UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

DATE: OCT - 1 2001

TO: The Commission
Todd A. Stevenson, Acting Secretary

FROM: Michael S. Solender, General Counsel MSS
Stephen Lemberg, Assistant General Counsel SL
Lowell F. Martin, Attorney-Advisor LFM

SUBJECT: NPR to Address Risks Posed by Certain Portable Bed Rails

VOTE SHEET

Attached is a staff briefing package recommending that the Commission direct the Office of the General Counsel (OGC) to begin preparing a notice of proposed rulemaking (NPR) addressing a risk of injury/death associated with certain portable bed rails.

Please indicate your vote on the following options.

I. Direct OGC to begin preparing a NPR in accordance with the recommendations in the staff briefing package.

_____ _____
(Signature) (Date)

II. Direct OGC to begin preparing a NPR but with the following changes from the recommendations in the staff briefing package (please specify).

_____

_____

_____

_____ _____
(Signature) (Date)

CPSA 6 (b)(1) Cleared

not been reviewed or accepted by the Commission

III. Do not direct OGC to begin preparing a NPR.

_____ _____

(Signature) (Date)

IV. Take other action (please specify).

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment

OPTIONS TO ADDRESS PORTABLE BED RAIL HAZARDS

October 2001

For Further Information, Contact:

Patricia L. Hackett
Directorate for Engineering Sciences
(301) 504-0494 x1309

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs or Products Identified
Initial PB Date 10/16/01
Exempted

CONTENTS

ATTACHMENTS

EXECUTIVE SUMMARY

On October 3, 2000, the U.S. Consumer Product Safety Commission (CPSC) published an Advance Notice of Proposed Rulemaking (ANPR) that initiated a rulemaking proceeding to address the risk of death and injury associated with portable bed rails (PBRs) for children. This package provides the status of progress made since the ANPR was issued and discusses the options available to the Commission to address hazards related to the use of portable bed rails.

Options for remedial efforts in this area include:

1. Publish a Notice of Proposed Rulemaking (NPR) to continue the rulemaking proceeding for a mandatory rule addressing the hazards posed by PBRs. This would include instructing the Office of General Counsel (OGC) to prepare for the Commission's consideration, a draft NPR using the proposed standard in **TAB B** as the basis for the rule. The approved NPR would then be published in the Federal Register. In addition, the staff will continue to participate with ASTM on the development a voluntary performance standard that will adequately address the PBR hazards.
2. Take no further action to address PBR hazards at this time and withdraw the ANPR.

A PBR is a device intended to be installed on an adult bed to prevent children from falling out of the bed. All PBR products sold today are of similar design. They consist of a vertical rail about 15 inches in height and about four feet in length. There are generally two or more arms that are at right angles to the plane of the rail and are intended to be slipped between the mattress support and the mattress. The PBR is intended to stay in place due to the weight of the mattress and the friction between the arms and the mattress or its support. Several models of PBRs also use a variety of slip resistant knobs, pads or other means on the arms that are intended to add resistance.

PBRs are intended for children who can get in and out of an adult bed unassisted. Manufacturers typically recommend the use of the product for children from 2 to 5 years of age. However, many of the reported incidents involved children younger than 2 years.

Since 1990, fourteen fatalities have occurred with this product. Twelve of these fatalities were a result of entrapment between the PBR and part of the bed. Eleven of the fourteen fatalities associated with this product occurred to children under two years of age.

Once installed, a PBR may be unintentionally moved outward, away from the mattress, if a force is applied in that direction. An outward force may originate from activity of the child in the bed, asleep or awake. Once moved outward, a gap can be created between the vertical portion of the rail and the side of the mattress. In addition, the PBR is designed in a way that allows it to be unintentionally installed so that a gap already exists, and no additional force is required to create it. For example, a parent or caregiver may not push the PBR in all the way to the mattress during installation.

In the majority of the fatality incidents, the creation of this gap is what led to the deaths and is what staff believes to be the primary hazard. A child can roll into or otherwise enter this gap and become entrapped. Once entrapped, they can be asphyxiated or strangled.

There are no existing CPSC regulations or voluntary standards that adequately address the risk of death associated with this product. In February 1998, the CPSC staff requested that ASTM develop a provisional standard for portable bed rails to address the hazard of entrapment-related deaths. In May 1999, CPSC staff drafted a proposed standard and submitted it to ASTM for consideration. It was never balloted. In July 2001, CPSC staff updated the proposed standard and forwarded it to the ASTM Subcommittee Chairman for review and distribution. As of September 2001, the ASTM Portable Bed Rail Subcommittee had not balloted a proposed performance standard for these products.

CPSC staff has made a preliminary estimate that the overall effectiveness of a PBR safety standard in preventing deaths related to entrapment and strangulation could range from approximately 50% to as high as 85%. That estimate is based on the number and type of fatal incidents pertaining to PBRs, and on the new requirements outlined in the proposed standard to ASTM. Those requirements include performance criteria and labeling requirements. The estimated costs associated with manufacturing complying PBRs are generally comparable to the upper end of the economic benefits estimate.

It has been over one year since the Commission voted 3-0 to publish an ANPR to initiate mandatory rulemaking for PBRs. Since that time, CPSC staff has been the driving force behind the writing and development of the proposed standard. Although the industry has been involved, a proposed voluntary safety performance standard has never been balloted by the ASTM Subcommittee.

The staff recommends that the Commission direct the Office of the General Counsel to prepare a draft NPR to continue mandatory rulemaking.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

MEMORANDUM

DATE: OCT - 1 2001

To: The Commission
Todd Stevenson, Acting Secretary

Through: Michael S. Solender, General Counsel MSS
Caroline J. Croft, Executive Director CJC

From: Ronald L. Medford, Assistant Executive Director, RLM
Office of Hazard Identification and Reduction
Patricia Hackett, Project Manager PH
Directorate for Engineering Sciences

SUBJECT: Options to Address Portable Bed Rail Hazards

I. ISSUE

The U.S. Consumer Product Safety Commission (CPSC) is considering whether to issue a Notice of Proposed Rulemaking (NPR) for a mandatory safety rule to address portable bed rail (PBR) hazards. The fatalities associated with PBRs are primarily due to entrapment and hanging incidents. Staff initially brought this issue to the Commission in September 2000 for consideration because of the continuing fatalities associated with PBRs and the lack of effective action on the part of ASTM to develop a voluntary standard that adequately addressed the hazard.

II. BACKGROUND

A PBR is a device intended to be installed on an adult bed to prevent children from falling out of the bed. Manufacturers intend PBRs for children who can get in and out of an adult bed unassisted. Although manufacturers typically recommend the use of the product for children from 2 to 5 years of age, they are being used for children younger than two. Since 1990, the staff is aware of 14 fatalities that have occurred.

All PBR products sold today are of similar design (See Figure 1). They consist of a vertical rail about 15 inches in height and about four feet in length. There are generally two or more arms that are at right angles to the plane of the rail and are intended to be slipped between the mattress foundation and the mattress. The PBR are intended to stay in place due to the weight of the mattress and the friction between the arms and the foundation/mattress. Several models of PBRs

CPSA 6 (b)(1) Cleared
No Mfrs/PrvtLblrs or Products Identified

also use a variety of slip resistant knobs, pads or other means on the arms that are intended to add resistance to help reduce the possibility of the PBR sliding out and away from the mattress.

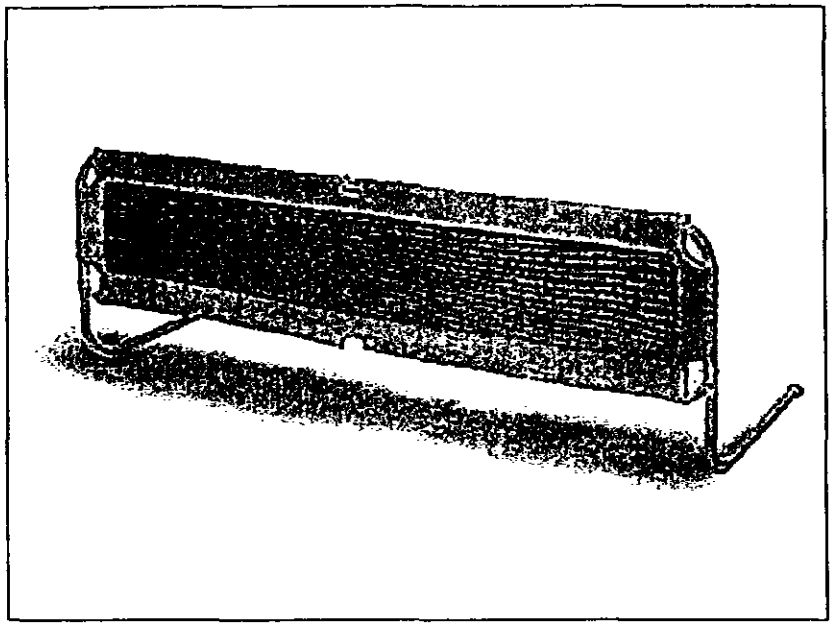

Figure 1: Typical Portable Bed Rail (PBR)

The amount of friction created to hold the PBR in place is dependent on a number of factors. In general, the PBR arms are designed so that they may be easily slipped between the mattress and the mattress support.

Once installed, a PBRs design may allow it to be unintentionally moved outward, away from the mattress if a force is applied in that direction. An outward force may originate from activity of the child in the bed, asleep or awake. Once moved outward, a gap can be created between the vertical portion of the rail and the side of the mattress. In addition, the PBR may be unintentionally installed incorrectly so that a gap already exists, and no additional force is required to create it. For example, a parent or caregiver may not push the PBR in all the way to the mattress during installation.

In the majority of the fatality incidents, the creation of this gap is what led to the deaths and is what staff believes to be the primary hazard. A child can roll into or otherwise enter this gap and become entrapped. Once entrapped, they can asphyxiate or strangle.

In February 1998, the CPSC staff requested that ASTM develop a provisional standard for PBRs to address the hazard of entrapment-related deaths. Because ASTM failed to act, in May 1999, CSPC staff drafted a proposed standard and submitted it to ASTM for consideration. This draft standard was never balloted by ASTM. In September 2000, the Commission voted 3-0 to proceed with an Advance Notice of Proposed Rulemaking (ANPR). The ANPR was published in October 2000. Since that time, CPSC staff has developed and submitted an updated draft proposed standard to ASTM. The latest staff proposal is reportedly going to be considered by the ASTM Subcommittee for PBRs (Subcommittee) at its October 24, 2001 meeting.

III DISCUSSION

A. Incident Data (TAB A)

The Division of Hazard Analysis (HA) performed a data search to determine how many PBR related fatalities have occurred.[1] From January 1, 1990 through August 22, 2001, CPSC has received reports of 14 PBR-related entrapment or hanging fatalities.[2] In addition, CPSC is aware of 7 incidents with injuries and 29 incidents without injury, all involving PBRs for the same time period (See Table 1).

In addition, the Office of Compliance received 30 reports of entrapment and hanging incidents (no deaths) from various manufacturers of PBRs. The data provided was minimal and only 17 contained enough information to run a cross check against CPSC data for duplicates. One duplicate was found, leaving 16 reports. Of the 16 reports, 4 involved an injury. Fourteen of the 16 involved entrapment or hanging between the PBR and the bed/mattress, and the other 2 of the 16 involved the child getting caught or stuck in the PBR.

Table 1: Portable Bed Rail Entrapment and Hanging Incidents

CPSC Data Files 1/1/90 to 8/22/01		*Incidents Reported to Compliance by Firms*		*Total*
Total	50	**Total**[3]	16	**66**
Deaths	14	Deaths	0	14
Incidents with Injury	7	Incidents with Injury	4	11
Incidents with No Injury	29	Incidents with No Injury or No Reported Injury	12	41

1. Deaths

The children involved in the 14 fatal incidents ranged from 3 months to 4 years of age. Eight of the fatalities were males and 6 were females. Three of the 14 children were disabled.[4] The beds on which the PBRs were used were a king size bed, a queen size bed, a full size bed, a bed described as an adult bed, two bunk beds, four toddler beds, 3 twin/single beds and a bed described as "youth size."

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[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 demonstrate 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 bed rails.

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

[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.

[4] The disabled children were 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.

In 10 of the 14 cases, the child became entrapped in an area between the mattress on the bed and the attached PBR. In one case, the child slipped through the bars of the PBR; in another case, a child was found hanging from a protrusion on the PBR itself; and in two cases, children were entrapped in the space between the headboard/bedpost and the PBR. The deaths were the result of asphyxia or strangulation, with the exception of one child who died of pneumonia due to cervical injury sustained by hanging. Additional information on each of the 14 fatalities is detailed in Appendix A of **Tab A.**

2. Incidents with Injury

There were a total of seven injuries reported to CPSC from January 1, 1990 through August 22, 2001. The seven injuries were: red marks on the head, a bruised back and swollen arm; a contusion to the neck; a red mark on the neck; a red mark to the neck area under the chin; a scraped nose and bruise to the back of the head; a bruised right temple; and a hairline fracture to the foot. These children were 6, 9, 14, 19, 23, 30 months and 3 years old, respectively. The beds involved were three twin beds, a king-size bed and three unspecified beds. In six of the cases, the children were found between the mattress and PBR. One case involved a PBR that snapped together in the middle with plastic couplers. The victim became entrapped when the PBR partially disengaged into a "V" shape where it snaps together. For further details on these cases, refer to Appendix A of **Tab A.**

3. Incidents with No Injury

The remaining 29 incidents (updated from 19 incidents reported in the June 2000 Staff Briefing Package) did not involve an injury. The children ranged in age from 4 months to 3.5 years old. In 26 of the incidents, the child got a part of his/her body entrapped between the mattress or bed and PBR. Two incident reports did not specify the exact location of the entrapment in relation to the bed/mattress and PBR. In one incident, it was stated that the child partially slipped through a PBR attached to the bed.

The incident reports received since the ANPR briefing package demonstrated the same patterns of entrapment as seen previously in the data. The most common scenario for the time period of January 1, 1990 through August 22, 2001 involved the arms of the PBR (that go under the mattress) slipping out and creating a space between the vertical portion of the rail and the side of the mattress. This was reported to have happened in some cases when the child rolled or pushed against the PBR itself.

B. Proposed Performance Requirements (TAB B & C)

In the past three years, Engineering Sciences (ES) and Laboratory Sciences (LS) Staff have been developing proposed performance requirements with regard to the entrapment hazard associated with PBRs. The first standard focused on a requirement that PBRs resist a static pull out force of 50 pounds. There were several other requirements included with the proposal but this one received the most attention and comments from industry. Testing conducted by the Directorate for Laboratory Sciences (LS) in 1999 showed that there were no PBRs on the market at that time that would meet this proposed requirement.

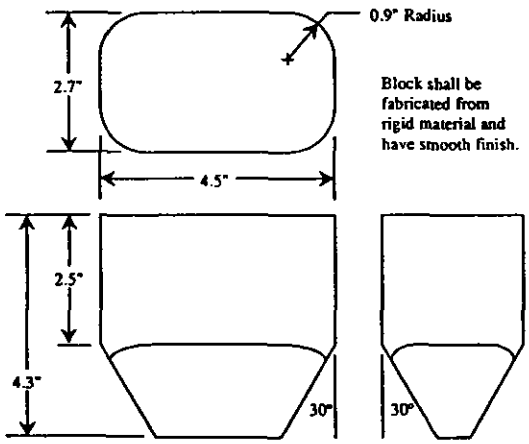
Since the development of the initial proposal in May 1999, the staff continued to analyze the hazard and developed a different proposal, using a wedge probe, in lieu of the static pull test. This change was made because the staff believes it is more representative of the events that can lead to a fatality. In addition, the use of a wedge probe is consistent with other established standards that address entrapment risks. The test provision included in the current staff proposal is very similar to a provision in the ASTM F 1427, Standard Specification for Bunk Beds and in the CPSC standard for bunk beds (16 CFR, Part 1213). **Tab B** contains the latest version of the staff's proposed requirements.

