASTM clarifies that consumer-adjusted components, such as straps and telescoping rods, must be attached to a bed rail component, but they are not required to be pre-adjusted for proper fit to the bed. This addresses the concern with the ambiguity of test requirements for consumer-adjustable installation components.

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IV. Staff Recommendations for Final Rule

The intent of the NPR was to address fatal incidents due to misassembly and misinstallation. Public comments included concerns with the potential for numerous test configurations, testing of zippered products, misassembly of adjustable components for installation, and repeatability of testing between labs.

CPSC staff's opinion is that the ASTM F2085-12 requirements adequately address staff's concerns about the consumer misassembly and misinstallation issues that were identified in the NPR. ASTM 2085-12 also addresses public comments and concerns about the potential for numerous test configurations, testing of zippered products, misassembly of adjustable components for installation, and repeatability of testing between labs. For this reason, CPSC staff recommends adopting as the final rule, ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails*.

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Appendix A: Comparison of NPR and ASTM F2085-12

I. Introduction

ASTM has recently published similar requirements to address misassembly and misinstallation. The new requirements in ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails*, are based on the CPSC's Proposed Rule (docket # CPSC-2011-0019) but are improved by simplifying test procedures, clarifying the language, and providing graphics that show pass and fail criteria and test configurations.

The following sections are a discussion of the NPR's proposed requirements versus ASTM F2085-12's requirements. The **ASTM** language is in **RED** font, and the **NPR** language is in **BLUE** font.

II. Comparison of Scope - NPR vs. ASTM

Table 1 shows the NPR-proposed revisions to the scope and changes made in the revised standard, ASTM F2085-12, published in January 2012. The ASTM revisions incorporate the recommendations made in the NPR and clarify that the bed rail standard does not apply to toddler bed guardrails.

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Table 1. Revision to Section 1. Scope

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature.	N/A - The NPR did not address toddler beds.		The ASTM scope was revised to clarify that the standard does not apply to guardrails attached to toddler beds. New language, shown underlined, was added.	1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature. This consumer safety specification does not cover guardrails that fall under the scope of Consumer Safety Specification F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard.
N/A – non-rigid bed rails are not included in the 2010 ASTM standard.	The NPR would revise ASTM F2085-10a to include inflatable and foam bed rails to the scope. Staff recommends that 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.	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.	ASTM adds non-rigid bed rails in the section 5 General Requirements	5.5 Non-rigid bed rails need only meet the general requirements of Section 5, the performance requirement of 6.3, and the warning requirements of 9.3.

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III. Comparison of Terminology - NPR vs. ASTM

Table 2 shows the NPR-proposed revisions to the Terminology section and changes made in the revised standard, ASTM F2085-12, published in January 2012.

Table 2. Revision to Section 3. Terminology

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
N/A – *captive hardware* is not included in the 2010 ASTM standard.	N/A - NPR did not define *captive hardware.*		ASTM adds terminology for *captive hardware*	3.1.4 *captive hardware*, *n*—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (See Fig 1).
N/A – following terms are not in the 2010 standard: • *Foam bed rail* • *Inflatable bed rail* • *Critical assembly component* • *Critical installation component* • *Misassembled/-functional bed rail*	The NPR would revise the terminology in section 3 of ASTM F 2085–10a by creating new terms for: • *Foam bed rail* • *Inflatable bed rail* • *Critical assembly component* • *Critical installation component* • *Misassembled/-functional bed rail*	3.1.10 *foam bed rail*, n— portable bed rail constructed primarily of non-rigid materials, such as fabric or foam.	ASTM adopts the terminology from the NPR but combines foam and inflatable bed rails into a single term, "*non-rigid bed rail.*"	3.1.12 *non-rigid bed rail*, *n*—portable bed rail constructed of non-rigid materials, including but not limited to fabric or foam, or that requires air be inflated into the product to achieve structure.
		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.		
		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.*	ASTM does not add terminology for critical assembly components because the subcommittee determines that all bed rail components are critical to safety.	
		3.1.13 *critical installation component, n* — any component of the bed rail that is used to attach the bed rail onto the bed.	ASTM creates a new definition for *installation component* that is similar to the NPR's definition for *critical installation component*.	3.1.8 *installation component, n* — component of the bedrail that is specifically designed to attach the bedrail to the bed and typically located under the mattress when in the manufacturer's recommended use position.

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ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
		3.1.14 *misassembled/functional bed rail, n* — a bed rail that has been assembled incorrectly but appears to function as a bed rail. Misassembly/functionality is determined by meeting one of the criteria listed in 6.9.	ASTM creates a definition for *misassembled bed rail* that is similar to the NPR's definition for *misassembled/functional bed rail.*	3.1.10 *misassembled bed rail, n*— a bed rail that has been assembled incorrectly but appears to function as a bedrail.
N/A — the 2010 standard did not address *consumer assembly and consumer adjustment* components	N/A - the NPR did not define *consumer assembly and consumer adjustment.*		ASTM creates terminology for *consumer assembly* and *consumer adjustment* to differentiate between components that require consumer adjustment, such as straps and telescoping rods and components that are fitted or fastened together to form the bed rail's structure.	3.1.6 *consumer adjustment*, *n* — those activities defined by the instructions to be taken by the consumer in order to properly fit and secure the bedrail to the mattress. 3.1.6.1 *Discussion* — Examples include sliding telescoping poles for proper fit, or initial adjustment for use, tightening of anchoring straps and positioning or changing of attachment components or locking pins. 3.1.7 *consumer assembly*, v. — the fitting together of components of the bedrail according to manufacturer instructions.

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ASTM does not include a definition for the term "critical assembly component" because all parts of a bed rail are considered critical to its function. CPSC staff agrees that most bed rails are designed such that all components are needed to meet the entrapment requirements. Some bed rails come with accessories, such as a flashlight or cup holder, and because these accessories are identified readily as non-critical, the term *critical assembly component* is not necessary.

In the NPR**,** the definition of *critical installation component* was used to identify parts of the bed rail that are required to attach the bed rail to the bed. **ASTM** uses three terms to identify installation components: *installation component, consumer assembly, consumer adjustment.* The intent of the NPR and ASTM definitions is to distinguish between a component that makes up the barrier structure of the bed rail and the components needed to install the bed rail. ASTM defines consumer assembly and consumer adjustment in the terminology section of the standard to distinguish between adjustable components, such as straps and poles needed to fit different mattresses sizes. These terms are needed to clarify testing requirements to address misinstallation. CPSC staff agrees that ASTM's added terminology is necessary to identify components subject to misinstallation requirements. This terminology is needed to clarify performance requirements to address the comment that requirements for installation components that are adjustable are ambiguous.

Terminology for *misassembled/functional bed rail* in the NPR has been simplified in the ASTM standard to *misassembled bed rail.* The ASTM definition removes the term *functional* to define a misassembled bed rail. The term *functional* may imply that a *misassembled/functional* configuration performs as intended and is safe. CPSC staff agrees that this may be confusing and agrees with ASTM's definition of *misassembled bed rail*.

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IV. Comparison of General Requirements NPR vs. ASTM

Table 3 shows the NPR-proposed revisions to the General Requirements section and changes made in the revised standard, ASTM F2085-12, published in January 2012.

Table 3. Revision to Section 5. General Requirements

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
N/A the 2010 ASTM standard did not address installation components	NPR would provide additional requirements to ASTM F2085-10a, such that critical installation components must be affixed permanently to a structural component(s) of the portable bed rail. This prevents the installation component, such as a strap or plate, from being lost.	5.6.1 Critical installation components shall be permanently affixed to a structural component(s) of the bed rail.	ASTM creates a requirement for installation components that is similar to the NPR's but also clarifies that consumer adjustable components, such as straps, are not required to be pre-adjusted to fit onto the bed. This is a practical exemption because bed rails are intended to fit on various sizes of adult beds.	5.7 Installation components that are required to meet the performance requirements of 6.4, 6.5, and 6.6 shall be fully assembled, inseparable, and permanently attached to a component requiring consumer assembly (this excludes any consumer adjustment).