1. Adjacent-Type PBR's

Adjacent-type PBRs are those in which the guard portion of the product is essentially a vertical plane that is pushed up against the side of the mattress and does not extend over the mattress surface. Figure 1 is an example of an adjacent-type PBR.

From January 1, 1990 through August 22, 2001, CPSC has received reports of 14 entrapment or hanging fatalities associated with PBRs. The ages of the victims at the time of the incident ranged from three months to four years. All fatal incidents to non-impaired children occurred to children from 3 to 19 months of age. Therefore, ESHF staff believes it is reasonable to design the probe based on the 5th percentile torso dimensions of children close to 3 months of age (see **TAB C**). Figure 2 shows the proposed Torso Probe for use with adjacent-type PBRs.

Figure 2: Proposed Torso Probe Design for Adjacent-Type Portable Bed Rails



This design is essentially a scaled-down version of the probe specified in the CPSC standard for bunk beds. The two top-view dimensions are based on the 5th percentile hip breadth of children three to five months of age (4.5 inches) (Snyder, Schneider, Owings, Reynolds, Golomb, & Schork, 1977) and the 5th percentile hip depth of children three to four months of age (2.7 inches) (Snyder, Spencer, Owings, & Schneider, 1975).

When a child enters the gap between a PBR and mattress, his or her own weight can assist in pulling the child into and through the gap. Since the oldest non-impaired child involved in a fatal incident was 19 months of age, ESHF staff believes that the force to be applied in performance testing should be based on the weight of the heaviest 19-month-olds to provide a margin for safety. According to CDC growth charts, the 95th percentile weight of a 19-month-old boy is approximately 31.5 pounds (National Center for Health Statistics & National Center for Chronic Disease Prevention and Health Promotion, 2000). Since the Torso Probe is applied between the mattress and PBR in the same way as a child who becomes "wedged" between these two; the weight of the probe would also tend to pull it into this space. Hence, ESHF suggests that the force used during performance testing of PBRs be equal to approximately 31.5 pounds minus the weight of the torso probe itself. LS estimates the weight of the probe is approximately 1.5 pounds, so ESHF believes that 30 pounds is an acceptable force to use for performance testing of PBRs.

The Torso Probe is placed between the vertical rail of the PBR and the side of the mattress. The probe is aligned in an orientation most likely to permit its passage (generally with vertical centerline of the probe as close as possible to perpendicular to the plane of the gap opening). The 30 pound force (133 N) is then gradually applied along the probe centerline in a manner to evaluate whether the probe will pass through the opening. In order to comply with the standard, there shall be no gap between the mattress and the PBR that will permit complete passage of the Torso Probe. Complete passage is defined as the entire probe passing the horizontal plane that extends from the top surface of the mattress toward the rail or guard portion of the PBR.

Use of the torso probe in the manner indicated above is limited to PBRs that have the common design of a vertical rail adjacent to the mattress, referred to as an adjacent-type PBR.

2. *Mattress-Top PBRs*

CPSC staff is aware of at least one design concept or prototype PBR, where the rail or guard portion sits on top of the mattress rather than adjacent to it. CPSC LS staff developed this design concept in 2000. A prototype can be seen in Figure 3 (this type of design will be referred to as a mattress-top PBR for the remainder of this memo). Anticipating that manufacturers may also opt to develop their own PBRs of similar design, a second wedge test was developed, to assure that mattress-top designs would also meet similar requirements.

PBRs of this kind limit access to any gap between the PBR and the side of a mattress. However, there is the potential for children to slip beneath the guard portion of the PBR or to push the PBR off the mattress. CPSC staff believes that performance testing with a wedge probe in the shape of a right triangle could address these hazards. Given that the same age children would be at risk as with adjacent-type PBRs, ESHF staff designed a wedge probe based on the same anthropometric dimensions as those used for the torso probe discussed earlier. Figure 4 shows the proposed Wedge Probe design for use with PBRs of this type.

Figure 3: Mattress-Top PBR (LS Prototype)

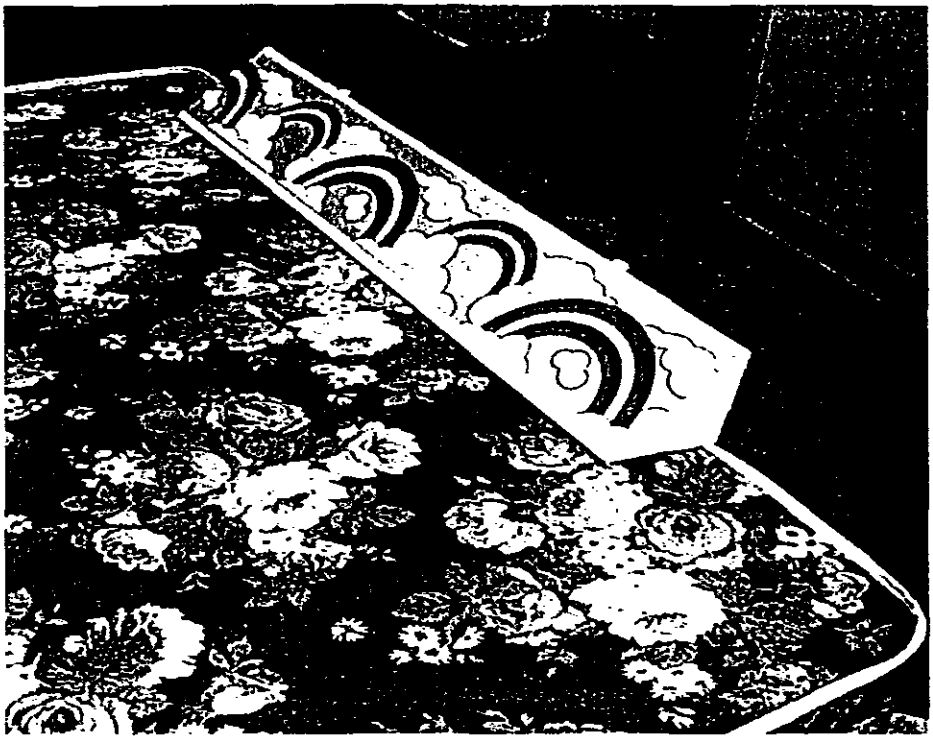
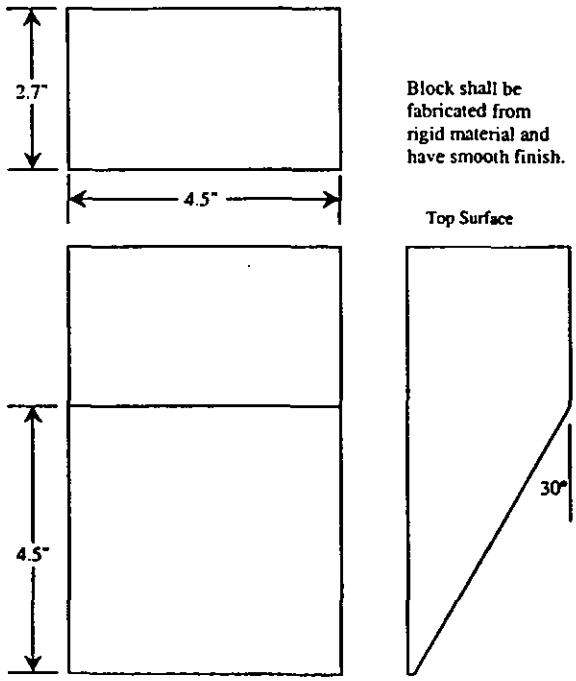


Figure 4: Proposed Wedge Probe Design for Mattress-Top PBRs



The worst-case scenario would be one in which a PBR is designed such that the guard portion only barely extends over the top surface of the mattress. In that case, a child who slipped beneath the guard would be in essentially the same situation as a child who enters the gap between an adjacent-type PBR and the side of the mattress. Therefore, ESHF staff believes it is reasonable to apply the same force in this test as would be applied in the performance testing of adjacent-type PBRs.

In this test, the Wedge Probe is placed flat on the mattress with the tapered end between the mattress and the underside of the guard portion of the rail. The probe is then pushed under the guard to a depth of ½-inch. The 30-lbf (133 N) force is gradually applied to the top surface of the probe in a direction toward the PBR and parallel to the mattress surface. When tested in accordance with this procedure, the Wedge Probe shall not penetrate to a depth greater than 4.5 inches and the PBR shall not displace horizontally such that the guard moves off the top mattress surface.

3. Mattress Platforms

In addition to the two different probe requirements, the proposed standard requires that the tests be performed on three different mattress platforms. This ensures that the product is being tested as a system, taking into consideration that the bed on which a PBR is used can possibly contribute to its performance. These platforms include two twin sized mattresses, one of very low quality and one of medium to high quality. The rationale behind picking two mattresses is to ensure that the PBRs function safely, and as intended on a wide variety of mattresses. The concern with a low-end mattress is that because it may be very flexible and compliant, it might allow a child to become entrapped simply because the mattress deflects and moves away from the PBR. With a higher end mattress, the key factor influencing the potential for hazard is thickness. Using an adjacent-type PBR design on a thick mattress can be a hazard because too much flexibility of the rail panel can cause a pocket to form, of sufficient size to entrap a small child, without any gap existing between the rail and the mattress.

The third platform designated for testing is a platform that would be associated with the lower foundation on a bunk bed assembly, where this foundation is less than 30 inches above the floor (referred to from this point on as the "lower foundation" of the bunk bed). Even though PBRs should not be used on toddler beds and bunk beds, over 40% of the fatalities occurred on these types of beds. Toddler beds and metal bunk beds often use similar support platforms in lieu of a box spring, in which the mattress support consists of tubular metal slats. Other types of bunk beds may have support systems that consist of wires or wooden slats. Some beds use a base called a bunkie board, which is typically a solid board that rests under the mattress. Because all of these support systems are less likely to contribute friction to hold onto the PBR arms, it makes them more susceptible to being pushed out of position. A metal tubular, lower foundation bunk bed has been included as part of the test platform requirements in the proposed standard. The metal tubular design was selected because it is a common foundation that can be found on many types of non-adult beds. This in no way reflects an approval or recommendation by staff to use

PBRs on non-adult type beds, but it does ensure that PBRs will have to be designed so that they reduce the hazard when used on other types of potential support platforms.

4. Labeling Requirements (TAB C)

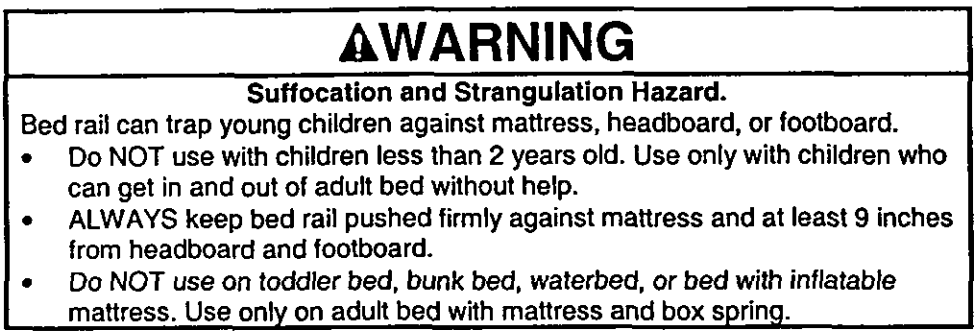
ESHF also reviewed the current labels required in ASTM F 2085 – 01, *Standard Consumer Safety Specification for Portable Bed Rails,* and provided suggestions and opinions of how the labeling can be improved. This standard only addresses labeling requirements, and does not contain any performance requirements. The standard requires that PBRs have a permanent warning label that uses the signal word "WARNING" preceded by a safety alert symbol. Given the potential severity of injury with PBRs, this signal word seems appropriate and ESHF staff recommends that this requirement be carried over into CPSC's proposed specification. The ASTM standard also requires the following statements to be included in the label:

- If a child's head or neck or body is trapped between the bed rail and bed, death or serious injury may occur.
- Use only on an adult bed with mattress and box springs.
- Use only for children who can get in and out of an adult bed unassisted.
- Never use in place of a crib.
- Never use on a bunk bed, waterbed, a bed with an inflatable mattress, or a toddler bed.
- To prevent entrapment, the minimum distance between the headboard/footboard and the bed rail shall be at least 9 inches.
- Always keep bed rail pushed firmly against the mattress.

To ensure a warning label is effective the consumer must notice and attend to it. Consumers are less likely to take the time to read a long and wordy warning label, so the label must be made as concise as reasonable to get the point across. The label above exceeds 100 words in length, which could keep some consumers from reading it. ESHF staff would prefer a shorter, more concise label for the CPSC proposed standard. The consumer must also comprehend the information that is presented in the label. As a whole, the above label is written at about a sixth-grade level. However, some of the sentences are written in awkward language (e.g., "If a child's head or neck or body...") or language that sounds more like a technical requirement than a discussion of how to use the product (e.g., "...the minimum distance between the headboard/footboard and the bed rail shall be at least 9 inches."). ESHF staff believes that any labeling requirement in the CPSC proposed specification should be written in simple, everyday language that most consumers are likely to understand. The language in the ASTM standard is not sufficiently comprehensible. The above label also fails to specifically describe the potential consequences of entrapment (i.e., suffocation and strangulation), something ESHF staff recommends. Therefore, ESHF staff suggests the label as seen in Figure 5 be included in the safety specification in lieu of the above statements.

ESHF staff believes the proposed label is more explicit, concise (81 words), and comprehensible than the ASTM label. In addition to including no passive sentences, the proposed label more specifically describes both the hazard and its consequences. Therefore, ESHF staff believes this label is more likely to be read and understood than the current ASTM label.

Figure 5: Proposed Warning Label for PBRs



C. Performance Evaluation of Current Bed Rail Designs and Prototypes (TAB D & E)

In order to develop the performance criteria included in the proposed standard, Laboratory Sciences (LS) staff conducted a variety of tests using various probes, PBRs and mattresses. Initially, the staff evaluated whether there was any significant difference between using an existing probe that had been developed for the bunk bed standard and an preliminary probe developed by ESHF. Using these two probes, five PBRs and three mattress platforms in a test matrix, staff was able to assess the effect and interaction of all three variables. This testing showed that there was no significant interaction between the rail itself and the probe that was used. **(See TAB D).** Because the preliminary probe developed by ESHF was based on the 3-5 month old torso dimensions and thus more applicable to the children at most risk, it was selected for further refinement and study. The Torso Probe resulted from this study.

Additional testing was done by LS staff to assess the performance of a variety of different PBRs using the Torso Probe. Four different PBRs recently purchased from retail stores, one PBR that had been acquired from Great Britain, as well as the prototype rail developed by LS were used in the testing. This testing was done on three different mattress platforms. In addition, testing with the use of sheets on the mattress was conducted. In order to pass the standard, the bed rail is installed as intended by the manufacturer and the probe is placed in the proper test position. A 30-pound force is applied to the probe. In the case of the adjacent-type PBRs, the Torso Probe robe cannot pass the plane of the mattress top. For mattress-top designs, the Wedge Probe cannot penetrate under the guard portion to the entire thickness of the probe, or 4.5 inches. The results of the testing are summarized in the Tables 2 through 4 and can be found in **TAB E.**

With the exception of one test for the adjacent-type PBRs, none passed the proposed requirements. Table 2 reports the actual force, in pounds that was required to fail the proposed requirements for adjacent-type PBRs.