The General Requirements in the NPR were intended to prevent components used to attach the bed rail to the bed, such as anchor plates and straps, from being discarded or lost. Any installation component would be attached permanently to a structural component(s) of the bed rail.

The ASTM General Requirements section combines 5.6, 5.6.1, and 5.6.2 of the NPR into one section. The ASTM and NPR General Requirements are essentially the same. Both require that components used to attach the bed rail to the bed shall be permanently attached to an assembly component that is required to make up the bed rail. This prevents components, such as anchor plates and straps, from being discarded or lost. The ASTM wording clarifies that consumer-adjusted components, such as straps and telescoping rods, are attached to a bed rail component but are not required to be pre-adjusted for proper fit to the bed. This addresses the concern with the ambiguity of test requirements for installation components that are adjustable.

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V. Comparison of Performance Requirements NPR vs. ASTM

Table 4. shows the NPR-proposed revisions to the Performance Requirements section and changes made in the revised standard, ASTM F2085-12, published in January 2012.

Table 4. Revision to Section 6. Performance Requirements

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
N/A – the 2010 ASTM standard did not address misassembly.	NPR would create a new section in ASTM F2085–10a to determine if a bed rail can be misassembled but appear to be functional. Conditions for misassembly would include: 1. missing components 2. missing fasteners 3. fabric mesh does not engage intended parts of the frame structure 4. components assembled inverted or with the wrong part	6.9 *Determining Misassembled/functional bed rail* - a bed rail shall be considered a misassembled/functional bed rail if: 6.9.1 – The bed rail can be assembled without any critical assembly component. 6.9.2 - The 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. 6.9.3 The 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. 6.9.4 The 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.	ASTM creates a requirement for *Determining Misassembled bedrail* that is similar to the NPR's but targets specifically misassembly scenarios such as: 1. missing horizontal components, 2. fastening the fabric mesh without engaging a horizontal bar, and 3. assembling parts to the wrong components or inverted	6.9 Bedrail components requiring consumer assembly shall not be able to be misassembled when evaluated to 6.9.1. 6.9.1 *Determining Misassembled bed rail* - a bed rail shall be considered a misassembled bed rail if it appears to be a functional bed rail under any one of the conditions listed in 6.9.1, 1, 6.9.1.2, or 6.9.1.3 and it does not meet the requirements of 6.4, 6.5, or 6.6. 6.9.1.1 The bedrail's fabric cover or mesh can be placed over the rigid frame structure without engaging all structural components of the frame as intended in final assembly (Fig. 5 and Fig. 6). When the bedrail is evaluated, zippers and other means of attachment should be fully fastened. If possible to fasten the means of attachments without engaging said structural components, evaluation for misassembly should account for that (see Fig. 6). NOTE 1—Any means of attachment, including, but not limited to, zippers, hooks and loops, and snaps, should be fully fastened. Fig. 7 represents a passing condition. 6.9.1.2 The bedrail can be consumer assembled with any horizontal structural components improperly positioned such as an inverted or interchanged, without permanent deformation or breakage of the component or bedrail. This excludes consumer adjustment or universal components that are designed to be interchangeable (Fig.8). 6.9.1.3 Bedrails where the positions of the arms are intended to be unidirectional are able to be assembled when the arms are rotated 180° about the vertical axis (Fig. 9).

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ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
N/A - the 2010 ASTM standard did not address misassembly or captive hardware.	NPR would create a new section in ASTM F2085–10a to require that fasteners, such as nuts and bolts, be attached or captive to the frame to prevent loss or non-use.	6.9.2 - The 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.	ASTM creates new section 5.8, which requires that all fasteners are captive or attached to the component. This is equivalent to section 6.9.2 of the NPR.	5.8 For products requiring consumer assembly, supplied hardware used for assembly of the bed rail such as screws, nuts or bolts shall be captive hardware to their respective components.
N/A - the 2010 standard does not have requirements to determine if a misassembled bed rail is acceptable.	NPR would create a new section in ASTM F2085–10a to determine the acceptability of a misassembled/functional portable bed rail. These new sections would provide the criteria for testing laboratories to determine the sufficiency of visual cues for misassembly.	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. 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. 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.	N/A - ASTM F2085-12 does not have requirements to determine whether a misassembled bed rail is acceptable. Instead, a misassembled bed rail fails the standard if it ***appears to be functional.*** A misassembled bed rail that appears to be **nonfunctional** passes the standard. This determination is up to the judgment of the test lab. The definition of misassembly and the figures that show examples of passing and failing bed rails should provide sufficient guidance for a test lab to make a determination.	

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The NPR Performance Requirements were intended to address fatalities and potential incidents due to consumer misassembly of the bed rail. The NPR would consider a bed rail to be misassembled if:

- The portable bed rail can be assembled without any critical assembly component;
- 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;
- 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; 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.

The tests in the NPR would set pass and fail criteria to determine whether the misassembled bed rail (as defined by the 4 conditions above) provides sufficient visual cues for a consumer to identify that the bed rail is misassembled. The tester applies a 10-lb downward force to the top rail of a misassembled bed rail. If the misassembled bed rail does not stay upright, or the top rail collapses by 6 inches, the misassembly is considered to have a sufficient visual cue for the consumer to recognize that the product is not assembled correctly.

The ASTM requirements to address misassembly are similar to the NPR's. ASTM places some of these requirements in the General Requirements section. One difference is that ASTM does not require that a misassembled bed rail fall over or collapse (as in 6.10.1 of the NPR) to give the consumer a visual cue that the bed rail is misassembled. The ASTM requirements state that a bed rail shall be considered misassembled if it ***appears to be functional*** after being misassembled in certain ways.

The ASTM requirements address the misassembly configuration due to missing fasteners. ASTM's Section 5.6 is equivalent to section 6.9.2 of the NPR and requires that nuts and bolts be attached to the bed rail structure to prevent the consumer from discarding or misplacing the fastener.

ASTM section 6.9.1.1 is equivalent to sections 6.9.3 and 6.9.4 of the NPR. These requirements identify a misassembled bed rail as a bed rail that can be assembled without a part or without the fabric engaging the entire frame as intended by the manufacturer. These requirements directly address the fatal incidents where the horizontal bar was not used or where the fabric was not properly installed over the bottom horizontal bar.

ASTM sections 6.9.1.2 and 6.9.1.3 are equivalent to 6.9.4 of the NPR and require that bed rail components cannot be interchanged or inverted. This prevents the consumer from assembling a component in a backward or upside-down position.

The difference between the ASTM requirements and the NPR requirements is that ASTM does not have a physical test that establishes pass and fail criteria to determine whether a misassembled bed rail appears to be functional. Determination of whether a misassembled bed rail *appears to be functional* (failing the standard) or *appears not to be functional* (passing the standard) is up to the judgment of the test lab. The definition of "misassembly" and the figures that show examples of passing and failing bed rails should provide sufficient guidance for a test lab to make a determination.

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VI. Comparison of Test Methods - NPR vs. ASTM

Table 5 shows the NPR proposed revisions to the Test Methods section and changes made in the revised standard, ASTM F2085-12, published in January 2012.

Table 5. Revision to Section 8. Test Methods

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
N/A – the 2010 standard does not have test requirements to determine if a misassembled bed rail is acceptable.	NPR would create a new section in ASTM F2085–10a to provide test criteria to determine the acceptability of a misassembled/functional portable bed rail	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 bed rail 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 bed rail legs to the vertical plane (see Figure 8). 8.7.3 Gradually apply 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 to most likely vertically deform the bed rail (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 bed rail 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.	N/A - ASTM F2085-12 does not have test requirements to determine if a misassembled bed rail is acceptable.	

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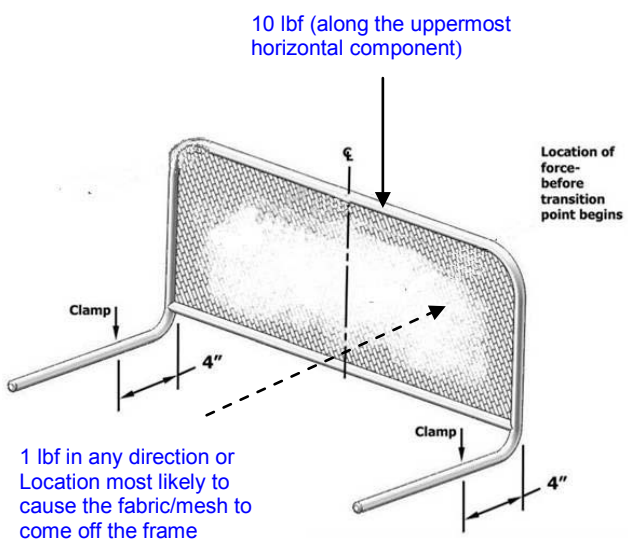
ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
		 Figure 8: Determining misassembly/functional bed rail test setup		

A significant difference between the NPR and the ASTM requirements is that there are no test requirements associated with the misassembly performance requirements in the ASTM standard. The test lab will conduct visual assessments of a bed rail after attempting to misassemble the bed rail. Test laboratories will be required to use some judgment to determine whether a bed rail can be misassembed. Test laboratory personnel are trained to understand the intent of the standards to which they are testing, and competent labs should be capable of making reasonable engineering judgments. Overall, the new ASTM standard should address the testing burden comments that were submitted by the JPMA.

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VII. Revisions to the Test Equipment Section in ASTM

Table 6. shows the revisions to the Test Equipment section in ASTM F2085-12.

Table 6. Revisions to Section 7. Test Equipment

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
7.1.1 *Test Platform 1*: 7.1.1.1 *Mattress Construction*—The mattress shall be of standard twin size, 38 by 74.5 in. 6 0.5 in. (0.97 by 1.89 m ± 13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft^3 +0.2, –0 (16 kg/m3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer, using hot water setting and longest normal cycle with the manufacturer's recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer.	N/A - The NPR would not revise the bed sheet.		ASTM relaxed the specifications for the sheet used for the mattress. The sheet specifications in the previous version (ASTM F2085-10a) are overly restrictive and this is not necessary for the testing.	7.1.1 *Test Platform 1*: 7.1.1.1 *Mattress Construction*—The mattress shall be of standard twin size, 38 by 74.5 in. 6 0.5 in. (0.97 by 1.89 m ±13 mm). The mattress shall be made from open cell polyurethane foam padding and be 4 to 5 in. (102 to 127 mm) thick with a density of 1 lb/ft^3 +0.2, –0 (16 kg/m^3 +3.2, –0). The mattress shall weigh between 6.0 and 9.5 lb (2.7 to 4.3 kg). There shall be no surface texture features (for example, quilting) on the test mattress. The mattress shall be covered with a standard twin sized fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.
7.1.2.1 *Mattress Construction*—The mattress6 shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89 m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick.[7] The mattress shall weigh 50 ± 10 lb (22.7 6 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 180 threads per square inch and fabric weight of approximately 3.5 oz/yd^2 (161 g/m^2). The sheet shall be laundered once before use in an automatic home washer using hot water setting and longest normal cycle with the manufacturer's	N/A - The NPR would not revise the mattress test platform 2.		ASTM relaxed the specification for Mattress test platform 2 Mattress test platform 2 specifications are unnecessarily restrictive and make it very difficult for a test lab to obtain this mattress. The new specification removes the IDL requirement section.7.1.2.2 or ASTM F2085-10a	7.1.2.1 *Mattress Construction*—The mattress[6] shall be of standard twin size, 38 in. by 74.5 in. ± 0.5 in. (0.97 m by 1.89 m ± 13 mm). The mattress shall be of an innerspring design and be between 10.0 in. (0.25 m) and 11.0 in. (0.28 m) thick.[7] The mattress shall weigh 50 ± 10 lb (22.7 ± 4.5 kg). The mattress shall be covered with a standard twin sized cotton fitted sheet. The sheet shall be white, 50/50 cotton/polyester blend. It shall have 100 to 300 threads per square inch.

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ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer. 7.1.2.2 *Mattress Performance*—The foam shall have an Indentation Load Deflection (ILD)4 of between 28 and 33 when tested in accordance with Test Methods D3574, method B1.				
No change	The addition of the force gage specification would help clarify the manner in which the force will be applied under the proposed test methods discussed in section (vii).	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 section7.6 of ASTM F 2085–10a.	ASTM added the force gage specification from the NPR.	7.6 *Force Gauge*—Gauge shall have a minimum range of 0 to 50 lb (222 N) with a maximum tolerance of 60.25 lb (1.11 N).

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VIII. Comparison of Marking and Labeling and Instructional Literature -NPR vs. ASTM

Table 7 shows the NPR's proposed revisions to the Marking and Labeling section and changes made in the revised ASTM F2085-12 standard. Table 8 shows the NPR's proposed revision to the Instructional Literature section and the changes made in the revised ASTM F2085-12 standard.

Table 7. Revisions to Section 9. Marking and Labeling

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
9.3.1.1 Suffocation and Strangulation Hazard 9.3.1.2 Death or Serious Injury Can Occur. 9.3.1.3 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 bed rail. 9.3.1.4 **BED RAIL USE**: Bed rail can trap young children against mattress, headboard, or footboard. 9.3.2 The warning statements shall also address the following: 9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib. 9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up). 9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard	NPR would revise ASTM F2085–10a section 9 *Marking and Labeling, to* make the appropriate age more explicit, to clarify the warning statements, and to increase warning visibility	9.3.1.1 ⚠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 portable bed rail.	ASTM 2085-12 revised sections 9.3.1.1, 9.3.1.2, 9.3.1.3, and 9.3.1.4 of the 2010 standard. ASTM 2085-12 deleted sections 9.3.2.1, 9.3.2.2, 9.3.2.3, and 9.3.2.4 of the 2010 standard. These revisions were intended to strengthen the warnings and clarify the appropriate user age and increase the warning visibility.	9.3.1 The warning statements shall include the following wording exactly as stated below: ⚠WARNING SUFFOCATION AND STRANGULATION HAZARD Gaps in and around bed rails have entrapped young children and killed infants. NEVER use with children younger than 2 years old. Use ONLY with older children who can get in and out of adult bed without help. NEVER use in place of crib. NEVER use unless bed rail is tight against mattress, without gaps, and at least 9 in. from headboard and footboard. Do not fill gaps with pillows, blankets, or other items that can suffocate children. NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use ONLY on adult bed. 9.3.2 For manufacturers' specific bed rails, the warning statements shall also address the following: Use only on (*manufacturer insert applicable bed and mattress/platform information*).
9.3.2.4 NEVER use on toddler	NPR would create a new section in ASTM F2085–10a to	9.4 Critical installation components must be	ASTM 2085-12 created new sections that require labeling	9.4 At least one installation component must be labeled with the

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ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer. 9.3.2.5 For manufacturers' specific bed rails: *(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	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	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. 9.4.1 The warning must including the following, exactly as stated below: ⚠WARNING – ENTRAPMENT HAZARD NEVER use portable 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	on installation components. This requirement is similar to the NPR	entrapment hazard warning in 9.4.1. The entrapment hazard warning shall 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" 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 The following warning shall be addressed: ⚠WARNING – ENTRAPMENT HAZARD NEVER use bed rail without properly securing bed rail to bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death. NOTE 2—Addressed means that verbiage other than what is shown can be used as long as the intent is the same or information that is product-specific is presented.