Table 2: Wedge Probe Testing-Adjacent-Type PBRs

Test Platform	*Average Force*	*Range of Force*
Toddler Bed*	6 lbs.	4-8 lbs.
Medium weight mattress**	19 lbs.	7.7-34.5 lbs.
Light weight mattress	9.9 lbs.	8.5-11 lbs.

*Four bed rails were used for the testing on the toddler bed platform. The fifth bed rail has a very different design that precludes its use on a standard toddler bed.
** The medium weight mattress platform had test runs with significant forces (above 20 pounds) for two different bed rails. The first bed rail tested at approximately 34 pounds. This is a PBR that attaches to the other side of the bed, which helps restrict its movement. (This rail was the one not used during the toddler bed testing). The other bed rail had a force of 26 pounds because the probe became trapped in a pocket that formed in the mesh side.

In addition to the above testing, a comparison test was conducted to determine the effect of having a fitted sheet on the mattress during testing. The test was performed using the Torso Probe for adjacent-type PBRs. The medium weight mattress platform and four adjacent-type PBRs were used. Tests were performed using a fitted sheet and then again without the fitted sheet. As can be seen in Table 3, using sheets resulted in slightly lower or equal forces required to fail.

Table 3: Fitted Sheet Testing

Bed Rail	**Test with fitted sheet**	**Test without fitted sheet**
Bed rail 1	6 lbs.	7 lbs.
Bed rail 2	1.3 lbs.	2 lbs.
Bed rail 3	1.3 lbs.	1.3 lbs.
Bed rail 4	4 lbs.	7 lbs.

Testing was also performed using the Wedge Probe on mattress-top PBRs. Because there are no other PBRs on the market today that use the mattress-top design, the prototype PBR, designed and built by LS staff, was the only PBR tested in this manner. The force required for the Wedge Probe to penetrate to a depth of 4.5 inches or greater, was recorded. As can be seen in Table 4, the LS prototype PBR passed the proposed test requirements of 30-pounds for the two mattress platforms it was tested on.

Table 4: Wedge Probe Testing- Mattress-Top PBR

*Mattress Platform**	*Position on Bed Rail*		
	Right	*Middle*	*Left*
Light weight mattress	30+ lbs.	30+ lbs.	30+ lbs.
Toddler bed	30+ lbs.	30+ lbs.	30+ lbs.

*Due to the construction of the LS prototype bed rail, it was not able to fit on to the medium weight mattress.

D. Potential Effectiveness of Proposed Standard for Portable Bed Rails (TAB F)

The proposed draft safety standard for PBRs primarily addresses entrapment risks associated with these products. There is also a test provision in the draft standard that addresses the risk of strangulation due to a child's clothing catching on a protrusion on the PBR.

There are provisions in the draft standard that address all of the scenarios observed in the fatal incidents. These provisions are either performance requirements, warning label and instructions requirements, or a combination of the two. CPSC technical staff estimates that performance provisions in the draft proposed standard could have prevented from seven to twelve incidents. The upper end of this range includes all of the incidents involving an entrapment in openings formed by the rail and mattress or openings in the rail itself (11 incidents) and the one hanging/strangulation incident. The lower end of this range excludes rail/mattress entrapment incidents that occurred on toddler beds (three incidents), and bunk beds (two incidents) since the draft proposed standard does not require that PBRs be tested on toddler beds[5] and all types of bunk beds. The two incidents involving openings between the end of a portable rail and a bedpost are excluded from both estimates.

The draft proposed standard does include a provision that requires testing a PBR on the lower foundation of a tubular metal bunk bed. One common characteristic of many toddler beds and bunk beds is that they typically do not have a "box spring" type of mattress support. The mattress may instead sit on evenly spaced tubular metal rod "slats." On other bunk bed designs, wooden slats may support the mattress. Other bunk bed designs may utilize a mattress that has a rigid, built-in lower frame that sits on top of a lip in the bunk bed structure. These designs may utilize slats, or sometimes just a few cross-frame wires, to provide back-up mattress support should the primary mattress support fail. Still other bunk bed designs use a solid wooden board, sometimes called a bunkie board, as the mattress support. Staff believes that PBRs designed to meet the standard requirements on tubular metal bunk beds may also reduce the risk of entrapment between the mattress and rail on many types of toddler beds and wooden bunk beds.

The fatal incidents that occurred in openings formed between the end of a rail and a rigid bed structure (e.g., a bedpost of a headboard) are addressed in the standard through warning label and installation requirements. These warnings direct the consumer to install a PBR with a minimum spacing of 9-inches from both the head and foot of the bed. This installation ensures that if a child's body falls through an opening between the bedpost and end of the rail, the child's head will also fall through the opening and no entrapment will occur. While the staff considers it necessary to include obvious and clear warnings to address this hazard pattern, the level of effectiveness of these warnings must be considered low in comparison to performance requirements that necessitate certain product design characteristics.

Other factors that may influence effectiveness are related to the creation of an essentially fixed PBR. Some of the discussions with PBR manufacturers and in the ASTM Portable Bed Rail Subcommittee have focused on the fact that PBR designs would need to change drastically in

[5] Unless the PBR is specifically marketed for use on a toddler bed.

order to meet the proposed tests. While current PBRs can be dislodged from the side of the mattress with relatively low forces (ranging approximately from 5-lbf to 20-lbf when applied perpendicular to the vertical face of the rail), new PBRs designed to meet the draft requirements would require a very firm attachment making it difficult to dislodge the rail. It is very likely that this attachment would be on the mattress itself and that the rail would have to extend partly over the top surface of the mattress. Because of the difference in design, mattress-top PBRs have the potential to greatly reduce the likelihood of the formation of a hazardous gap between the mattress and PBR.

Based on the above considerations, the CPSC staff preliminarily estimates that the overall effectiveness of a PBR safety standard in preventing deaths related to entrapment and strangulation could range from approximately 50% to as high as 85%.

E. Voluntary Standards Activities (TAB G)

In February 1998, CPSC staff requested that ASTM develop a provisional safety standard for PBRs and the ASTM F-15 Executive Committee endorsed the CPSC request. A month later, the JPMA held a conference call with manufacturers to discuss injury data and the need for a safety standard. The initial ASTM organizational meeting was held almost one year later, in February 1999. In May 1999, CPSC staff drafted a proposed standard for the ASTM Working Group to review. Manufacturers agreed to test their products to the proposed standard and to bring the results to the next meeting.

In September 1999, the ASTM Portable Bed Rail Subcommittee held a meeting and voted to form two task groups. One group would develop labeling and instruction requirements for PBRs and submit these requirements for a "tri-level" (Subcommittee, full committee and ASTM society) ballot as soon as possible. The second task group would work on PBR performance requirements. Once completed, performance requirements would be sent to ballot for addition to the standard for labeling and instructions. In December 1999, CPSC staff met with members of the Subcommittee at the CPSC Engineering Laboratory to discuss the draft proposed performance standard and to observe PBR design concepts that may address entrapment hazards. Subcommittee members explained why they disagreed with the requirements and rationale proposed by CPSC staff. Manufacturers felt that the proposed testing requirements were too stringent and not appropriate for the product. The testing requirements would require that the product be totally redesigned. They also voiced concern that new hazards would result from any possible redesign.

By January 2000, only two or three manufacturers had tested their products to the proposed standard and the products could not pass the requirements. Other manufacturers said they had not yet tested their products but they would guess that they also would not pass the test. The attendees agreed to submit the CPSC draft proposed standard for Subcommittee ballot so that the entire Subcommittee membership could vote and provide written comments on the proposed requirements.

In February 2000, two years after CPSC staff first contacted ASTM, the Subcommittee attendees voted to withdraw a ballot containing CPSC staff proposed performance requirements.

The reasons given for withdrawing the standard were that it would receive several negative votes and that certain issues should be resolved before performance requirements are balloted.

In April 2000, the Subcommittee met again, with CPSC staff in attendance. The proposed standard, its rationale and proposed design changes were discussed. Minor, non-significant changes were discussed and agreed upon during the April 2000 Subcommittee meeting.

While the Subcommittee has expressed a willingness to continue work on a performance standard, it was not able to reach agreement on the draft standard by the time of the ANPR briefing to the Commission in September 2000. Since that time, there have been two additional scheduled Subcommittee meetings as well as several other meetings and phone conferences, which were held specifically for the purpose of discussing the standard. Despite these meetings, there has been no significant progress on the part of industry with regard to improving the standard.

In July 2001, ES and LS staff rewrote the initial proposed standard to include the wedge tests as described earlier in this memo. This change in approach was developed solely by CPSC staff based on testing five different PBRs using different probes on three different mattress platforms. On July 20, 2001, CPSC staff provided this new proposed standard to the ASTM Subcommittee chairman for review and distribution to the rest of the Subcommittee. On September 5, 2001, representatives of one manufacturer met with CPSC staff to discuss the new proposed standard and their new design concepts regarding PBRs. At the time of that meeting, the proposed standard had not been shared with the remaining members of the Subcommittee. The staff requested again, that it be distributed.

F. Industry Concerns

After CPSC staff submitted the first proposed standard to ASTM in May 1999, several manufacturer members of the Subcommittee asserted that the proposed CPSC requirements were too severe and lacked adequate rationale. Most manufacturers contend that incidents involving infants represent a misuse of the product and that standard requirements should not be based on these cases.

The CPSC staff agrees that PBRs should not be used in place of a crib when placing infants down to sleep. However, the staff believes that given the incident data, it is apparent that use of PBRs with infants is reasonably foreseeable. It is therefore appropriate to base performance requirements on infant anthropometry.

During a recent meeting held with an industry representative, other concerns, specific to the new proposed standard, were raised. One of these concerns deals with the selection of mattress platforms for testing. This manufacturer believes that including a lower foundation of a bunk bed or toddler bed platform is not acceptable because its products are not intended for those types of beds. Although the staff agrees that PBRs should not be used with either of these beds, the incident data indicates that they are used on these beds and thus warrants the use of one or these type beds as a test platform in the standard.

In addition, the issue has been raised of whether making a PBR more resistant to movement, i.e., making it more of a fixed barrier, will make it a greater hazard for older children. CPSC staff does not believe that this is a significant concern. It is possible that more children could have died had an adult/caregiver not intervened. In almost half the near-miss PBR related incidents in the CPSC data files, the caregiver was alerted to the child's situation when they heard cries, screams or other noises from the child. In other instances, the child was found in a hazardous position and freed by the caregiver before great harm could occur. The average age of the children involved in these near-miss cases was 25 months old versus the children in the death cases who were on average 15 months old. In support of this premise, HA summarized data for fatalities on the wall side of a bed. In a ten year span, CPSC recorded 265 incidents where children five years and younger died when entrapped or were found dead between the wall and the bed. Of these incidents, 96% occurred to children under the age of 2 years **(See TAB H).**

One of the primary concerns expressed by manufacturer members of the Subcommittee is that the adoption of the CPSC staff proposed standard could result in bed rail designs that would be more complex than current designs, which could result in additional incidents. One issue to consider with a "fixed" PBR is a hazardous gap between the end of a rail and a bedpost. If a consumer installs a PBR with a less than 9-inch gap to the bedpost, a fixed PBR may present more of an entrapment hazard than non-fixed PBRs that are more easily dislodged. The likelihood of this occurrence cannot be quantified by analysis of the available data. The incident data available to CPSC staff does not identify any close call incidents or complaints in which a child fell to the ground through a gap between the bedpost and end of a PBR.

Another concern associated with the complexity issue and fixed PBRs is the reliance on correct consumer installation. First, as discussed above, the consumer must ensure that the PBR is installed with at least a 9-inch gap from the head and foot of the bed. Second, the consumer must ensure that the attachment mechanism is fully employed. This likely involves one or more additional installation steps in comparison to the installation of current PBR designs. The likelihood that a caregiver would install the rail incorrectly, or that an incorrectly installed PBR would pose an increased entrapment hazard compared to current PBRs will be highly dependent on the product design. These issues reinforce the need for new PBR designs that are easily installed on a variety of beds and mattress types, and designs that minimize the potential for incorrect installation. In addition, clear and noticeable warnings for proper installation on the product and in the instructions are needed.

G. Response to Public Comments (TAB I)

CPSC received four public comments in response to the October 3, 2000 ANPR for PBRs. Comments were received from the following people/organizations:

1. Comment from Mary Ellen Fise, General Counsel for the Consumer Federation of American
2. Comment from Russ Butson, Director of Product Safety, Evenflo Company, Inc.
3. Comment from Eduardo Montorro, Robert Garnett, Harold Gomez and Amy Rodriguez (no affiliation provided)
4. Comment from the Juvenile Products Manufacturers Association (JPMA)

CPSC Engineering Sciences (ES) Staff and Hazard Analysis (HA) staff provided detailed responses to all comments received. Please refer to their accompanying memos **(TAB A and F)** for those details. Major issues raised are discussed below.

Comment:

Comments from the Evenflo Company, Incorporated, generally oppose mandatory performance standards for PBRs. The reason for their opposition centers on the belief that mandatory standards are not necessary in addition to the voluntary standards that are now being developed by ASTM.

Response:

CPSC has been working with ASTM for over 3 1/2 years in an attempt to develop a performance standard for PBRs. As of September 1, 2001, there exists only one standard relating to PBRs that has been through the voting process. This standard primarily deals with markings and labeling of the product and does not address any performance requirements. Two proposed standards that deal with performance requirements have been submitted to the Subcommittee. CPSC staff developed both of these proposed standards. Neither one of them has been balloted by ASTM, nor have any other members of the Subcommittee proposed an alternative standard in this time period that has gone to ballot.

Comment:

Evenflo also takes issue with CPSC's characterization of the safety risks associated with PBRs. Evenflo states that the data presented in the PBR options package indicates that the fatality rate from falls from beds is 22 times greater than the fatality rate where PBRs are present. Evenflo further asserted that PBRs do not present an unreasonable risk of death any more than do windows, since there are almost as many fatal incidents involving children rolling from beds and out of windows.

Response:

The fatality data presented in this briefing package does not represent a statistical rate of fatality. These data are anecdotal and only represent reports of deaths that the Commission has received for a specified period of time. A precise fatality rate is not known because staff does not know how often a PBR is used. The issue before the Commission relates to the risk of death associated with a PBR that is marketed as a safety device intended to keep a child from falling out of bed. The entrapment hazard is not apparent to the parent or caregiver. A review of the 14 fatal incidents suggests that these fatalities would not have occurred had the PBR not been present.

Comment:

Evenflo and JPMA asserted that the primary factor in the fatal incidents is that the children were sleeping in inappropriate bedding since the majority of incidents involved children under the age of 2 years. Manufacturers contend that PBRs are only intended for children who can get in and

out of an adult bed unassisted (generally starting around 2 years of age). Evenflo suggested that public education that warns caregivers not to place infants in adult beds is the best way to approach this problem.