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Table 8. Revisions to Section 11. Instructional Literature

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, and adjustment instruction and warnings, where applicable, shall be included. 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: Discontinue use if damaged, broken, or if parts are missing	NPR would revise the language in section 11.1 of ASTM F2085–10a to add the word "installation" among the topics in the instructional literature. This requirement would add clear instructional literature for installation components to provide consumers easy-to-understand information for securing portable bed rails on beds.	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 instructions and warnings, where applicable, shall be included.	ASTM adopts the language recommended in the NPR and clarifies the use of warning statements in the instructions.	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. 11.1.1 The instructions shall contain the warning statements required by 9.3.1 , and, where applicable, 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.

IX. **Conclusion**:

The intent of the NPR was to address the misassembly issues that have resulted in fatal incidents and potentially fatal incidents due to misinstallation. Public comments included concerns with the potential for numerous test configurations, testing of zippered products, misassembly of adjustable components for installation, and repeatability of testing between labs.

CPSC staff's opinion is that the ASTM F2085-12 requirements adequately address staff's concerns about consumer misassembly and misinstallation issues identified in the NPR. The ASTM standard limits the requirements to components that were identified in the incident data. This reduces the number of misassembly combinations and prevents unnecessary testing. Added figures clarify the pass and fail criteria of the requirements.

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Appendix B – ESME Staff Response to NPR Comments

Public Comments to NPR Recommendations

On April 11, 2011, the CPSC published a proposed rule in the *Federal Register,*[1] requesting public comment on the proposed requirements. Public comments are available at Regulations.gov, docket # CPSC-2011-0019. Appendix B is staff's response to the technical comments.

<u>Comments concerning proposed misassembly and misinstallation requirements</u>

The Juvenile Products Manufacturers Association (JPMA) and Mr. Kenneth Walsh, submitted comments that expressed concerns with the proposed requirements to address misassembly and misinstallation of bed rails.

Juvenile Products Manufacturers Association (JPMA) Comments

JPMA stated that "the proposed added language is vague, arbitrary and invites unacceptably variability in test conditions." JPMA was concerned about the requirements for zippered products because a consumer could partially zip up a product in an infinite number of ways, resulting in an infinite amount of testing. JPMA was also concerned that the proposed requirement of assembly components, installation components, and adjustable components was ambiguous, and they said it needed to be clarified.

JPMA recommended adopting ASTM F2085-10a as the final rule without additional performance requirements to address misassembly or misinstallation. JPMA believes that the IDIs do not provide sufficient evidence to conclude that misassembly was the cause of deaths. JPMA recommended that the CPSC conduct an information campaign to educate consumers better on safe sleep environments for infants.

Kenneth Walsh, Bureau Veritas Comment

Mr. Walsh did not have specific recommendations to address misassembly and misinstallation incidents, but he did have the following concerns: (1) the infinite number of assembly/testing configurations; (2) the repeatability of this test between manufacturers and independent test labs; and (3) the consistency with which this proposed test can be applied at testing facilities.

In summary, the commenters expressed the following concerns with the proposed requirements:

1. The proposed requirements in the NPR will result in numerous combinations of misassembled bed rail configuration, which, in turn, would require an unreasonable amount of testing,
2. The proposed requirements for testing zippered products will have infinite configurations of misassembly and result in infinite testing.
3. It is not clear in the proposed requirements if a consumer-adjustable component, such as

[1] Federal Register / Vol. 76, No. 69 / Monday, April 11, 2011 / Proposed Rules docket # CPSC-2011-0019

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a strap that is used to attach the bed rail to the bed, would be subject to the misassembly requirements.

4. Due to ambiguity within the proposed requirements, repeatability and consistency of the testing between laboratories and manufacturers would be difficult.

Staff Response: Prior, during, and beyond the comment period, the ASTM bed rail subcommittee working group drafted alternate performance requirements that eliminated the need for testing and limited the misassembly possibilities to configurations likely to present an entrapment hazard. The requirements were balloted, approved, and published in January 2012, as ASTM 2085-12. CPSC staff recommends adopting ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails* to be the Final Rule.

A significant difference between the NPR and ASTM 2085-12 is that there are no test requirements or procedures in the ASTM standard to determine if a misassembled bed rail lacks sufficient vertical structure or provides sufficient visual cues that would notify a consumer that the bed rail is not assembled properly. This should simplify testing and reduce the total number of tests.

The new standard focuses the testing on components that were identified in the incident data. This should reduce the number of misassembly combinations and prevent unnecessary testing compared to the proposed requirements in the NPR. Added figures clarify the pass and fail criteria of the requirements.

The test laboratory personnel will conduct visual assessments of a bed rail after attempting to misassemble the bed rail. Test personnel will have to use some judgment to determine whether a bed rail can be misassembled. Test personnel should be trained to understand the intent of the standards to which they are testing, and competent labs should be capable of making reasonable engineering judgment.

The new ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails,* requirements are simple and clear, compared to the NPR proposal. ASTM 2085-12 addresses public comments and concerns with the potential for numerous test configurations, testing of zippered products, misassembly of adjustable components for installation, and repeatability of testing between laboratories.

<u>Comments concerning Foam and Inflatable Bed Rails</u>

There were several comments requesting that inflatable and foam bed rails: be included in the scope, meet all of the requirements in the standard, and have requirements to address potential suffocation hazard

Staff Response: Non-rigid bed rails are included in the scope of ASTM 2085-12 and will require a warning label. However the standard was developed for rigid-side bed rails, and many of the tests would not be applicable for these products. CPSC staff requested ASTM to consider additional requirements for these types of products. The ASTM subcommittee agreed to work on this issue and pursue bringing in manufacturers to develop requirements. If additional

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requirements are developed and accepted by ASTM, these requirements will be reviewed by CPSC staff to determine whether the revision is acceptable for adoption into the CFR.

Comments Concerning Test Platform

A test laboratory commented that the specifications for the mattress test platform 2 and the bed sheeting is too restrictive and that it is difficult to obtain the specified mattress and sheet.

Staff Response: CPSC staff agrees that the mattress test platform 2 and the bed sheeting specification are unnecessarily restrictive. ASTM F2085-12 was revised to allow an available mattress and bed sheet.

Miscellaneous comments

Comment: Recommend portable bed rails be sold in sets of two to reduce entrapment between the wall or a piece of furniture. (***Several Commenters)***

Staff Response: Double-sided bed rails are available to consumers. CPSC staff is not aware of entrapment incidents between the wall and the bed where a single bed rail was being used. Staff believes that entrapment between the bed and the wall is not related to use of a bed rail and requiring two may not address this hazard. CPSC staff believes that consumer education is needed to address the hazard of entrapment between the wall and the mattress.

Comment: The CPSC does not add address issues like daily changing of bed sheets or other routine use that will result in movement or stress on the product.

Staff Response: A review of the data did not indicate that changing of bedding contributed to an incident. The ASTM standard has requirements that test the strength of the bed rail. CPSC staff believes these requirements are adequate.

Comment: It is not addressed in the docket that portable bed rails can be used in various mattress systems.

Staff Response: CPSC staff's review of bed rail products showed that most bed rails are adjustable to fit various mattress sizes.

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TAB C: Human Factors Staff's Response to NPR Comments and Revised Requirements Associated with Warning Statements for Portable Bed Rails

TAB C

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

DATE: February 1, 2012

DATE: January 13, 2012

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

THROUGH: George A. Borlase, Ph.D., P.E., Associate Executive Director,
Directorate for Engineering Sciences

Robert B. Ochsman, Ph.D., CPE, Director,
Division of Human Factors, Directorate for Engineering Sciences

FROM: Timothy P. Smith, Engineering Psychologist,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Staff Response to NPR Comments and Revised Warning Requirements for Portable Bed Rails

BACKGROUND

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) requires the U.S. Consumer Product Safety Commission (CPSC) 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 such standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Section 104(f) of the CPSIA defines a durable infant or toddler product as a durable product intended for use, or that may be reasonably expected to be used, by children younger than 5 years old. Portable bed rails, which are products intended to prevent children[1] from falling out of an adult bed, are considered to be under the purview of section 104 of the CPSIA.

The ASTM International[2] (ASTM) voluntary standard, ASTM F2085, *Standard Consumer Safety Specification for Portable Bed Rails*, establishes requirements for portable bed rails. This standard was developed by ASTM in response to incident data supplied by CPSC staff and is intended to minimize entrapments between the portable bed rail and mattress that can result in asphyxiation and entanglements on protrusions. The current version of the standard is ASTM F2085–12.

[1] Bed rails are intended for children about 2 to 5 years old who can get in and out of an adult bed without help.
[2] ASTM International was formerly known as the American Society for Testing and Materials.

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On March 16, 2011, CPSC staff delivered to the Commission a draft notice of proposed rulemaking (NPR) and a briefing package that assessed the effectiveness of the voluntary standard and presented staff's draft proposed rule for portable bed rails. The most recent published version of the voluntary standard at the time the NPR was drafted was ASTM F2085–10a; therefore, this is the version of the standard upon which the NPR was based. On April 6, 2011, the Commission voted unanimously (5–0) to approve publication of the draft NPR, with changes. The NPR appeared in the *Federal Register* on April 11, 2011.

The NPR included revisions to section 9, *Marking and Labeling*, of ASTM F2085–10a. This section includes requirements for warning statements that must appear on the product and its retail packaging. The revisions to this section included: (1) the addition of a new subsection (9.4) that specified requirements for an entrapment hazard warning to be affixed to all critical installation components and (2) minor changes to the warning language in subsections 9.3.1.1 and 9.3.1.3, as shown in the following table:

ASTM F2085–10a	NPR
9.3.1.1 Suffocation and Strangulation Hazard	9.3.1.1 ⚠WARNING: Suffocation and Strangulation Hazard
9.3.1.3 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 bed rail.	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.

The public comment period closed on June 27, 2011, and the CPSC received 16 comments. Eight of the comments addressed, at least partially, the proposed warning requirements.[3] This memorandum responds to issues raised in these comments and discusses revised warning requirements intended to address these issues.

DISCUSSION

PUBLIC COMMENTS

All eight comments that addressed the warning requirements appear to support the requirements specified in the NPR, at least in terms of the general approach to improving the warning language that was in the voluntary standard. However, some comments raised specific issues and suggested that additional revisions to these requirements would be helpful. These comments and the responses to these comments by staff from the CPSC's Division of Human Factors (ESHF), appear below.

[3] Comments CPSC-2011-0019-0003, -0009, -0010, -0011, -0012, -0015, -0016, and -0017.

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Warning Language Revisions

One comment (-0003) stated that the warning labels should include age limits because children younger than 2 years old should not use these products. One comment (-0011) pointed out the importance of describing the hazard more concisely than the warning in ASTM F2085–12. Another comment (-0017) stated that the NPR revision to the primary warning provides a false sense of security for those with children who can get in and out of an adult bed without help, and that the proposed wording of the entrapment hazard warning for critical installation components is misleading because correct installations can also result in entrapment and death.

ESHF staff agrees that the primary portable bed rail warning label that appears on the product and its retail packaging should include an explicit age recommendation or restriction and that the warning statements in the previous edition of the voluntary standard, ASTM F2085–10a, lacked this specificity. For example, the only explicit reference to age in this warning label is the parenthetical phrase in the statement, "Use only with children who can get in and out of adult bed without help (typically 2 years and up)." Because the NPR warning language did not make this explicit, ESHF staff believes that the latest revision to the primary warning in ASTM F2085-12 would address the commenter's concern and result in a warning that is less confusing to consumers. In addition, the warning is more concise to increase the likelihood that consumers will take the time to read the warning and extract its content. A detailed discussion of the proposed revision can be found in the *ASTM Subcommittee Activities* section of this memorandum.

ESHF staff disagrees that the entrapment hazard warning for critical installation components misleads consumers because correct installations also can result in entrapment and death. The purpose of the entrapment hazard warning is to alert consumers to the importance of installing the portable bed rail correctly. The statement in question, "Incorrect installation can allow the portable bed rail to move away from the mattress, which can lead to entrapment and death," refers specifically to incorrect installation as the mechanism by which the portable bed rail can move away from the mattress. Nothing in the warning suggests that other mechanisms of entrapment exist that do not involve movement of the portable bed rail. Moreover, the portable bed rail itself includes a more comprehensive warning that discusses other sources of entrapment, such as the placement of the portable bed rail relative to the headboard or footboard of the adult bed, which clearly shows that other hazards and entrapment scenarios exist.

One comment (-0003) stated that the warning labels should describe the materials used when producing the portable bed rails. Another comment (-0010) stated that there should be a strict warning about modification of the portable bed rail and its components.

ESHF staff disagrees that the warning requirements should include provisions that specify the materials used to produce the portable bed rail. Warnings should be employed only when a significant hazard exists, yet the commenter has not identified what hazard such a warning requirement would be intended to address or whether the addition of this information would dilute the hazard warnings as currently proposed. The consequences of exposure to the hazard and appropriate avoidance behavior in response to the hazard also are key pieces of information that should be present in a warning unless this information can be readily inferred. The commenter does not specify either of these pieces of information, and ESHF staff is unclear

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about what hazard the commenter is intending to address. Thus, ESHF staff does not believe that including in a warning label a description of the materials used to produce the portable bed rail is appropriate at this time.

ESHF staff also disagrees that the warning requirements should include provisions regarding the modification of the portable bed rail and its components. ESHF staff interprets the commenter's position as seeking warning language that warns against the consumer physically altering the portable bed rail components. To staff's knowledge, this has not been an issue. Thus, mandating such warning language does not appear to be supported by the data.

Warning Graphics or Symbols

One comment (-0012) recommended that the warning labels have graphic symbols that illustrate the relevant hazards.

ESHF staff does not deny the potential usefulness of graphics to illustrate the hazards associated with portable bed rails and acknowledges that a pictogram or similar graphic may convey this information to consumers more quickly than text. However, the design of effective graphics can be difficult. Some seemingly obvious graphics have been found to be poorly understood, and some may give rise to interpretations that are opposite the intended meaning (so-called "critical confusions") (*cf.* Johnson, 2006; Wogalter, Silver, Leonard, & Zaikina, 2006). We will continue to consider whether the use of a graphic would be appropriate and may take further action in the future if we believe graphic symbols would help further reduce the risk of injury associated with these products.

Warning Visibility

Two comments (-0010 and -0017) emphasized the importance of the warnings and their text being highly visible.