Response:

The CPSC staff agrees that PBRs should not be used in place of a crib when placing infants down to sleep. However, the staff believes that given the incident data, it is apparent that use of PBRs with infants is reasonably foreseeable. The PBR, as a safety device, should both keep a child from falling out of bed and prevent fatal entrapments for foreseeable users. It is therefore appropriate to develop a performance standard that is based on intended users of the product and foreseeable younger users for whom the product is not intended.

Comment:

Evenflo submitted comments on the 50-pound push-out test for PBRs proposed by CPSC staff. The 50-pound test was based on the push out strength characteristics of 5-yr-old children. Evenflo asserted that this test does not take into account other, more likely causes of a gap between a PBR and a mattress, such as incorrect installation.

Response:

The CPSC staff made revisions to the draft proposed bed rail standard that address some of the issues related to a fixed or immovable PBR. The originally proposed 50-pound push-out test addressed the creation of a gap between a mattress and a PBR when the PBR moves away from the mattress. However, there are other possible actions that could result in a hazardous gap. For example, a gap could be created when a mattress deforms, or when a mattress slides away from an immovable PBR. In addition, a gap could be formed by a combination of PBR movement and mattress movement or deformation. In order to address these possibilities, the CPSC staff revised the proposed draft standard to replace the push-out test with a test that utilizes probes. The procedure involves placing the pointed end of a probe into the opening between the mattress and PBR. This opening may be in a vertical plane for PBRs that are installed adjacent to the mattress side, or the opening may be in the horizontal plane for PBRs that are installed such that they overlap the top mattress surface. The probe dimensions are based on the hip dimensions of children 3 to 5 months of age. A 30-pound force (representing the weight of a 19-month old child) is applied to the probe. While applying the 30-pound force, the opening may enlarge, either through PBR movement, mattress movement, mattress deformation, or some combination of these actions. If the probe penetrates the opening to a certain depth, it fails the test. This ensures that if part of a child's body enters an opening, the opening will remain small enough to prevent entrapment that could lead to asphyxiation. Compared to the previously proposed 50-pound push-out test, the probe procedure is a better test of the PBR, bed, and mattress as a system. Testing with a probe is consistent with other product standards that address entrapment related deaths, such as standards for playground equipment and bunk beds.

Comment:

JPMA asserted that the work of the ASTM Subcommittee has thus far resulted in a standard that addresses labeling, as well as performance criteria related to openings and protrusions. JPMA claimed that it was inaccurate for the CPSC staff to characterize the ASTM standard as dealing with only labeling issues.

Response:

"ASTM F 2085 Standard Consumer Safety Specification for Portable Bed Rails" was approved on March 10, 2001. This standard contains general requirements relating to existing federal standards that apply to all children's products (e.g., sharp points and edges, and small parts). The standard also contains requirements for marking and labeling on the product and retail packaging, and for the instructional literature. The standard does not include requirements that address entrapment in openings or strangulation associated with clothing catch points on protrusions.

Comment:

JPMA stated the following: *"While there have been a handful of deaths associated with infants placed in adult beds in the past decade, during the same time period entrapments between the mattress and walls on adult beds resulted in approximately 271 deaths of children age 5 and under."* JPMA went on to state *"Historically children in the 2-5 age range have not experienced serious injuries on the non-wall side of the bed where such barriers are traditionally used."*

Response:

CPSC received reports of 47 deaths involving children 1 month to 2 years old from January 1, 1990 to May 17, 2000 involving a fall from a bed (excluding bunk beds). For the same time period, there were 233 deaths of children 5 years of age and younger involving entrapments between the bed/mattress and wall. The 271 deaths refer to entrapments between the bed/mattress and wall plus incidents between the bed and wall with no entrapment indicated, and falls out of windows from the bed/mattress. Regardless, this rulemaking is not directed at entrapments other than those involving PBRs.

In reviewing data involving falls from beds (excluding bunk beds and wall side incidents) from January 1, 1990 to May 17, 2000, there were four two year olds reported to have died. In 2000, there were an estimated 78,650 bed-related injuries treated in hospital emergency rooms involving children ages 2-5 years. Of those bed-related injuries, an estimated 1,350 were either hospitalized, treated and transferred to another facility or dead on arrival. Additionally, 17,520 injuries were diagnoses that are traditionally considered serious: hemorrhage, concussion, dislocation, fracture, and internal injury. The most prevalent hazard pattern, among the 78,650 bed-related injuries to children 2-5, was falls from beds.

H. Economic Preliminary Regulatory Analysis (TAB J)

In order to issue a mandatory rule under the authority of the Federal Hazardous Substance Act (FHSA), the Commission must publish a preliminary regulatory analysis of the proposed rule and reasonable alternatives. Tab J contains a preliminary analysis from the Directorate for Economic Analysis (EC) addressing this requirement, as well as requirements dealing with the potential economic effects to small entities and potential environmental impacts. Product and market information, likely benefits and costs of the proposed rule are discussed below.

1) Product and Market Information

Industry sources report that there are currently between 3 and 5 manufacturers of PBRs. All of these firms are major suppliers of juvenile products to the U.S. market. Annual sales of PBRs have been estimated to be 750,000 units per year with an average retail price of $18. The average useful life is estimated to be 2-4 years.

2) Potential Costs of Proposed Rule

Currently, there are no firms now producing PBRs that meet the proposed performance requirements. One firm estimates that the additional materials required for the change in design for compliance will increase the retail price by approximately $7 per unit, or roughly 40% of the current price. Another manufacturer agreed with this estimate.

3) Potential Benefits of Proposed Rule

There were 14 fatalities associated with entrapments in PBRs in the time period of January 1990 to August 2001. This averages to 1.2 deaths per year. Based on the effectiveness of 50-85% estimated by ES, there would be a reduction of approximately 0.59 to 1.03 deaths per year. Using 2 years as the expected useful life of a PBR, there would be about 1.5 million bed rails in use at any given time. Dividing the reduction of deaths by 1.5 million PBRs in use, the annual risk of death can be determined to be 0.4 to 0.69 per million bed rails in use. Multiplying the risk of death by the statistical value of life of $5 million results in the expected cost of these deaths per bed rail. This figure ranges from $2.00 to $3.45 per PBR. Assuming the 2 year life span, the expected benefits would range from about $4.00 to about $6.90 over its expected useful life. An assumption of a 4-year product life, as opposed to 2 years, does not affect the benefits estimate.

4) Comparison of Costs and Benefits

The costs associated with the proposed rule are expected to take two forms: research and development costs, and costs of additional materials needed to construct complying PBRs. By their nature, R&D costs per unit are spread out over the number of units made during the entire production period, and over a period of several years may approach zero. Manufacturers estimate that additional materials needed to comply with the rule would be about $7 per unit.

Based on the incident data, market information and level of effectiveness, the rule would result in benefits of $4.00 to $6.90 per complying unit, over its expected useful life. Thus, the

estimated costs of the proposed standard are generally comparable to the upper end of the benefits estimate.

I. Discussion Summary

The basic issue involved with the entrapment/hanging hazard is whether or not a PBR can be designed so that it can be used safely without the risk of a fatality or serious injury. This includes its use for children under the age of two and use on a mattress that does not have a box spring platform. The children in this age range are the ones most likely to suffer an entrapment/hanging fatality or injury. Therefore, with or without a PBR present, parents and caretakers are putting infants to bed in a variety of sleeping environments and deaths are occurring.

CPSC staff has preliminarily estimated that the overall effectiveness of a PBR safety standard in preventing deaths related to entrapment and strangulation could range from approximately 50% to as high as 85%. That estimate is based on the number and type of fatal incidents pertaining to PBRs and the new requirements outlined in the proposed standard to ASTM. Those requirements include performance criteria and labeling requirements. In addition, the estimated costs associated with the manufacturing of complying PBRs are generally comparable to the upper end of the economic benefits estimate.

It has been over one year since the Commission voted 3-0 to publish an ANPR to initiate mandatory rulemaking. Since that time, CPSC staff has been the driving force behind the writing and development of the proposed standard. Although the industry has been somewhat involved, the proposed safety performance standard has never been balloted by the Subcommittee.

IV. OPTIONS

Options for remedial efforts in this area include:

1. Publish a Notice of Proposed Rulemaking (NPR) to continue the rulemaking proceeding for a mandatory rule addressing the hazards posed by PBRs. This would include instructing the Office of General Counsel (OGC) to prepare a draft NPR for Commission consideration, using the proposed standard in **TAB B** as the basis for the rule. The approved NPR would then be published in the Federal Register. In addition, the staff will continue to participate with ASTM on the development a voluntary performance standard that will adequately address the PBR hazards.
2. Take no further action to address PBR hazards at this time and withdraw the ANPR.

V. CONCLUSIONS AND RECOMMENDATIONS

The staff concludes that current PBR designs are inadequate to prevent entrapment deaths of young children, even when the product is properly installed. There is no voluntary safety standard in existence that addresses the performance requirements of PBRs. It is estimated that the proposed draft standard developed by CPSC staff would have a high effectiveness in reducing deaths due to entrapment or strangulation and thus could be used as the basis for a mandatory rule. Therefore, the staff recommends that the Commission instruct OGC to prepare an NPR to continue mandatory rulemaking.

TAB A

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: AUG 28 2001

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 Update

This updates the June 7, 2000 memorandum on entrapment and hanging incidents involving portable youth bed rails.[1] It also responds to the public comments received in response to the U.S. Consumer Product Safety Commission (CPSC) October 3, 2000 Advance Notice of Proposed Rulemaking (ANPR).

Deaths

Since the June 2000 memorandum, two additional portable bed rail-related entrapment fatalities were reported.[2] Thus, from January 1, 1990 through August 22, 2001, CPSC has received reports of 14 portable bed rail-related entrapment or hanging fatalities.[3]

The children involved in the 14 fatal incidents ranged from 3 months to 4 years of age. Eight of the fatalities were males and 6 were females. Three of the 14 children were disabled.[4] The beds on which the bed rails were used were a king size bed, a queen size bed, a full size bed,

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[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] A 4-month old female was found between the crib-size mattress of her toddler bed and the netting of the bed rail with her face against the mattress. Her death was due to postural asphyxia. The other death occurred when a 6-month-old female was sleeping with her parents in their queen size bed equipped with a portable bed rail. She was discovered wedged between the bed rail and mattress. The cause of death was probable positional asphyxia.

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

[4] The disabled children were 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.

a bed described as an adult bed, two bunk beds, four toddler beds, 3 twin/single beds and a bed described as "youth size".

In 10 of the 14 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 case, a child was found hanging from a protrusion on the bed rail itself; and in two cases, 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 pneumonia due to cervical injury sustained by hanging. Additional information on each of the 14 fatalities is detailed in Appendix A (attached).

Incidents with Injury

Two injuries were reported since the June 2000 memorandum.[5] Including these injuries, there were a total of seven injuries reported to CPSC from January 1, 1990 through August 22, 2001. The seven injuries were: red marks on the head, a bruised back and swollen arm; a contusion to the neck; a red mark on the neck; a red mark to the neck area under the chin; a scraped nose and bruise to the back of the head; a bruised right temple; and a hairline fracture to the foot. These children were 6, 9, 14, 19, 23, 30 months and 3 years old respectively. The beds involved were three twin beds, a king-size bed and three unspecified beds. In six of the cases, the children were found between the mattress and bed rail. One case involved a bed rail that 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 29 incidents (updated from 19 incidents in the options package) did not involve an injury. The children ranged in age from 4 months to 3.5 years old. In 26 of the incidents, the child got a part of his/her body entrapped between the mattress or bed and bed rail. Two incident reports did not specify the exact location of the entrapment in relation to the bed/mattress and bed rail. In one incident, it was stated that the child partially slipped through a bed rail attached to the bed.

[5] A 3-year-old female suffered a hairline fracture to her foot when it became wedged between the portable bed rail and her bed while sleeping. This child had often managed to move the bed rail (usually by rolling into it in her sleep). A 19-month old male got his neck trapped in a 4-5 inch space between the mattress and bed rail, suffering a red mark to his neck under his chin.

Table 1 shows a breakdown of the incidents by death, injury and no injury for the CPSC data files and also incidents that were reported to Compliance.[6]

Table 1: Portable Youth Bed Rail Entrapment and Hanging Incidents

CPSC Data Files 1/1/90 to 8/22/01		Incidents Reported to Compliance by Firms		Total
Total	**50**	**Total[7]**	**16**	**66**
Deaths	14	Deaths	0	14
Incidents with Injury	7	Incidents with Injury	4	11
Incidents with No Injury	29	Incidents with No Injury or Not Reported	12	41

Source: The Indepth Investigation file, the Injury or Potential Injury Incident file, the Death Certificate file, the National Electronic Injury Surveillance System, and Office of Compliance case files
U.S. Consumer Product Safety Commission/EPHA/EXC

Comments on Incident Data

The incident reports received since the June 2000 memorandum demonstrated the same patterns of entrapment as seen previously in the data. The most common scenario for the time period of January 1, 1990 through August 22, 2001 involved the rods/bars of the bed rail (that go under the mattress) slipping out and creating a space. This was reported to have happened in some cases when the child rolled or pushed against the bed rail itself.

Response to Public Comments

CPSC received four public comments in response to the October 3, 2000 ANPR for portable youth bed rails. Those comments related to the hazard data are discussed below.

of American

Comment CH 01-1, received from the Consumer Federation of America (CFA), favors the continuance of the rulemaking process towards a mandatory standard that would declare certain portable bed rails banned hazardous substances. CFA takes this position based on their feeling that industry has failed to develop a voluntary standard that would eliminate the entrapment risk associated with bed rails.

Response:

The CPSC staff position is that performance tests to eliminate entrapment hazards related to bed rails (whether through a mandatory or voluntary standard) are important considering the vulnerable age group involved in the incidents. Failure to address the issue could have potentially fatal consequences.

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[6] Included in Table 1 are reports of entrapment and hanging incidents involving portable youth bed rails that the Office of Compliance received from manufacturing firms. These cases are discussed in detail in the June 2000 memorandum.

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

Comment from Russ Butson, Director of Product Safety, Evenflo Company, Inc.

Comment CH 01-2, from the Evenflo Company, Incorporated, opposes mandatory performance standards for portable bed rails. The reason for their opposition centers on the belief that mandatory standards are not necessary in addition to the voluntary standards that are now being developed by the American Society for Testing and Materials (ASTM). Evenflo also takes issue with CPSC's characterization of the safety risks associated with portable bed rails. Evenflo states that the data presented in the portable bed rail options package indicates that the fatality rate from falls from beds is 22 times greater than the fatality rate where bed rails are present. They also have concerns over CPSC's use of the term "near-miss" and deemed the presentation of the incident data cursory and inadequate.

Response:

The fatality data presented in the options package does not represent a statistical rate of fatality. These data are anecdotal and only represent reports of deaths that the Commission has received for a specified period of time. They are neither a complete count of all the deaths that occurred during that time period or a sample of known probability of selection. However, they do provide a minimum number of deaths and illustrate the circumstances surrounding the deaths.

The staff used the term "near miss" to imply the potential for a worst case scenario, given that the non-fatal scenarios were similar to the scenarios in the fatal cases. In almost half of the near miss cases, the caregiver was alerted to the situation by cries, screams or other noises. In other instances, the child was found in a hazardous position and was freed by the caregiver before harm occurred. Staff believes there was a possibility that without the intervention of a caregiver, these incidents could have led to more serious consequences

The data presented in the options package were based on a detailed review of all the available hard copy documents associated with these cases to ascertain the pertinent facts. The information presented in the options package appendices regarding the specific incidents was condensed to include only a synopsis of the events.