ESHF staff agrees that the warning labels on a portable bed rail should be highly visible, and believes that highly conspicuous warnings are more likely to result in consumer compliance. The warning requirements specified in the NPR already specify that the primary warning and the new entrapment warning must be in contrasting colors and conspicuous. Furthermore, the NPR would have added a safety alert symbol (⚠) and the all-uppercase signal word "WARNING" to the primary warning label (see the table in the *Background*), which should increase visibility. However, ESHF staff notes that the hazard statement in the new entrapment warning is written in all-uppercase text ("ENTRAPMENT HAZARD"); whereas, the hazard statement in the primary warning is not ("Suffocation and Strangulation Hazard"). ESHF staff believes that reformatting the hazard statement in the primary warning with all-uppercase text ("SUFFOCATION AND STRANGULATION HAZARD") would highlight this information and increase the warning's visibility. This revision, along with the other revisions referenced earlier, is in the *ASTM Subcommittee Activities* section.

Other Labeling Issues

Two comments (-0010 and -0011) stated that the connection points for assembly should be labeled clearly or color coded.

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The new performance requirements for portable bed rails in ASTM F2085-12 (see ESME staff memorandum) specify that those components requiring consumer assembly shall not be able to be misassembled if the portable bed rail appears to be functional under various misassembly scenarios. Based on these performance requirements, staff believes that mandating the labeling of all assembly connection points is not needed at this time.

ASTM Subcommittee Activities

CPSC staff, in collaboration with the ASTM Subcommittee on Portable Bed Rails, developed proposed revisions to the warnings requirements to address issues that were raised in the comments and to clarify the warning statements. These revisions were incorporated into the latest version of the voluntary standard, ASTM F2085–12. The following table shows the warning requirements in sections 9.3.1 and 9.3.2 of ASTM F2085–10a, the NPR, and ASTM F2085–12.

ASTM F2085–10a	NPR	ASTM F2085–12
9.3.1 The warning statements shall include the following, exactly as stated below:	9.3.1 The warning statements shall include the following, exactly as stated below:	9.3.1 The warning statements shall include the following wording, exactly as stated below:
9.3.1.1 Suffocation and Strangulation Hazard	9.3.1.1 ⚠WARNING: Suffocation and Strangulation Hazard.	9.3.1 ⚠WARNING SUFFOCATION AND STRANGULATION HAZARD Gaps in and around bed rails have entrapped young children and killed infants.
9.3.1.2 Death or Serious Injury Can Occur.	9.3.1.2 Death or Serious Injury Can Occur.	NEVER use with children younger than 2 years old. Use ONLY with older children who can get in and out of adult bed without help. NEVER use in place of crib.
9.3.1.3 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 bed rail.	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.	NEVER use unless bed rail is tight against mattress, without gaps, and at least 9 in. from headboard and footboard. Do not fill gaps with pillows, blankets, or other items that can suffocate children.
9.3.1.4 **BED RAIL USE**: Bed rail can trap young children against mattress, headboard, or footboard.	9.3.1.4 **BED RAIL USE**: Bed rail can trap young children against mattress, headboard, or footboard.	NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use ONLY on adult bed.
9.3.2 The warning statements shall also address the following:	9.3.2 The warning statements shall also address the following:	9.3.2 For manufacturers' specific bed rails the warning statements shall also address the following:

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ASTM F2085–10a	NPR	ASTM F2085–12
9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib.	9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib.	Use only on (*manufacturer insert applicable bed and mattress/platform information*).
9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up).	9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up).	
9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard.	9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard.	
9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	
9.3.2.5 For manufacturers' specific bed rails:	9.3.2.5 For manufacturers' specific bed rails:	
(1) Use only on (*manufacturer insert applicable bed and mattress/platform information*).	*(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	

ESHF staff believes that the new ASTM F2085–12 warning requirements address the public comments received on the NPR and are superior to the requirements in the prior version of the voluntary standard and the NPR. The age at which children should not be using a portable bed rail has been made explicit with the statement, "NEVER use with children younger than 2 years old." Also, the statement immediately following that, "Use ONLY with older children who can get in and out of adult bed without help," clarifies that children must meet both criteria: they must be at least 2 years old, and they must be able to get in and out of an adult bed without help. Additional revisions to the language, such as the statement, "Gaps in and around bed rails have entrapped young children and killed infants," clarify for consumers the mechanism by which children are dying or becoming injured.

The new warning requirements in ASTM F2085–12 also result in a considerably more concise warning, which may increase the likelihood that consumers will take the time to read the warning and encode the information. For example, the NPR warning requirements would have resulted in a warning approximately 148 words long; whereas, the warning requirements in ASTM F2085–12 result in a warning that is 102 words long. The revised warning language also is written at a

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slightly lower grade level than the NPR warning language,[4] which means that people who read the warning may be more likely to understand it.

CONCLUSIONS

ESHF staff suggests revisions to the proposed warning requirements to address public comments received in response to the NPR for portable bed rails and to clarify the warning statements. These revisions appear in the latest version of the voluntary standard, ASTM F2085–12. ESHF staff believes that they are superior to the requirements in the prior version of the voluntary standard and the NPR.

[4] The Flesch-Kincaid grade level of the revised warning language is 5.4, whereas, the reading level of the NPR warning language is 6.7, assuming that the warning statements that were required to be "addressed" were written in the exact language used in the standard.

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TAB D: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011

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

Memorandum

Date: December 9, 2011

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

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011.

Introduction

The incident data presented in the Portable Bed Rail NPR briefing package in March 2011[1] was extracted on April 1, 2010. This memorandum includes portable bed rail-related incident data reported to CPSC staff from April 1, 2010 through November 9, 2011. The reports of emergency department-treated injuries (none of which were fatal) were ambiguous in the product descriptions, and hence, are excluded from this analysis.

Portable Bed Rail NPR incident data

The proposed rule summarized the data for incidents related to portable bed rails from January 1, 2000 through March 31, 2010. For that period, CPSC 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 non-injury 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. Of the 13 fatalities, there were 2 deaths that 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 3 cases of portable bed rail misassembly. In 3 additional fatal incidents, the contributing factor(s) that led to the hazardous entrapment scenario could not be determined. The beds used in all 8 cases

[1] http://www.cpsc.gov/library/foia/foia11/brief/bedrailNPR.pdf.

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were adult size. The remaining 5 (of the 13) fatal incidents had no product or scenario-specific information.

Since the publication of the NPR, staff received additional information through in-depth, follow-up investigations on 4 of the 5 deaths that were categorized as having insufficient information in the NPR. One of the 4 fatalities (document number 0427019066) is now known to have occurred from partial displacement of the bed rail leading to the entrapment of the decedent. Another fatality, document number 0406130408, listed earlier as lacking sufficient information, remains in that status; CPSC field investigators were unable to establish contact with anyone with firsthand knowledge of the product or the scenario of the incident. The third fatality reported, in document number 0717000449, is now known *not* to have involved any portable bed rail; what was originally reported as a bed rail has now been confirmed to be a crib rail. Finally, it seems unlikely that the fourth fatality, as reported in document number 0442078182, was associated with a portable bed rail. The decedent, co-sleeping with a sibling and a parent, suffocated. The role, if any, of a portable bed rail, now seems questionable.

New Incident Data[2] on Portable Bed Rails

A search of the CPSC epidemiological databases showed that there were 23 new portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. These incidents reportedly occurred between 2009 and 2011. Four of the 23 incidents were fatal, and 19 were nonfatal incidents, 8 of which reported an injury. In addition, CPSC staff has received additional information, through in-depth follow-up investigations, on 4 deaths that were listed has having insufficient information at the time of the publication of the NPR.

Among the 23 newly reported incidents that specified age (18 out of 23), 3 reported a child less than 15 months old. The majority of the incidents (15 out of 18) reported the child's age to be between 15 months and 4 years.

A. Fatalities

Among the newly reported incidents, there were 4 fatalities. One resulted from a misinstalled bed rail (document number X1190536A), where the decedent was strangled by the straps of the reinforced anchor system. The second fatality (document number I1170672A) occurred when the infant slipped through the torn section of the mesh and got caught when the bed rail flipped down and caught him at the neck. The remaining 2 fatalities (document numbers 0906085374 and 0948097318) lack any information on the product or scenario-specific details.

B. Nonfatal Incidents

Among the newly reported incidents, there were 19 nonfatal incidents, 8 of which resulted in injuries.

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[2] The CPSC databases searched were the In-Depth Investigations (INDP) file, the Injury or Potential Injury Incidents (IPII) file, and the Death Certificates (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor are they a sample of known probability of selection. 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 November 9, 2011. All data coded with product code 4075 and age as 6 years or younger (to accommodate any physically disabled children) were extracted. Upon careful joint review with the CPSC's Directorate for Engineering Sciences staff, some cases (adult bed rails, for example) were excluded.

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The 8 injuries sustained were mostly bumps and bruises; one case reported laceration that was severe enough to require multiple stitches, and another reported a fractured collarbone. None of the injuries required hospitalization.

C. Hazard Pattern Identification

The hazard patterns identified among the 23 incident reports are grouped in descending order of frequency of incidents, as follows:

- *Hinge-lock failure:* There were 8 incidents, including 4 injuries and 1 fatality, where the hinge-lock mechanism failed to keep the side panel in an upright position. The hazard in the fatality was a combination of hinge-lock failure and torn mesh panel (see below).

- *Displacement of bed rail*: There were 7 incidents, including 3 injuries, where the bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail.

- *Sharp surfaces:* There were 3 incidents, including 1 injury, due to sharp surfaces on the bed rail.

- *Worn or poor quality fabric on mesh panel:* There was 1 fatal incident that was attributable, in part, to the torn mesh panel and, in part, to the hinge-lock failure of the bed rail (see above).

- *Misinstallation:* One strangulation fatality on the straps of the reinforced anchor system of the bed rail was due to the improper installation of the bed rail.

- *Miscellaneous or unknown issues:* There were 4 incidents, including 2 fatalities with insufficient information on the product or scenario. Of the 2 nonfatal incidents, 1 reported hazards from broken screws, while the other reported design issues with the bed rail.

Conclusion

The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the data included in the NPR. Among the newly reported incidents, there were 4 fatalities. In addition, CPSC staff conducted follow-up investigations on 4 deaths that were listed as having insufficient information at the time of publication of the NPR; 2 of them are now known to be unrelated to the use of a portable bed rail.

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TAB E: Final Regulatory Flexibility Analysis of Draft Final Rule for Portable Bed Rails

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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Memorandum

Date: January 6, 2012

TO : Rohit Khanna
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SUBJECT : Final Regulatory Flexibility Analysis of Draft Final Rule for Portable Bed Rails

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 of the CPSIA 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 bed rails are not explicitly mentioned in section 104, they are a durable toddler product of longstanding interest to the agency.

In March 2011, the CPSC proposed adopting the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for portable bed rails (F2085–10a *Standard Consumer Specification for Portable Bed Rails*) with a few modifications. Staff recommended that portable bed rails meet additional performance requirements to address fatal incidents resulting from misassembly and potentially fatal incidents that resulted from misinstalled portable bed rails. In response to injury data supplied by CPSC staff, ASTM revised the voluntary standard to reduce entrapment hazards by incorporating requirements for misassembled and misinstalled portable bed rails similar to those recommended by CSPC staff.[1] In November 2011, ASTM balloted a revision to the standard ASTM F2085-10a that contained

[1] Memorandum from Mark Kumagai, Mechanical Engineering, dated January 4, 2012, Subject: Comparison of ASTM 2085-12 Standard Consumer Specification for Portable Bed Rails with the Proposed Requirements in the NPR Docket # CPSC- 2011-0019.

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the additional requirements and also included an expanded scope to cover non-rigid portable bed rails. They published a revised standard on January 1, 2012. The current version of the voluntary standard is F2085–12. Staff now recommends adopting the current voluntary standard without changes.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the 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. a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

The Product

As specified in the current ASTM standard (F2085–12), 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 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"). Portable bed rails constructed primarily from nonrigid materials, such as fabric, foam, or an inflatable device, are also covered by the voluntary standard.

Both portable bed rails, made for a specific manufacturer's adult-size beds, and "universal" portable bed rails, which can attach to any adult-size bed, are included under the voluntary standard. However, guardrails, which are used with crib mattresses on toddler beds, are not covered under the voluntary standard. They are covered by the CPSC's standard for toddler beds,[2] as opposed to the voluntary standard for portable bed rails.[3]

[2] The rule became effective on October 20, 2011.
[3] Guard rails are: (1) sold with a crib, or (2) can be purchased separately to convert a crib to a toddler bed.

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Other products not covered by the voluntary standard include:

- Side rails that connect the headboard to the footboard and may or may not have any barrier purpose;
- 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).

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 17 known manufacturers or importers supplying bed rails to the U.S. market. Thirteen are domestic manufacturers (76 percent), and three are domestic importers (18 percent). The remaining firm has an unknown supply source, and there is no publically 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; an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 12 of the domestic manufacturers and three of the domestic importers known to be supplying portable bed rails to 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.[4] Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard F2085–10a (the previous voluntary standard). Among them, 4 are JPMA-certified as compliant with the ASTM standard F2085–10a, and 1 firm claims compliance. Of the 3 importers, 1 firm is JPMA-certified as ASTM compliant with F2085–10a, and 1 firm claims to be in compliance. All 7 firms, which are either JPMA-certified or claim compliance with the ASTM standard F2085–10a, are small. However, none of these firms meet the current voluntary standard requirements (F2085–12).

JPMA estimates that current annual sales of portable bed rails are approximately 750,000 units, and retail sales is approximately $20 million. 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 in recent years, and bed rails remain in use for 3 to 5 years, then currently, there might be 2.25 million to 3.75 million bed rails in use.

[4] Since 1976, JPMA has run a voluntary Certification Program for several juvenile products, beginning with high chairs. Products voluntarily submitted 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.

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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.[5]

Reason for Agency Action and Legal Basis for the Draft Final Rule

Under Section 104 of the CPSIA, the CPSC can promulgate a mandatory standard for portable bed rails that is substantially the same as, or more stringent than, the voluntary standard. The current voluntary standard (F2085-12) has four modifications from F2085-10a. The first two changes specify test procedures for determining when bed rails are considered to be misassembled and misinstalled. The third change requires different warning labels and makes the warning statements more concise. The last change includes non-rigid portable bed rails under the scope of the voluntary standard and specifies performance requirements. CPSC staff recommends adopting the current voluntary standard with no changes.

Compliance Requirements of the Draft Final Rule

CPSC staff recommends adopting the current voluntary ASTM standard (F2085–12) with no modifications. Key components of F2085–12 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 occurring when a child slips through an opening in the bed rail or when a child becomes trapped 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.

Portable bed rails constructed primarily of non-rigid materials or foam and inflatable bed rails are also covered by the voluntary standard, but the requirements for misinstallation and misassembly do not apply to non-rigid products.

[5] Memorandum from Risana T. Chowdhury, dated December 9, 2011, Subject: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011.