Comment from Eduardo Montorro, Robert Garnett, Harold Gomez and Amy Rodriguez

Comment CH 01-3, from Eduardo Montorro, et al, proposes a mandatory rule banning portable bed rails that do not come with specific warnings and instructions.

Response:

Warnings and instructions without an adequate performance standard will not eliminate the risk of death or injury. Staff determined that among the data, the most common scenario was that the two rods/bars that go under the mattress slipped out, creating a space between the mattress/bed and bed rail. There were some reports that this happened when the child rolled or

pushed against the bed rail itself. These types of events could only be addressed with a performance standard and not labeling or installation instructions.

Comment from the Juvenile Products Manufacturers Association (JPMA) submitted by their counsel, Rick Locker

Comment CH 01-4 from JPMA opposes a mandatory rule declaring portable bed rails to be banned hazardous substances and supports the development of an ASTM voluntary standard addressing labeling and certain performance criteria. However, they further state that if an ASTM voluntary standard is not developed and implemented, then JPMA would support a rule banning portable bed rails that did not have specified warnings and instructions. JPMA, through Mr. Locker, uses some of the CPSC data to support their position.

Response:

JPMA stated that the data collected by CPSC indicate that children in the 2 to 5 year age range are not subject to any serious risk of injury with bed rails currently marketed. However, from January 1, 1990 through August 22, 2001, 19 children between the ages 2 to 4 were involved in fatal and non-fatal incidents of entrapment or hanging. Five of the 19 children in this age group were either injured or died.

They also stated the following: *"While there have been a handful of deaths associated with infants placed in adult beds in the past decade, during the same time period entrapments between the mattress and walls on adult beds resulted in approximately 271 deaths of children age 5 and under."* CPSC received reports of 47 deaths involving children 1 month to 2 years old from January 1, 1990 to May 17, 2000 involving a fall from a bed (excluding bunk beds). For the same time period, there were 233 deaths of children 0-5 years of age involving entrapments between the bed/mattress and wall. The 271 deaths refer to entrapments between the bed/mattress and wall plus incidents between the bed and wall with no entrapment indicated, and falls out of windows from the bed/mattress.

They go on to state that: *"Historically children in the 2-5 age range have not experienced serious injuries on the non-wall side of the bed where such barriers are traditionally used."* In reviewing options package data involving falls from beds (excluding bunk beds and wall side incidents) from January 1, 1990 to May 17, 2000, there were four two year olds reported to have died. In 2000, there were an estimated 78,650 bed-related injuries treated in hospital emergency rooms involving children ages 2-5 years. Of those bed-related injuries, an estimated 1,350 were either hospitalized, treated and transferred to another facility or dead on arrival. Additionally, 17,520 injuries were diagnoses that are traditionally considered serious: hemorrhage, concussion, dislocation, fracture, and internal injury. The most prevalent hazard pattern, among the 78,650 bed-related injuries to children 2-5, was falls from beds.

Lastly, JPMA said that on average the deaths and injuries involved children under 7 months of age. Assuming that JPMA is referring to the deaths and injuries involving hanging and entrapment with portable bed rails cited in the June 2000 memorandum, the average age of

the children involved in the 12 fatalities was 14 months and the average age of the 5 injured children was 16 months.

Appendix A

Portable Youth Bed Rail Entrapments and Hangings

Deaths and Near-Misses 1/1/1990 to 8/22/01

	Deaths				
	Document #	Date	Age/Sex	City/State	Narrative
1	900209HCC2155	03/06/1990	7 MO M	Marceline, MO	Child suffocated when his body slipped feet first through horizontal bars in a bed rail and he was pinned head first into the mattress of a single size bed. Accidental asphyxiation due to suffocation.
2	920310HCC1596 9151029634	08/02/1991	3 MO M	Clarksville, VA	Child's head became entrapped between the bottom of a portable bed rail and mattress resulting in his hanging. One of the L-shaped rods had pulled out from under the mattress of the full size bed. He died of asphyxia.
3	91112HCC1470 X91B0438A1	10/31/1991	15 MO F	Newark, NJ	Child was found hanging half out of the bed stuck between the mattress and a portable safety side rail. The rail had pinned the victim's neck and upper body to the mattress. The bed rail was installed on the lower bunk of a bunk bed. The cause of death was mechanical asphyxia.
4	920302HCC0122 X9231206A1 9106192347	11/10/1991	14 MO M	Lancaster, CA	Child was found hanging by his shirt collar which caught on a metal clip with a small metal tab on the exterior of a portable bed rail on a single size bed. Cause of death was ligature strangulation.
5	940110HCC1085	06/23/1993	2 YR F	Naples, FL	A child with brain deformities was found with her face inside a 2-3 inch gap between the mattress and attached side rail of her toddler bed. The bed rail is designed with a tubular extension to fit under the mattress to hold it in place. The railing was secured below the mattress to the bottom slats of the bed with string. The cause of death was positional asphyxia.
6	950815HCC4107 9406185601	10/14/1994	7 MO M	Oceanside, CA	Child's neck became trapped in a 2-3 inch gap between the end of a retractable bed rail and bed post of a small twin bed. The victim died of restrictive asphyxia.

	Document #	Date	Age/Sex	City/State	Narrative
7	960215HCC5012 X961288A 9555036345 X9611117A X9772446A	12/08/1995	2.5 YR F	North Fond du Lac, WI	Child suffering from cerebral palsy was found lying on her stomach with her head wedged between the mattress of her "youth size" bed and a portable bed rail . The left side of her face was against mattress and a plastic sheet that covered the mattress was covering much of the child's face. The cause of death was positional asphyxia.
8	960402HCC5086 X9641825A1 X9720379A	03/07/1996	5 MO M	Aiken, SC	Child was placed on adult bed with portable bed rail. He was found entrapped face down with his face towards the mattress between the bed rail and mattress. The cause of death was asphyxia.
9	970127CCN0290 G9710223A	01/15/1997	19 MO M	Chicago, IL	Child became trapped between a portable bed rail and upper bunk mattress on wall side of a bunk bed. The victim was hanging/suspended with the back of his head on the guard rail and his mouth pressed into the mattress. He died of pneumonia due to a cervical injury sustained by hanging.
10	980327HCC3723 X9832550A	03/18/1998	4 YR M	Bothell, WA	Mentally retarded boy became trapped between a wooden portable bed rail with vertical slats and mattress of a toddler bed. The victim's head/neck area was caught at the bottom of the bed rail with his head against the mattress and his torso and feet under the bed. The cause of death was asphyxia due to hanging.
11	990317HCC0349 9837042368	08/17/1998	7 MO M	Waynesville, NC	Child became trapped in a toddler bed with a youth guardrail. His head was entrapped between the bed's headboard and the youth bed rail. The cause of death was asphyxia.
12	990712HCC0579 9837061207	11/07/1998	5 MO F	Raleigh, NC	Child was found stuck between the mattress of a king size bed and a portable guard rail with her chin on the mattress, according to her grandfather. The cause of death was asphyxiation. The Medical Examiner believes the child's neck was resting on the guardrail causing strangulation.

	Document #	Date	Age/Sex	City/State	Narrative
13	000814CCC2740 9931005502	04/29/1999	4 MO F	Gering, NE	Child was found between mattress (crib size) and the netting of a bed rail. Her face was against the mattress. The toddler bed this occurred on did not come equipped with bed rails. The caregiver purchased a bed rail and attached it to the bed. Death due to postural asphyxia.
14	000913HWE6005 H0090103A X0072883A	05/21/2000	6 MO F	Sacramento, CA	Child was sleeping with parents (who are hearing impaired) in their queen size bed using a portable bed rail. She was discovered on her side wedged between the bed rail and mattress. The cause of death was probable positional asphyxia. Father said that although the rail was positioned between the mattress and boxspring it did not stay in place. Police photographs show a gap measured of 3 inches between the rail and mattress.

Total Deaths=14

	Incidents with injury				
1	900706HWE5005 F9075005A	06/22/1990	23 MO M	San Francisco, CA	Child became entrapped between bed and portable guard rail. The rail shifted out of position when the child rolled against it. His torso was trapped in the space with his head towards the floor and under a bed placed perpendicular to his twin bed. He was gasping for air when found and suffered a scraped nose and a bruise to the back of his head.
2	H9130132A1	01/00/1991	14 MO M	Phoenixville, PA	Child was in adult bed and rolled against a mesh-sided bed rail, creating a 5-6 inch space. He slipped through the space and was caught at the chin on the bed rail, causing a red mark on his neck. Two poles slip under the mattress to secure the bed rail in place.
3	H9560295A	05/00/1995	6 MO M	Avon, MA	Child was found dangling upside down between the mattress and wooden bed rail with his left foot and right arm caught between the bed rails slats. He had an indentation and red marks on the right side of his head, a bruise on his back and swelling on his left arm. Type of bed not specified in report.

	Document #	Date	Age/Sex	City/State	Narrative
4	H9660068A	06/09/1996	30 MO M	Sheffield, MA	Child was sleeping in a twin bed with a side rail that has 2 bars that insert between the mattress and box spring. Victim pushed side rail outwards from the bed and slipped feet first through the side rail. His head was stuck between the mattress and side rail. He suffered a bruise to his right temple.
5	990119CCC1231 H9910102A	01/04/1999	9 MO F	Easley, SC	The product involved was a metal-framed bed rail with mesh netting composed of two pieces that snap together with plastic couplers. It was used on the victim's twin bed. She was found with her head and neck caught in a space between the bed and the bottom of the bed rail due to the middle of product partially disengaging into a "v" where it snaps together. She was in a semi-standing position on her tiptoes. She suffered a contusion/red mark to her neck.
6	I0110381A	01/21/2001	3 YR F	Pembroke Pines, FL	Portable bed rail was used on the child's bed. While sleeping she wedged her foot between the bed and bed rail, suffering a hairline fracture to her foot. Over the year and a half on use, the child has often managed to move the bed rail out (usually by rolling into it in her sleep). The child has been found on the floor some mornings with the bed rail almost completely out.
7	H0140013A	04/01/2001	19 MO M	Cave Creek, AZ	Child's neck became trapped in the 4-5 inch space between the mattress and mesh bed rail. Consumer pulled the bed rail outwards to create a bigger space to free her son. He suffered a red mark to the neck area under his chin.

Total Injuries=7

	Document #	Date	Age/Sex	City/State	Narrative
	Incidents with No Injury				
1	921211CCC1111 H92B0011A0	10/28/1992	3.5 YR M	N. Kingston, RI	Portable bed rail was used on a single bed for a child with cerebral palsy. The rail folded down from the upright position and the child was found dangling between the rail's frame and the mattress. He was facing forward with his back against the mattress and his neck and upper body caught in the 1.25 inch opening . No injury.
2	920325CNE5107 N9230050	03/18/1992	3 YR F	Riverdale, NY	Head got caught between a portable bed rail and the mattress of the bed. Thinks child pushed against the rail causing it to move out from the mattress, letting her slip through the space feet first. No injury.
3	950418CCC2596 C9530032A1	07/15/1993	3 YR M	Churubusco, IN	Child was in an adult size double bed with a guard rail installed. He was found asleep with his hips between the mattress and bed rail and his legs below the rail. His torso was still on the mattress. The bed rail extenders had slid out from under the mattress. No injury involved.
4	H9590203A	01/00/1994	3.5 YR M	Marinette, WI	Got head and upper body caught in a space between the guard rail and the side of the mattress. The curved metal pieces with rubber stoppers which go between the mattress and box springs slide out when the child leans against the guard rail. No injury.
5	950601CNE5374 N560002A	05/19/1995	2 YR F	Sharpsburg, PA	Child became entrapped between the bottom rail of a portable bed rail and the mattress of the twin bed she was sleeping on. Her neck and face were towards the mattress and her feet were just touching the floor. No injury.
6	951002CNE5002 N95A0002A	08/27/1995	2 YR F	Orlando, FL	Child became entrapped between the bed rail and mattress of her twin bed when the bed rail attachment slipped out from under mattress. She was suspended with her face into the mattress and her feet dangling. No injury.
7	H9650180A	05/14/1996	23 MO M	Webster Grove, MO	Child leaned against wooden bed rail and his body became stuck between the bed's mattress and the bed rail in a 3-4 inch space. He was uninjured.

	Document #	Date	Age/Sex	City/State	Narrative
8	H9690202A	09/18/1996	17 MO M	Springfield, VA	Child rolled over in bed and the bed rail slid a little from underneath the mattress causing him to become lodged between the mattress and bed rail. No injury.
9	H96A0001A	09/30/1996	19 MO M	Charleston, IL	Child pushed bed rail's mesh side with his feet. The bed rail partially slid from underneath the mattress creating a space between it and the mattress. The child then slipped through the space getting caught at his thighs. No injury.
10	970327CCC1051	02/17/1997	2.5 YR M	Boca Raton, FL	Parents purchased a wooden bed rail with two arms that slid under the mattress for use with child's trundle bed. Child was found wedged in a space between the bed rail and mattress with his face pressed up against the mattress. He was partially off the bed with the top of his body and head wedged. The arms of the bed rail were still in place, but due to the flexibility of the rail a space was created by the child's weight. No injury was sustained.
11	H9770106A	06/25/1997	18 MO M	Washington, MI	Child became caught between a mattress and soft plastic mesh-sided safety rail. He was freed by placing pressure against the mesh siding. No injury.
12	980415CNE5131 N9840007A **(two events of entrapment)**	04/051998	30 MO M	Windsor Locks, CT	Child pushed his bed rail out from under his twin bed mattress and fell into the space between the mattress/box spring and bed rail twice. No injury. Bed rail was mesh-framed and had 2 tubes to place between the mattress and box spring.
13	C9910005	06/00/1998	3.5 YR F	Coppell, TX	Child was found wedged between the mattress and bed rail due to the flexibility of the "feet" and rail when leaned against. This created the space. There was no slipping of the bed rail involved. No injury reported.
14	H980139A	07/14/1998	2.5 YR F	Johnston, IA	Child was found with her head hanging down in the 5-6 inch space between the metal support of the guard rail and the mattress of her twin bed. No injury. Consumer feels the 4 inch long plastic rubber "stoppers" do not secure the guard rail to the mattress, causing it to move.

	Document #	Date	Age/Sex	City/State	Narrative
15	H98B0215A	11/22/1998	2.5 YR F	Willowgrove, PA	Child was found wedged between the bed rail and mattress after she pushed against the bed rail creating a 6-8 inch gap. Her arm and head slipped through the opening. The bed rail is held in place by two bars that slip under the mattress. Report does not mention an injury.
16	I99B0017 (two events of entrapment)	00/00/1999	Unk Age Male	Denver, Co	Portable bed rail has pulled out a foot from the bed and child was found on the floor twice and wedged twice in less than a week's time. It is unknown if the child was injured.
17	I99A0008	Between 08/00/97 and 10/01/99	1.5 YR M	Reading, PA	Child partially slipped through a mesh net bed rail attached to parents' bed. Child was freed and no injury is mentioned. Parent now makes sure new bed rail is firmly pushed against the bed when in use.
18	I0090333	07/00/2000	19 MO M	Santa Cruz, CA	Child got his head stuck between his bed rail and his bed. He is in a twin bed with a bed rail that slips under the mattress. Parent has since stuffed pillow in the space between the railing and mattress. No injury.
19	I0090083	07/00/2000	2 YR F	East Lansing, MI	Child became trapped between the side of the mattress of her twin bed and a bed rail. Her entire body was off the bed and stuck. No injury. Mother pushes bed rail in every night before child goes to sleep.
20	I0080308	08/20/2000	17 MO F	Penn Valley, PA	Bed rail was installed on a queen size bed at grandmother's house. It had some "give" when locked in place. Mother said the rail would rotate about 15 degrees or more, leaving room for the child to slide down below the part of the bed rail that would keep her on the bed. Child fell between the bed rail and the bed and was caught by the neck, facing away from the mattress, at the lower part of the bed rail.
21	I0110300	10/00/2000	18 MO F	Pittsburgh, PA	Child was asleep and leaned against the bed rail, pushing it out away from the mattress. She fell between the mattress and bed rail where she became entrapped. (Consumer talked to CPSC engineer and confirmed entrapment scenario.)

	Document #	Date	Age/Sex	City/State	Narrative
22	I0140260	04/13/2001	22 MO F	Oak Harbor, WA	Child got caught between the bed rail and the mattress, wedged so tightly she couldn't move. Mother had bought and tested (?) every bed rail on the market and thought this was the safest. Consumer had rolled against the railing with her full adult body weight and it did not move. However, after a couple of weeks of use the incident happened with the daughter.
23	H0150260A	05/11/2001	4 MO M	Cumberland, RI	Child was in twin size bed with a rectangular mesh bed rail with two metal arms. Consumer found son in a crevice created between the bed rail and mattress. Child was crying and taking deep breaths.
24	I0150377A	05/23/2001	2 YR F	Ham Lake, MN	Bed rail was mesh with legs that go between then mattress and box spring. Child slipped between the side of the bed and the rail trapped by her neck between the bottom rail the bed. Her bottom ended up on the ground so she was not dangling. No injury.
25	H0170010A	07/02/2001	22 MO M	Wichita, KS	Consumer found son trapped in between the plastic portable bed rail and the son's twin size bed. No injuries.
26	**I0180231 (two events of entrapments)**	08/15/2001	27 MO M	Las Vegas, NV	Week previous to 8/15 incident the child was caught between the rail and bed, hanging above the floor. During this first incident the child was in a vertical position with his upper body above the rail, but on 8/15 the only thing holding him up was his head and an arm. Unknown if injured.

Total Near-Misses=29

Source: U.S. Consumer Product Safety Commission, INDP, IPII, DTHS and NEISS

TAB B

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: September 27, 2001

To : Patricia L. Hackett, Division of Mechanical Engineering
Project Manager, Portable Bed Rails
Ext. 1309

Through : Hugh McLaurin, Associate Executive Director
Directorate for Engineering Sciences
Nick Marchica, Director, Division of Mechanical Engineering

From : Scott Heh, Mechanical Engineer, Division of Mechanical Engineering
Ext. 1308

Subject: *Draft Proposed Safety Standard for Portable Bed Rails*

In May 1999, CPSC staff developed a draft proposed safety standard for portable bed rails for consideration by the ASTM Subcommittee for Portable Bed Rails. This draft standard was included in a briefing package that transmitted a draft Advance Notice of Proposed Rulemaking (ANPR) to the Commission in September 2000. The ANPR was approved by the Commission and published in the Federal Register in October 2000. Since May 1999, there have been several ASTM Subcommittee and task group meetings that focussed on the development of a performance based safety standard. In these meetings, and in written comments responding to the ANPR, portable bed rail manufacturers stated several concerns regarding the CPSC staff proposed standard.

The attached draft standard contains several revisions to the May 1999 version. Some of these revisions respond to industry comments on the proposed standard. Other revisions are based on further information and analysis completed by CPSC staff since the publication of the ANPR. This draft standard was the subject of an ASTM Portable Bed Rail task group meeting held on September 26, 2001.

The most significant change contained in the attached draft standard is the addition of a torso probe and wedge probe test that replaces the 50-pound push out test that was proposed in the May 1999 draft. Other changes in the standard include: testing on the lower foundation of a bunk bed assembly, testing on a thick and a thin mattress, testing that is specific to the design characteristics of the product, and testing for hazardous protrusions. Rationale for these provisions is included in the attached document. The revised draft standard also contains improved provisions for warning labels and instructions.

DRAFT 9/27/01

STANDARD CONSUMER SAFETY SPECIFICATION FOR PORTABLE BED RAILS

1. Scope

1.1 This consumer safety specification establishes requirements for the design and performance of portable bed rails. It also contains requirements for labeling and instructional material.

1.2 This consumer safety specification is intended to minimize hazards to children resulting from normal use and reasonably foreseeable misuse of portable bed rails.

1.3 For the purpose of this consumer safety specification, a portable bed rail is a device intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2 years to 5 years of age).

1.4 The values stated in inch-pound units are to be regarded as the standard. The SI values given in parentheses are for information only.

1.5 The following precautionary caveat pertains only to the test methods portion in Section 7 of this specification: *This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 3359 Test Methods for Measuring Adhesion by Tape Test

2.2 *Federal Standards:*

16 CFR Part 1500 - Federal Hazardous Substances Act Regulations, including Sections:

1500.48 - Technical Requirements for Determining a Sharp Point in Toys and Other Articles Intended for Use by Children Under 8 Years of Age,

1500.49 - Technical Requirements for Determining a Sharp Metal or Glass Edge in Toys and Other Articles Intended for Children Under 8 Years of Age,

16 CFR Part 1501 - Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration or Ingestion Hazards Because of Small

Parts.

16 CFR Part 1303 - Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint;

3. Terminology

3.1 *Description of Terms Specific to This Standard:*

3.1.1 *arm, n - for the purpose of this specification,* a device(s) attached to a bed rail that extends between the mattress and mattress foundation and is intended to help secure the bed rail to the bed.

3.1.2 *portable bed rail, n* - a portable railing installed on the side of an adult bed and/or the mattress surface which is intended to keep a child from falling out of bed.

3.1.3 *permanent, adj.* - a marking or label shall be considered permanent if, during an attempt to manually remove it without the aid of tools or solvents, it cannot be removed, or it tears upon removal, or such action damages the surface to which it is attached.

3.1.4 *conspicuous, adj*-- a label that is visible, when the portable bed rail is in the manufacturer's recommended use position, to a person standing near the unit at any one position around the unit but not necessarily visible from all positions.

3.1.5 *nonpaper label, adj*—any label made of fabric or other material (such as plastic or metal) which either will not tear without the aid of tools, or tears leaving a sharply defined edge.

3.1.6 *paper label, adj*—any label material (except fabric) which tears without the aid of tools and leaves a fibrous edge.

3.1.7 *adjacent type bed rail, n*—a portable bed rail in which the guard portion (portion that a child would contact when rolling toward the mattress edge) of the unit is essentially a vertical plane that is pushed against the side of the mattress. The guard remains immediately next to the mattress and does not extend over the mattress surface.

3.1.8 *mattress-top bed rail, n*—a portable bed rail in which the guard portion (portion that a child would contact when rolling toward the mattress edge) extends over the sleeping surface of the mattress.

4. General Requirements

4.1 *Wood Parts,* shall be smoothly finished and free from splinters.

4.2 *Federal Regulations* - Bed rails shall conform to the following Federal regulations:

- 16 CFR Part 1303 Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint;
- 16 CFR Part 1500 Federal Hazardous Substances Act Regulations, including:
  - Section 1500.48 Technical Requirements for Determining a Sharp Point in Toys and Other Articles Intended for Use by Children Under 8 Years of Age;
  - Section 1500.49 Technical Requirements for Determining a Sharp Metal or Glass Edge in Toys and Other Articles Intended for Children Under 8 Years and Age; and
- 16 CFR part 1501 Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration or Ingestion Hazards Because of Small Parts.

5. Performance Requirements

5.1 *Enclosed Openings*:

5.1.1 When tested in accordance with 7.1, there shall be no openings in the structure of the bed rail that will permit complete passage of the Torso Probe shown in Fig. 1.

5.2 *Openings Created by Bed Rail Displacement of Adjacent Style Portable Bed Rails*:

5.2.1 When tested in accordance with the procedure in 7.2, there shall be no opening between the mattress and the bed rail that will permit complete passage of the Torso Probe shown in Fig. 1. Complete passage is defined as the entire Torso Probe passing the horizontal plane that extends from the top surface of the mattress toward the guard portion of the bed rail.

5.3 *Openings Created by Displacement of Mattress-Top Portable Bed Rails:*

5.3.1 When tested in accordance with the procedure in 7.3, the Wedge Probe (Fig. 2) shall not penetrate to a depth greater than 4.5 inches and the bed rail shall not displace horizontally such that the inner edge of the bed rail moves off the top mattress surface. The inner edge of the bed rail is the edge where the Wedge Probe is inserted.

5.4 *Protrusions:*

5.4.1 Neither string on the weight gage shall stay attached to a protrusion when tested in accordance with the procedure in 7.4.

5.5 *Openings between bedposts (headboard, footboards, etc.) and ends of portable bed rail*

5.5.1 When installed in accordance with the manufacturer's instructions on test platforms 1, 2, and 3, there shall be a minimum of 9-inches (229-mm) between the left and right ends of the portable bed rail and the corresponding left and right ends of the test mattress.

6. Test Equipment

6.1 Test Beds:

6.1.1Test Platform 1:

(a) Mattress: The mattress shall be a standard twin size, approximately 39 in. by 75 in. (0.99 m by 1.91 m). The mattress shall be made from open cell polyurethane foam padding and be 4 in. (100m) thick[1] with a density of approximately 1 lb/ft^3 (16 kg/m^3). The covering material (ticking) for the mattress shall be a printed, non-woven fabric. There shall be no surface texture features (e.g., quilting) on the test mattress. The mattress shall be covered with a standard twin sized cotton fitted sheet.

(b) Mattress Support: The support shall be a common twin sized box spring measuring approximately 6 in. thick by 39 in. by 75 in. (150 mm by 0.99 m by 1.91 m). The box spring shall be of typical frame construction that is topped with a rigid board that has a layer of approximately ¼ in. to 3/8 in. of open cell foam and covered with a non-woven fabric similar to that of the test mattress.

6.1.2 Test Platform 2:

(a) Mattress: The mattress shall be a standard twin size, approximately 39 in. by 75 in. (0.99 m by 1.91 m). 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[1] with a minimum 400 coils (based on a full-size design) made from 12

[1] Thickness is measured when the mattress is located on a box spring. Measurement is from the top surface of the box spring to the center of the top-ticking seam.

3/4 - 14 gauge steel. There shall be no pillow top padding on the surface of the test mattress. The mattress shall be covered with a standard twin sized cotton fitted sheet.

(b) Mattress Support: The support shall be a common twin sized box spring measuring approximately 6 in. thick by 39 in. by 75 in. (150 mm by 0.99 m by 1.91 m). The box spring shall be of typical frame construction that is topped with a rigid board that has a layer of approximately ¼ in. to 3/8 in. of open cell foam and covered with a non-woven fabric similar to that of the test mattress.

6.1.3 Test Platform 3:

(a) Mattress: The mattress shall be a standard twin size, approximately 39 in. by 75 in. (0.99 m by 1.91 m). The mattress shall be made from open cell polyurethane foam padding and be 4 in. (100m) thick[1] with a density of approximately 1 lb/ft^3 (16 kg/m^3). The covering material (ticking) for the mattress shall be a printed, non-woven fabric. There are no surface texture features (e.g., quilting) on the test mattress. The mattress shall be covered with a standard twin sized cotton fitted sheet.

(b) Mattress Support: The support shall be the lower mattress foundation of a common tubular metal bunk bed. The lower foundation shall consist of tubular metal slats approximately 5/8 inch diameter and spaced from 3.5 to 4 inches apart.

6.2. Torso Probe: Block shall be fabricated from a rigid material and have a smooth finish. This probe is to be used for test methods 7.1 and 7.2. (See Figure 1)

6.3 Wedge Probe: Block shall be fabricated from a rigid material and have a smooth finish. This probe is to be used for test method 7.3. (See Figure 2)

6.4 Test Board - A rectangular rigid board that is 4.5 in. by 15.6 in. (114 mm by 370 mm) and a minimum thickness of ½ in. (12 mm). This test board is to be used for test method 7.1.

6.5 Ring gage – A plastic ring with a 1.0-in. O.D. and a 0.625-in. I.D. (See Figure 3). This gage is used for protrusion testing.

6.6 Weight Gage – A 4.4 lb. Weight. Attached to the weight are a 30-in. (762 mm) loop of cord and a 6-in. (152-mm) loop of cord. The materials are steel and # 18 seine twine/mason line (See Figure 4). This gage is used for testing protrusions.

6.7 Test Load – Weights with a total mass of 30 lbs (13.6 kg) that are distributed evenly along the length of the test board.

7. Test Methods

7.1 Test method – for Enclosed Openings Within Portable Bed Rail.

7.1.1 Install the bed rail on Test Platform 1 in accordance with the manufacturer's instructions.

7.1.2 Place the test board on the mattress. Align the long side of the test board with the edge of the mattress adjacent to the bed rail and center the test board within the length of the bed rail. Slide the test board to the right along the mattress surface until the end of the test board is aligned with the right end of the portable bed rail. Distribute the 30-lb test load evenly along the length of the test board.

7.1.3 Place the Torso Probe shown in Fig. 1 into any opening in the bed rail at and around the area where the test load compresses the mattress and any other opening in the rail above the test load compression area. Place the probe, tapered end first, in the orientation most likely to permit its passage and gradually apply a force of 30-lbf (133 N) in a direction perpendicular to the plane of the opening. Sustain the force for 5 seconds.

7.1.4 If the portable bed rail moved during testing, reinstall the bed rail according to the manufacturer's instructions.

7.1.5 Keeping the long side of the test board aligned with the mattress edge, slide the test board 15-inches (380-mm) to the left along the length of the portable bed rail. Repeat the Torso Probe test in 7.1.3. Continue testing with the Torso Probe along the entire bed rail length, sliding the test board at intervals no greater than every 15 in. (380 mm).

7.1.6 Repeat 7.1.1 – 7.1.5 with the portable bed rail installed on Test Platform 2.

7.1.7 Repeat 7.1.1 – 7.1.5 with the portable bed rail installed on Test Platform 3.

1

7.2. Test Method for Displacement Test for Adjacent Style Portable Bed Rails

7.2.1 Install the portable bed rail on Test Platform 1 in accordance with the manufacturer's instructions. The bed rail shall be centered along the length of the mattress.

7.2.2 Starting at one end of the rail, place the tapered end of the Torso Probe shown in Fig. 1 into the intersection of the mattress edge and the face of the rail. Gently apply sufficient force to the probe to create a small gap such that the tapered end enters the gap to a depth of ½-in (13-mm). Align the probe in the orientation most likely to permit its passage (generally with vertical centerline of the probe as close as possible to perpendicular to the plane of the gap opening).

7.2.3 Gradually apply a force of 30-lbf (133 N) along the probe centerline in a manner to force the probe through the opening. Sustain the force for 5 seconds.

7.2.4 Reinstall the bed rail prior to testing a new location.

7.2.5 Repeat the probe test along the entire length of the bed rail, at intervals not to exceed 12-inches (0.3 m).

7.2.6 Repeat 7.2.1-7.2.5, with the portable bed rail installed on Test Platform 2.

7.2.7 Repeat 7.2.1-7.2.5, with the portable bed rail installed on Test Platform 3.

7.3 *Test Method for Displacement of "Mattress-Top" Style Portable Bed Rails*

7.3.1 Install the portable bed rail on Test Platform 1 in accordance with the manufacturer's instructions.

7.3.2 Starting at one end of the bed rail, place the Wedge Probe shown in Fig. 2 on its side with the tapered end between the mattress and the underside of the inner edge of the rail. The longer side of the probe that forms the right angle shall be against the mattress surface. The short side of the right angle shall be perpendicular to the mattress surface. Push the probe under the guard to a depth of ½-inch (13-mm).