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The current ASTM standard (F2085-12) revises the misassembly and misinstallation performance requirements, removes one performance requirement, and revises the warning statements from F2085-10a: [6]

- Misassembly requirements
    - The current voluntary standard adds illustrations and figures to the misassembly performance requirements to show examples of correctly and incorrectly assembled bed rails. The performance requirements are intended to prevent entrapment.
    - The modified testing requirements will reduce the number of configurations required for testing and allow more consistent evaluation in determining when bed rails are misassembled.
    - The current voluntary standard does not include the CPSC staff–proposed requirement from the notice of proposed rulemaking to use visual cues to determine acceptability of misassembled/functional bed rails as part of the draft final rule. As the performance requirements for misassembly have been revised, the visual cues requirement is replaced with a requirement for testing components.

- Misinstallation requirements:
    - CPSC staff included a performance requirement in the proposed rule that critical installation components [be] affixed to structural components of the bed rail.
    - The current voluntary standard includes a requirement that products which require consumer assembly, use captive hardware. Installation components must be permanently attached to the bed rail. A warning label is also required.

- Warning labels:
    - The current voluntary standard modifies warning labels to identify suffocation and strangulation hazards. The revised warning labels consolidate all of the warning statements required in the voluntary standard and further clarify the hazards. In addition, manufacturers must label applicable bed and mattress and platform information for intended use with the product. At least one installation component must be labeled with the entrapment hazard warning.

- Non-rigid portable bed rails:

    - CPSC staff recommended including non-rigid bed rails in the proposed rule. Foam and inflatable bed rails must meet the general requirements for portable bed rails and the requirement for enclosed openings. Foam and inflatable bed rails must also contain warning label statements.
    - The scope of the current voluntary standard was modified to include nonrigid bed rails. Non-rigid bed rails, including foam or inflatable bed rails, must meet the

[6] Memorandum from Mark Kumagai, Mechanical Engineering, dated January 4. 2012, Subject: Comparison of ASTM 2085-12 Standard Consumer Specification for Portable Bed Rails with the Proposed Requirements in the NPR Docket # CPSC- 2011-0019 and memorandum from Timothy P. Smith, Division of Human Factors, Directorate for Engineering Sciences, dated December 28, 2011, Subject: Human Factors Staff Response to NPR Comments and Revised Warning Requirements for Portable Bed Rails.

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general requirements and the requirement for enclosed openings. Non-rigid bed rails must also meet the warning label requirement.

The misinstallation requirement may help prevent entrapment in bed rails. This new requirement ensures that installation components are permanently attached to the bed rail and requires labeling on the installation component. ASTM clarifies that consumer adjusted components such as straps and telescoping rods must be attached to a bed rail component but are not required to be pre-adjusted for proper fit to the bed. In order to bring their bed rails into compliance, manufacturers could preassemble the installation component. Alternatively, manufacturers could opt to redesign their products entirely.

Adding illustrations and figures to the test procedures reduces the likelihood of incorrectly assembling portable bed rails. Similarly, firms would need to revise their current warning statements to include a more concise description of suffocation and strangulation hazards and to clarify the intended age use for the product.

Portable bed rails constructed primarily of non-rigid materials, such as 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 voluntary standard requirements for misassembly and misinstallation do not apply to non-rigid products.

Issues Raised by Public Comments

There were several public comments that resulted in modifications that are reflected in the draft final rule. Other than a slight reduction in testing costs that would be associated with the elimination of the visual cues requirement, none of the modifications affect the final regulatory flexibility analysis for portable bed rails. Commenters raised two issues concerning the initial regulatory flexibility analysis, which are summarized in the appendix. Staff agrees with both comments and both have been acknowledged in the final regulatory flexibility analysis.

Other Federal Rules

The Commission is in the process of implementing sections 14(a)(2) 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)(2) of the CPSA requires every manufacturer of a children's product which is subject to a children's product safety rule to certify that the product complies with all applicable safety rules. Section 14(i)(2)(A) of the CPSA 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 representative samples to ensure continued compliance, (iii) for verifying that a product tested by a conformity assessment body complies with applicable safety rules, and (iv) for safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler.

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Since portable bed rails now will be subject to a mandatory standard, they will be subject to the certification requirements of section 14(a)(2) of the CPSA. Moreover, portable bed rails are children's products and are subject to the third-party testing requirements of section 14(d)(2)(A) of the CPSA.

Portable bed rails are also subject to the lead and phthalate limit requirements under sections 101(a) and 108 of the CPSIA. Section 101(a) of the CPSIA limits the amount of lead content in children's products. Section 108 of the CPSIA prohibits certain phthalates in concentration of more than 0.1% in children's toys and child care articles. "Child care articles" are defined as consumer products "designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking and teething."

Impact on Small Businesses

There are 17 firms currently known to be producing or selling portable bed rails in the United States. Of these firms, 12 are small domestic manufacturers, and three are small domestic importers. The remainder of this analysis focuses on these 15 small domestic firms.

Small Domestic Manufactures

The impact of the draft final rule on small manufacturers may differ based on whether they are compliant with the preceding ASTM standard (F2085-10a). Of the 12 domestic manufacturers, five produce portable bed rails that are certified as compliant by JPMA or claim to be in compliance with the voluntary standard F2085-10a.

The products of seven firms that are not in compliance with F2085-10a may require substantial modifications to meet F2085-12. The costs associated with these modifications could include product redesign, development and marketing staff time, product testing, and focus group expenses. It is possible that some firms may change the type of materials used to make portable bed rails, resulting in some cost increase. Costs may also rise if additional materials are required, or need to be redesigned. The actual costs of product modifications are 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 on the five firms which produce portable bed rails that are compliant with the voluntary standard F2085-10a may be less significant. Firms already in compliance with F2085-10a may require fewer modifications in order to bring their product into compliance with the current voluntary standard. Some firms may opt to preassemble component(s) rather than redesign their product. If firms decide to preassemble products, then portable bed rails may require larger shipping boxes. Shipping larger boxes is likely to increase shipping costs, and increased shipping costs may be significant in some cases. Larger boxes will also require greater storage space and may cause some retailers to reduce portable bed rails from their shelves and inventories.

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All manufacturers will need to modify existing warning labels. Costs associated with the new warning label would be low because no new materials are used. However, eliminating the visual cues and reducing the number of warnings may result in a small reduction in costs.

At least four small manufacturers' product lines consist entirely or primarily of nonrigid portable bed rails. These firms may need to alter the warning label and requirements for enclosed openings, but otherwise are not likely to be affected significantly by the voluntary standard.

Additionally, once the final rule and notice of requirements are in effect, all manufacturers will be subject to the additional costs associated with the third-party testing and certification requirements.

Small Domestic Importers

All three small domestic importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the current voluntary 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.[7]

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

Alternatives

Section 104 of the CPSIA requires CPSC to adopt a mandatory standard substantially the same as, or more stringent than, the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. One alternative would be to set an effective date later than the staff-recommended six months. This would allow suppliers (and manufacturers) additional time to modify and/or develop compliant portable bed rails, thereby spreading the associated costs over a longer period of time.

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

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Appendix / Public Comments

Shipment costs

One comment (CPSC 2011-0019-0013) stated that the shipping costs are a significant portion of the product's total cost and thus increasing the box size to contain a preassembled product could potentially increase cost to ship the product by 50%.

CPSC staff agrees that preassembling portable bed rails may require larger boxes, and that shipping larger boxes will likely increase shipping costs. It is possible that the increased shipping costs could be significant for some small firms.

Size of Products

The same commenter stated that the proposed rule may result in adverse retail response to stocking bulkier packages on shelves or in inventory or retailers dropping products or refusing to accept the price increase thus placing the cost burden on manufacturers.

CPSC staff agrees that, all else equal, larger box sizes for bed rails will require additional space on shelves and in inventories. As a result, some retailers might choose to decrease the number or model types of portable bed rails that they offer to the public which could, in turn, have the effect of reducing sales by manufacturers.

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