7.3.3 Gradually apply a force of 30-lbf (133 N) to the short side of the probe in a direction toward the bed rail and parallel to the mattress surface. Sustain the force for 5 seconds.

7.4 *Test Method for Entanglement on Protrusions*

7.4.1 Place the product in the manufacturer's recommended use position. Using the ring gage (Fig. 3), evaluate the unit's protrusions using the following procedure. Evaluate the inside (facing

toward center of bed) and outside of the product from the center of the top rail to a plane 11 in. (280 mm) from the floor. Orient the ring gage perpendicular to the plane of the protruding object. Attempt to place the ring gage hole over the protrusion. If the protrusion extends beyond the outer face of the ring gage, continue evaluating by means of the string and weight gage (Fig. 4). Place the short string around the protrusion with the weight freely hanging down. Then place the long string around the protrusion with the weight hanging over the top rail and freely hanging on the other side (Fig. 5).

8 Marking and Labeling

8.1 Each product and the retail packaging shall be marked clearly and legibly to indicate the following:

8.1.1 Name and place of business (city, state and mailing address, including zip code, or toll-free number) of the manufacturer, importer, distributor, or seller.

8.1.2 Model number, stock number, catalog number, item number, or other symbol expressed numerically, or otherwise, such that only articles of identical construction, composition, and dimensions shall bear identical markings. The manufacturer shall change the model number whenever a significant structural or design modification is made that affects its conformance with this consumer safety specification.

8.1.3 Code mark or other means that identifies the date (month and year as a minimum) manufactured.

8.2 Any upholstery label required by law shall not be used to meet the requirements of 8.1.

8.3 Each product and the principle panel of the retail packaging shall have warning statements. The warning statements shall be in contrasting colors, permanent, conspicuous, and san serif style font. The warning statements shall be preceded by the safety alert symbol " ! " and the word "WARNING." The word "WARNING" and the safety alert symbol 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.

8.3.1 The warning statements shall include exactly as stated below:

Suffocation and Strangulation Hazard.

Bed rail can trap young children against mattress, headboard, or footboard.

- Do NOT use with children under 2 years old. Use only with children who can get in and out of adult bed without help.
- ALWAYS keep bed rail pushed firmly against mattress and at least 9 inches from headboard and footboard.
- Do NOT use on toddler bed, bunk bed, waterbed, or bed with inflatable mattress. Use only on adult bed with mattress and box spring.

8.4 These warnings shall be visible on the product when in the manufacturer's use position. If not, an additional conspicuous label using the safety alert symbol " ! ," the word "WARNING," and a description of the location of the warnings shall be provided. The same character size requirements are to be followed for this warning as described in 8.3.

9. Permanency of Labels and Warnings

9.1 A paper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed, it tears into pieces upon removal, or such action damages the surface to which it is attached.

9.2 A nonpaper label (excluding labels attached by a seam) shall be considered permanent if, during an attempt to remove it without the aid of tools or solvents, it cannot be removed or such action damages the surface to which it is attached.

9.3 A warning label attached by a seam shall be considered permanent if it does not detach when subjected to a 15-lbf (67-N) pull force applied in any direction using a ¾-in. (19-mm) diameter clamp surface.

9.4 *Adhesion test for warnings applied directly onto the surface of the product.*

9.4.1 Apply the tape test defined in Test Method B, Cross-Cut Tape Test of Test Methods D 3359, eliminating parallel cuts.

9.4.2 Perform this test once in each different location where warnings are applied.

9.4.3 The warning statements will be considered permanent if the printing in the area tested is still legible and attached after being subjected to this test.

9.5 A nonpaper label, during an attempt to remove it without the aid of tools or solvents, shall not be removed or shall not fit entirely within the small parts cylinder defined in 16 CFR 1501 if it can be removed.

10. Instructional Literature

10.1 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.

10.1.1 The instructions shall contain statements, which are stated exactly as the warning statements in 8.3.1 and the following: Discontinue use if damaged, broken or if parts are missing.

10.2 Warning statements located within the instructional literature shall meet the same requirements as specified in 8.3.

FIGURES

Figure 1 - Torso Probe

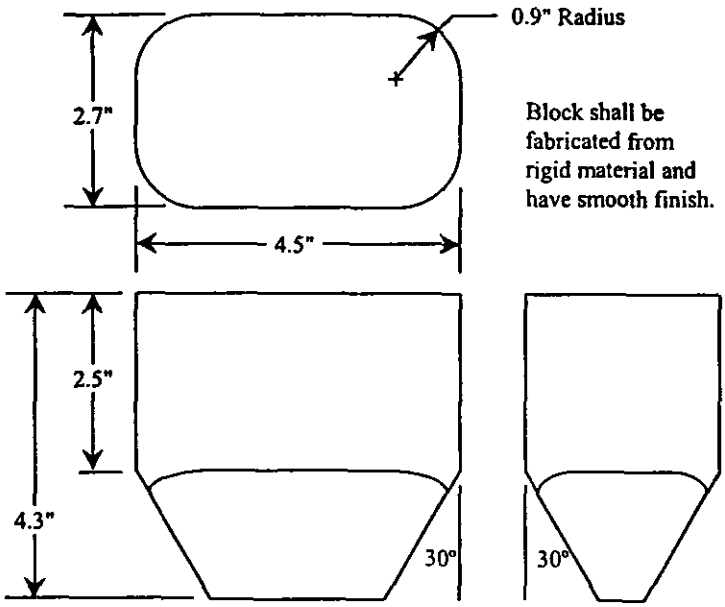
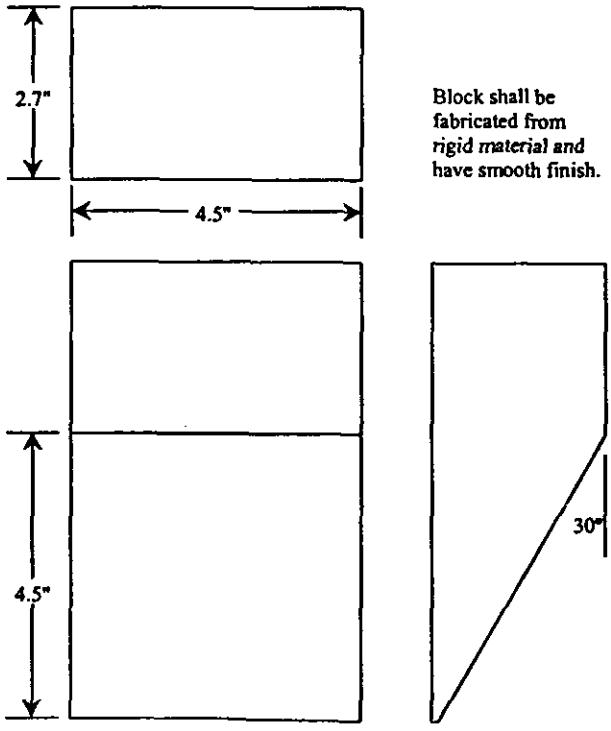
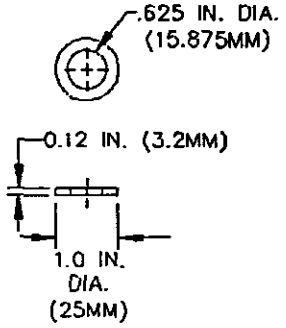


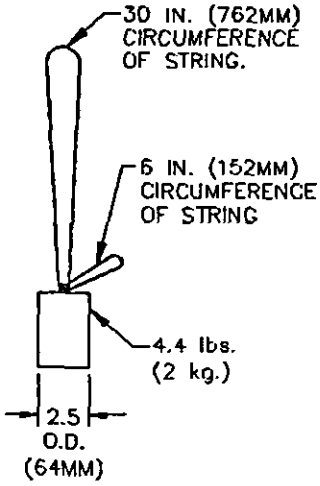
Figure 2 -Wedge Probe





Material: plastic

Figure 3 Ring Gage



Material: Steel and
18 seine twine/mason line

Figure 4 Weight Gage

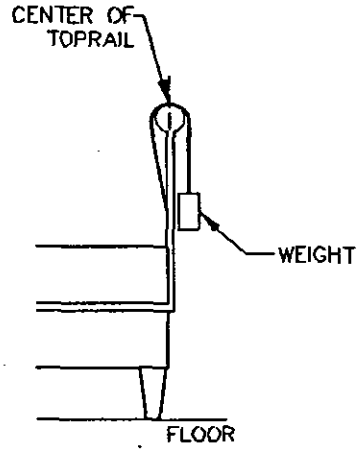


Figure 5 Test over top rail

RATIONALE

Section 1.3 CPSC staff recommends that infants never be placed in an adult bed. Since portable bed rails are intended for use on adult beds, CPSC staff recommends that bed rails be intended and labeled for use by children ages 2 to 5 years.

Sections 5.1, 5.2, 5.3: Fatal incidents associated with portable bed rails involved children ranging in age from 3 months to 4 years. Eight of these incidents involved children under the age of 1-year. Four incidents involved children between one and two years of age. Two children were older than 2 years (2 ½ years and 4 years). Three of the children were disabled, including the two oldest children. Since the fatal incidents (without physical or mental impairment contributing factors) involved children ranging in age from 3 months to almost 2 years, the staff recommends that the torso and wedge probes be based on the body dimensions of the youngest user at risk. The width at the top of the probes (2.7 inches) is based on the 5th percentile hip depth of a 3 to 4-month-old child. The length of the probes (4.5 inches) is based on the 5th percentile hip breadth for children 3 to 5 months of age.

The use of a torso or wedge probe is consistent with other established standards that address entrapment risks such as standards for playground equipment and bunk beds.

Section 5.4.1: Protrusions can present strangulation hazards by creating catch points for strings and loose clothing. One of the bed rail related fatalities involved a 14-month-old child who hung by his shirt collar that was caught on a protrusion. The proposed protrusion provisions are copied from a requirement now being proposed for the ASTM Standard for Children's Play Yards.

Section 5.5: A 9-inch gap between the end of a portable bed rail and the end of a mattress ensures that if a child's body falls into an opening between the end of a rail and a bedpost, the child's head will also fall through the opening, avoiding an entrapment.

Sections 6.1.1 through 6.1.3:

Test Platform 1 is lightweight, inexpensive, and commonly available. The mattress is combined with a typical box spring support. This bed was chosen to represent a reasonably foreseeable use that would be a "worst case" mattress for portable bed rail retention performance.

Test Platform 2 is a moderately priced, thick mattress. It was chosen to ensure that bed rail performance was not influenced by mattress thickness. Bed rails should be designed to accommodate a variety of mattress thicknesses, from the thinnest (Test Platform 1) to the thickest (Test Platform 2).

Test Platform 3 is a lower mattress foundation[2] of a tubular metal bunk bed. Even though PBRs should not be used on toddler beds and bunk beds, over 40% of the fatalities occurred on these types of beds, indicating that the installation of PBRs on non-adult beds is a reasonably foreseeable misuse of the product. Toddler beds and metal bunk beds often use similar support platforms in lieu of a box spring, in which the mattress support consists of tubular metal slats. Other types of bunk beds may have support systems that consist of wires or wooden slats. Some beds use a base called a bunkie board, which is typically a solid board that rests under the mattress. Because all of these support systems are less likely to contribute friction to hold the PBR arms, it makes them more susceptible to being pushed out of position. A metal tubular, lower foundation bunk bed has been included as part of the test platform requirements in the proposed standard. The metal tubular design was selected because it is a common foundation that can be found on many types of non-adult beds. This in no way reflects an approval or recommendation by staff to use PBRs on non-adult type beds, but it does ensure that PBRs will have to be designed so that they will reduce the entrapment hazard when used on other types of potential support platforms.

Section 6.4: The test board width is based on the 5th percentile hip breadth of a 3- to 5-month-old (4.5 inches). The 14.6-in length of the test board is based on crown-rump body length of a 5th percentile 3- to 5-month old child.

Sections 7.1, 7.2, 7.3: All forces and test loads are either 30 lbf or 30 lbm. This is based on the

[2] The lower bed foundation is the lower bunk that has a bed foundation that is less than 30-inches above the ground. Any bed foundation that is greater than 30-inches above the ground is already required to have guardrails on both sides per the bunk bed mandatory standard (16 CFR Parts 1213, 1500, and 1513).

95th percentile weight of a 19-month-old boy (based on CDC growth charts) of 31.5 pounds. A 19-month old was chosen since that is the oldest fatality to date, ignoring those with physical or mental impairments. Thus, the force of 30 pounds approximately equals 31.5 minus the weight of the probe itself (since the weight of the probe will help push it through a gap between the PBR and mattress). To provide confidence that an opening does not pose an entrapment hazard, the staff believes it is appropriate to combine the body dimensions of the youngest user at risk (3-month-old) with the body weight of the oldest user at risk (19-month old).

TAB C

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

MEMORANDUM

September 26, 2001

To: Patricia L. Hackett
Project Manager, Portable Bed Rails Project
Division of Mechanical Engineering, Directorate for Engineering Sciences

Through: Hugh M. McLaurin
Associate Executive Director
Directorate for Engineering Sciences

Through: Robert B. Ochsman, Ph.D.
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 Assessment for the Portable Bed Rails Project

Introduction

Staff from the U.S. Consumer Product Safety Commission (CPSC) has proposed a safety specification for the design and performance of portable bed rails, which are meant to prevent children from falling out of beds. The intent of this specification is to minimize entrapment and hanging incidents to children resulting from normal and foreseeable use of these products. Staff from CPSC's Division of Human Factors (ESHF) has been requested to propose dimensional requirements for a wedge-shaped probe to be used in performance testing, force requirements to be used in conjunction with the wedge-shaped probe, and labeling requirements for portable bed rails.

Discussion: Probe Design & Force Requirements

Adjacent-Type Portable Bed Rails

Adjacent-type portable bed rails are those in which the guard portion of the product is essentially a vertical plane that is pushed up against the side of the mattress and does not extend over the mattress surface. A gap or separation between the portable bed rail and mattress can present a risk of entrapment. CPSC staff had originally considered a simple pull-out performance test requirement for portable bed rails, but this was abandoned for several reasons. First, it is obvious that a portable bed rail that slides away from the side of the bed can create a hazardous gap.

However, a portable bed rail that is designed to mount to the bed frame could still create a gap if the top mattress were to slide away from the bed rail. In addition, a pull-out test that is based on children's maximum pushing capabilities also presumes that children are deliberately pushing out the portable bed rail and becoming entrapped in the resulting gap. Most incidents do not appear to be a consequence of children intentionally pushing out the portable bed rail, but are rather a result of children rolling into the bed rail during sleep—thereby creating a gap—and rolling into that gap. Therefore, CPSC staff believed a wedge-shaped probe that approximates a child's body should be used to test the entrapment potential. Since small children would fit into a gap more easily than large children, ESHF staff believes such a probe should be designed based on the anthropometric dimensions of the smallest children at risk.

From January 1, 1990 through March 9, 2001, CPSC has received reports of 14 entrapment or hanging fatalities associated with portable bed rails (McDonald, 2001). The ages of the victims at the time of the incident ranged from three months to four years. Eight of these incidents involved children under one year of age, and three involved children between one and two years of age, the oldest being 19 months. The remaining three incidents involved children two years old or older, but all three of these children suffered from some form of physical and/or mental impairment (i.e., cerebral palsy, mental retardation, or brain deformities), which could have contributed to the fatalities. Therefore, all fatal incidents to non-impaired children occurred to children from 3 to 19 months of age. For this reason, ESHF staff believes it is reasonable to design the probe based on the 5th percentile dimensions of children approximately three months old. Figure 1 shows the proposed design for use with portable bed rails.

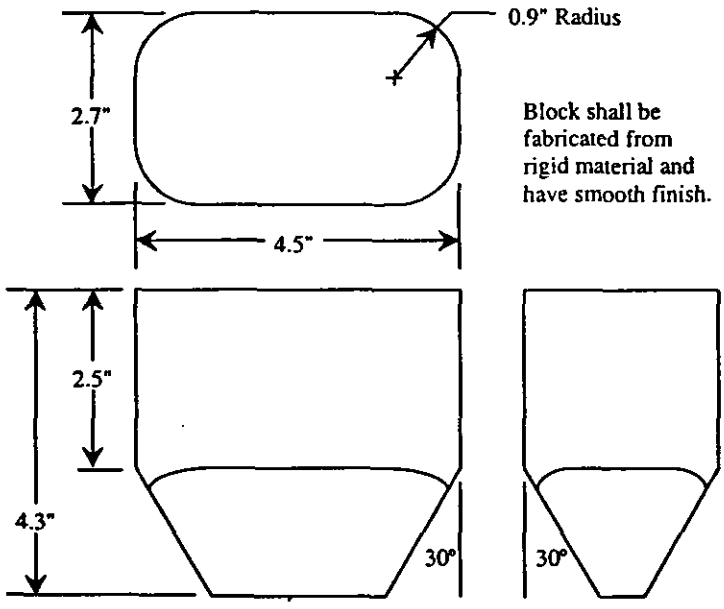


Figure 1: Proposed probe design for adjacent-type portable bed rails.

This design is essentially a scaled-down version of the probe specified in the federal mandatory standard for bunk beds (16 CFR, Part 1213). The two top-view dimensions are based on the 5th percentile hip breadth of children three to five months of age (4.5 inches) (Snyder, Schneider, Owings, Reynolds, Golomb, & Schork, 1977) and the 5th percentile hip depth of children three

to four months of age (2.7 inches) (Snyder, Spencer, Owings, & Schneider, 1975). ESHF staff believes that a portable bed rail that will not permit passage of this probe will not permit passage of the torsos of those children most at risk for entrapment.

When a child begins to enter the gap between a portable bed rail and mattress, his or her own weight can assist in pulling the child into and through the gap. Since the oldest non-impaired child involved in a fatal incident was 19 months of age, ESHF staff believes that the force to be applied in performance testing should, at a minimum, be based on the weight of the heaviest 19-month-olds to provide a margin for safety. According to CDC growth charts, the 95th percentile weight of a 19-month-old male is approximately 31.5 pounds (National Center for Health Statistics & National Center for Chronic Disease Prevention and Health Promotion, 2000). This value exceeds the 95th percentile weight of a female of the same age, meaning more than 95% of all children 19 months old would weigh less than this. Since the probe would be applied between the mattress and portable bed rail in the same way as a child who becomes "wedged" between these two, the weight of the probe itself would also tend to pull it into this space. Hence, ESHF staff believes it is reasonable to use approximately 31.5 pounds minus the weight of the probe as the minimum force to be applied during performance testing of portable bed rails. Laboratory Sciences estimates that the weight of such a probe could be approximately 1 ½ pounds, so ESHF believes that 30 pounds would be an acceptable force to use for performance testing of portable bed rails.

There have been non-fatal incidents of entrapments involving portable bed rails to children over 19 months of age. In fact, the oldest non-disabled children involved in entrapment incidents were approximately 3 ½ years old (McDonald, 2001). However, these children are at a reduced risk for entrapment and the proposed performance testing criteria should protect some of these older children as well. For example, the probe is to be fabricated from a rigid material, will have a smooth finish, and is designed in a wedge shape to encourage easy passage of the probe between the mattress and portable bed rail. A child's body, on the other hand, does not have these characteristics and offers greater resistance to passage into this space. The performance test also focuses the entire force on a small, compact area (i.e., the area in contact with the probe) based on the smallest dimensions of an infant approximately three months of age. Children of this age would be incapable of exerting 31.5 pounds between the mattress and portable bed rail, and a child who could exert 31.5 pounds in this space would exert this force over a larger surface area than proposed in performance testing. Lastly, the 95th percentile weight of a 3 ½-year-old is about 40 pounds (NCHS & NCCDPHP, 2000). Therefore, it is unlikely that even these children would exert more than 31.5 pounds on the space between the portable bed rail and the mattress unless the child's body was already in the gap.

Mattress-Top Portable Bed Rails

Mattress-top portable bed rails are those in which the guard portion of the product extends over the sleeping surface of the mattress. Portable bed rails of this kind limit access to any gap between the portable bed rail and the side of a mattress. However, there is the potential for children to slip beneath the guard portion of the portable bed rail or to push the bed rail off the mattress. CPSC staff believes that performance testing with a wedge probe in the shape of a right triangle could address these hazards. Given that the same age children would be at risk as with

adjacent type portable bed rails, ESHF staff has designed the wedge probe based on the same anthropometric dimensions as those used for the probe discussed earlier. Figure 2 shows the proposed wedge design for use with portable bed rails of this type.

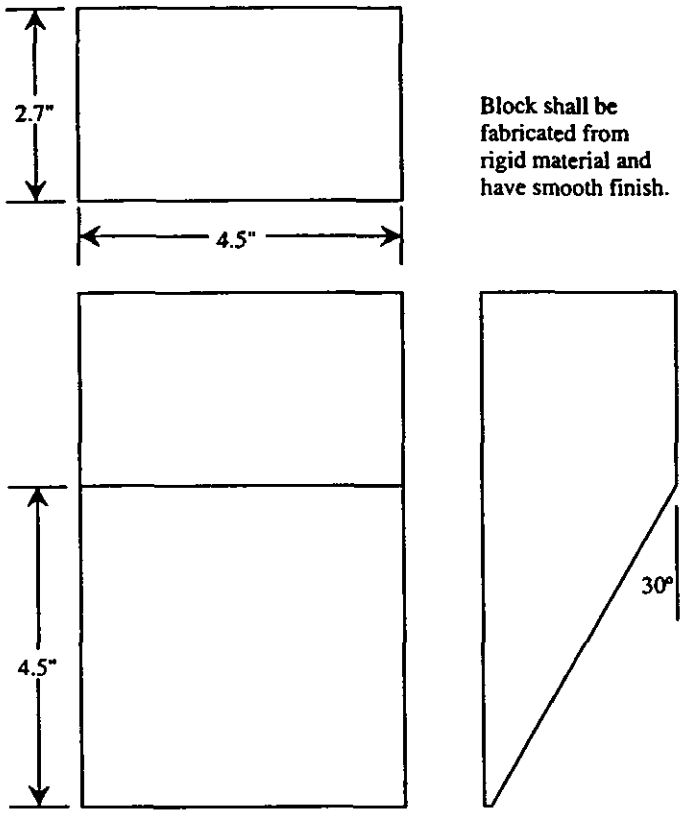


Figure 2: Proposed wedge probe design for mattress-top portable bed rails.

The probe is placed on the mattress with the long flat side facing down and the edge of the wedge fitted between the mattress and the guard portion of the portable bed rail. A force then is applied to the opposite end (i.e., the end opposite the edge of the wedge) to determine if the probe can pass into the gap between the portable bed rail and the top of the mattress. The worst-case scenario would be one in which a portable bed rail is designed such that the guard portion only barely extends horizontally over the top surface of the mattress. In that case, a child who slipped beneath the guard would be in essentially the same situation as a child who enters the gap between an adjacent type portable bed rail and the side of the mattress. Therefore, ESHF staff believes it is reasonable to apply the same force in this test as would be applied in the performance testing of adjacent type portable bed rails.

Discussion: Labeling Requirements

ASTM F 2085 – 01, *Standard Consumer Safety Specification for Portable Bed Rails*, requires that portable bed rails have a permanent warning label that uses the signal word "WARNING" preceded by a safety alert symbol. Given the potential severity of injury with portable bed rails, this signal word seems appropriate and ESHF staff recommends that this requirement be carried

over into CPSC's safety specification. The ASTM standard also requires the following statements to be included in the label:

- If a child's head or neck or body is trapped between the bed rail and bed, death or serious injury may occur.
- Use only on an adult bed with mattress and box springs.
- Use only for children who can get in and out of an adult bed unassisted.
- Never use in place of a crib.
- Never use on a bunk bed, waterbed, a bed with an inflatable mattress, or a toddler bed.
- To prevent entrapment, the minimum distance between the headboard/footboard and the bed rail shall be at least 9 inches.
- Always keep bed rail pushed firmly against the mattress.

To ensure a warning label is effective the consumer must notice and attend to it. Consumers are less likely to take the time to read a long and wordy warning label, so the label must be made as concise as reasonable to get the point across. The label above exceeds 100 words in length, which could keep some consumers from reading it. ESHF staff would prefer a shorter, more concise label for CPSC's safety specification. The consumer must also comprehend the information that is presented in the label. As a whole, the above label is written at about a sixth-grade level. However, some of the sentences are written in awkward language (e.g., "If a child's head or neck or body...") or language that sounds more like a technical requirement than a discussion of how to use the product (e.g., "...the minimum distance between the headboard/footboard and the bed rail shall be at least 9 inches."). ESHF staff believes that any labeling requirement in the CPSC safety specification should be written in simple, everyday language that most consumers are likely to understand. The language in the ASTM standard is not sufficiently comprehensible. The above label also fails to specifically describe the potential consequences of entrapment (i.e., suffocation and strangulation), something ESHF staff recommends. Therefore, ESHF staff suggests the following label be included in CPSC's safety specification in lieu of the above statements:

⚠WARNING

Suffocation and Strangulation Hazard.

Bed rail can trap young children against mattress, headboard, or footboard.

- Do NOT use with children less than 2 years old. Use only with children who can get in and out of adult bed without help.
- ALWAYS keep bed rail pushed firmly against mattress and at least 9 inches from headboard and footboard.
- Do NOT use on toddler bed, bunk bed, waterbed, or bed with inflatable mattress. Use only on adult bed with mattress and box spring.

ESHF staff believes the proposed label is more explicit, concise (81 words), and comprehensible than the ASTM label. In addition to including no passive sentences, the proposed label more specifically describes both the hazard and its consequences. Therefore, ESHF staff believes this label is more likely to be read and understood than the ASTM label.

Conclusions

ESHF staff has proposed two wedge-shaped probes to use during performance testing of two different types of portable bed rails. Both probes were designed based on the smallest lower torso dimensions of children approximately three months of age, who are the youngest children at risk of entrapment and hanging with portable bed rails. The forces to be applied during testing are based on the weight of the heaviest children 19 months old, who are the oldest non-impaired children involved in a fatal incident with portable bed rails. ESHF staff has also proposed warning label requirements for portable bed rails that is likely to be better understood than the current ASTM F 2085 – 01 labeling requirements.

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TAB D

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: August 15, 2001

TO : Patricia L. Hackett
Project Manager
Directorate for Engineering Sciences

THROUGH: Susan W. Ahmed
Associate Executive Director
Directorate of Epidemiology

Russell H. Roegner
Director
Division of Hazard Analysis

FROM : Michael A. Greene, Ph. D.
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : Analysis of Experimental Data: Effect of Wedge Design on the Force Required to Displace Bed Rails

Attached is an analysis of the data from the experiment that was conducted to determine the effect of wedge design and other factors on the amount of force required to displace bed rails.

Effect of Wedge Design and Mattress Type on the Force Required to Displace Bed Rails

Summary

The experiment measured the amount of force required for full penetration of a wedge between the mattress and the portable bed rail. The purpose of the experiment was to determine if wedge design, mattress or bed rail had an effect on this force.

The experiment was a complete factorial design that considered three mattress/bed combinations, two wedge types and five bed rails. Runs were made under two sets of conditions, first with the bed rails normally positioned on the bed, and second with the bed rails artificially restrained to offer more resistance against displacement from the bed. The restrained tests used only two mattress/bed combinations rather than three. While randomized, the run sequence was designed to minimize setup time for the experiment.

Wedges and the mattresses/bed combination were statistically significant factors in both restrained and unrestrained tests. This means that one wedge measured significantly higher forces than the other wedge, and the different mattresses also had significant differences in displacement forces. There was a wedge-mattress interaction for the unrestrained tests, but no interaction was found for the restrained tests. Such an interaction cannot be ruled out for the restrained tests because of the more limited number of mattresses/bed combinations used. Finally, while the bed rails had significantly different measurements there was no significant interaction between bed rail and wedge.

Because wedge was a significant factor, a standard designed around one wedge could work with the other wedge, providing that the displacement force was calibrated to the difference between wedges. The appearance of mattress as a significant factor means that changing the mattress would have a practically meaningful effect on the force. As a result, it would be important to consider the characteristics of a mattress to be specified for bed rail testing. The mattress-wedge interaction suggests that the calibration would need to take into account the specific combination of mattress and wedge. The absence of interaction between bed rail and wedge means that after the other calibrations are made, choice of a particular wedge does not produce results that are biased toward one bed rail over another.

Introduction

The key research question is if the two wedges are interchangeable for testing the bed rails. Although the force required to displace the two wedges is likely to be different, given the design of these wedges, there are four main possibilities as follows:

1. Complete Interchangeability of the Wedges. The displacement forces for the two wedges are close enough so that either can be used without any calibration. The difference in measurements does not depend on the mattress or bed rail.

2. Interchangeability with Calibration. The difference in forces between the two wedges is meaningful and regular. The standard can be calibrated to the wedge that is chosen. The difference in forces does not depend on the mattresses or the bed rail.

3. Interchangeability with Calibration and Specification of the mattress. The difference in displacement force depends on the mattress as well as the wedge. In this situation, the wedges are still interchangeable after calibration, but the calibration for the wedges are different for each mattress.

4. No calibration possible. The difference in forces depends on the bed rail either by itself or in addition to the other factors. In this case, the wedges are not interchangeable. Also, because the calibration factor differs by bed rail tested, both wedges must be tested with a particular bed rail to obtain the calibration factor. As a result, in practice, it would not be possible to test a new bed rail with one wedge, apply a calibration factor and then have a reasonable estimate for the measurement if the second wedge had been used.

The purpose of the experimental design is to determine which of these scenarios is the most likely possibility.

Method

Experimental Design

The experimental design was a complete factorial design with blocking. Each factor was tested against all possible combinations of other factors. This involved a total of 30 separate tests to cover 2 wedge types, 2 beds and 3 mattresses (3 mattress/bed combinations, for brevity just described as mattresses) and 5 bed rails. This procedure was repeated twice, once for the bed rails in unrestrained condition and the second for the restrained bed rails. As noted above, the use of restraints was to simulate a newer design of bed rails that would offer more resistance to displacement than present bed rails.

A randomized block design was selected to make the testing more efficient. In this design all the tests on a given mattress are completed before the next mattress is tested. The process involves first choosing one of the three mattresses at random, then selecting the five bed rails in random order. Once the bed rail is installed, then the order of the wedges is also randomized. The design and the data for both restrained and