

Memorandum

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TO:

NOTE:

Initial

The Commission

Sadye E. Dunn, Secretary

FROM:

Michael S. Solender, General Counsel

Stephen Lemberg, Assistant General Counsel

Lowell F. Martin, Attorney-Advisor

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

VOTE SHEET

Attached is a staff briefing package recommending that the Commission issue an advance notice of proposed rulemaking (ANPR) addressing a risk of injury/death associated with certain portable bed rails. Tab H of the package is a draft <u>Federal Register</u> notice that would commence a rulemaking proceeding by issuing an ANPR.

(Signature)	(Date)	
	(2 1.0)	
Approve the draft Federal Register notice with the	e following changes (please specify	[,]).
		
<u>-</u>		
(Signature)	(Date)	3414
	CPSA 6 (b)(1) Classed	11/

(Date)
(Date)

OPTIONS TO ADDRESS PORTABLE BED RAIL HAZARDS

June 2000

For Further Information, Contact:

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

NOTE: This document has not been reviewed or accepted by the Commission.

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- TAB H Draft Advanced Notice of Proposed Rulemaking (ANPR), Office of General Counsel, (undated)

EXECUTIVE SUMMARY

This package provides the U.S. Consumer Product Safety Commission (CPSC) with options to address hazards related to the use of portable bed rails. A portable bed rail is a device intended to be installed on an adult bed to prevent children from falling out of the bed. These portable bed rails are intended for children who can get in and out of an adult bed unassisted (manufacturer's typically recommend from two to five years of age). However, many of the reported incidents involved children younger than 2 years.

Since 1990, twelve fatalities have occurred with this product. Eleven of these fatalities were a result of entrapment between the portable bed rail and part of the bed. One was due to hanging from the portable bed rail. Nine of the twelve fatalities associated with this product occurred to children under two years of age. The cause of death in these incidents was asphyxia or strangulation ¹

In addition to the fatalities, 24 non-fatal incidents were reported. Five of these resulted in injuries. Nine of the 24 incidents involved children under the age of two years.

As a general rule, manufacturers do not recommend the use of this product for children under two years of age. The staff agrees with this recommendation because the use of this product assumes that the child would be sleeping on an adult bed. It has been shown that there are several hazards associated with placing children younger than 2 years to sleep in adult beds.² Despite the recommendations, it is apparent that the product is being used for infants and that this age group is most susceptible to fatalities.

There are no existing Commission 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. As of June 2000, the ASTM Portable Bed Rail Subcommittee had not balloted a proposed performance standard for these products.

The staff recommends that the Commission initiate a rulemaking proceeding to address the hazards posed by portable bed rails by publishing an Advance Notice of Proposed Rulemaking (ANPR).

¹ One child died of pneumonia due to the cervical injury sustained by hanging

² Suad Nakamura, Ph.D, Marilyn Wind, Ph.D, Mary Ann Danello, Ph.D, "Review of Hazards Associated with Children Placed in Adult Beds", Archives of Pediatrics & Adolescent Medicine, October, 1999 Volume 153.



Memorandum

MEMORANDUM

DATE: JUN 28 2000

The Commission To:

Sadye E Dunn, Secretary

Michael S. Solender, General Counsel M) 5 Through:

Pamela Gilbert, Executive Director

Ronald L. Medford, Assistant Executive Director, Purchased Lands From:

Office of Hazard Identification and Reduction Patricia Hackett, Project Manager Directorate for Engineering Sciences

SUBJECT: Options to Address Portable Bed Rail Hazards

ISSUE I.

The issue at hand is whether the U.S. Consumer Product Safety Commission (CPSC) should begin a proceeding that could result in a mandatory rule to address portable bed rail hazards. The fatalities associated with portable bed rails are primarily due to entrapment and hanging incidents. This issue is being brought to the Commission for consideration because of the continuing fatalities associated with portable bed rails and the lack of effective action on the part of ASTM to develop a voluntary standard that will adequately address the hazard.

IL. BACKGROUND

A portable bed rail is a device intended to be installed on an adult bed to prevent children from falling out of the bed. These portable bed rails are intended for children who can get in and out of an adult bed unassisted (manufacturers typically recommend from 2 to 5 years of age). Since 1990, twelve fatalities have occurred. These fatalities were all a result of entrapment between the portable bed rail and part of the bed or due to hanging from the portable bed rail. The majority of the fatalities associated with this product occurred to children under 2 years of age. Thus it is apparent that this product is being used by children outside the manufacturer's intended age range.

NOTE: This document has not been reviewed or accepted by the Commission Initial

Offine 1-800-638-CPSC(2772) + CPSC's Web Site http:///

Firms Notified,

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, CSPC staff drafted a proposed standard and submitted it to ASTM for consideration. As of June 2000, the ASTM Portable Bed Rail Subcommittee had not balloted a proposed standard for these products

III DISCUSSION

A. Incident Data

The Division of Hazard Analysis (HA) performed a data search to determine how many incidents occurred where a victim became entrapped or hung between a bed or mattress and the attached portable bed rail during the time period of January 1, 1990 to March 14, 2000. The most common scenario was that the two rods/bars that go under the mattress slipped out or were not installed snuggly against the mattress, creating a space between the portable bed rail and the mattress for entrapment TAB A contains a memo detailing the results of the search.

Table 1 shows a breakdown of the incidents by death, near-miss with injury and near miss without injury:

Table 1: Portable Youth Bed Rail Entrapment and Hanging Incidents

CPSC Data Files 1/1/90 to 3/14/00		Incidents Reported to Compliance by Firms		Total
Total	36	Total ²	16	52
Deaths	12	Deaths	0	12
Incidents with Injury	5	Incidents with Injury	4	9
Incidents with No Injury	19	Incidents with No Injury or Not Reported	12	31

1. Deaths

The children involved in the fatal incidents ranged in age from 3 months to 4 years of age. Only three of the twelve children were two years of age or older, and they were disabled in some capacity. The beds on which the portable bed rails were used were adult size beds, bunk beds, toddler beds, twin/single beds and a bed described as "youth size".

In 8 of the 12 cases the child became entrapped in an area between the mattress on the bed and the portable bed rail. In one case, the child slipped between the rails themselves. Another child

The databases searched were the in-depth investigation file, the injury or Potential injury incident file, the Death Certificate file and the National Electronic Injury Surveillance System

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

was found hanging from a protrusion on the portable bed rail Lastly, two children were found entrapped in the space between the portable bed rail and the headboard/bedpost of the bed. In all but one fatality, the cause of death was listed as asphyxia or strangulation One child died of pneumonia due to the cervical injury sustained by hanging. Additional information on each of the fatalities is detailed in TAB A.

2. Incidents with Injury

Five of the non-fatal incidents resulted in minor injuries: red mark on the head; a bruised back and swollen arm; a contusion to the neck; a red mark on the neck; a scraped nose and bruise to the back of the head; and a bruised right temple. These children were 6, 9, 14, 23 and 30 months old respectively. The beds involved were 3 twin beds, a king-size bed and the type of bed in the last case was not given in the report. In 4 of the cases, the children were found between the mattress and portable bed rail. The fifth case involved a portable bed rail, which snapped together in the middle with plastic couplers. The victim became entrapped when the portable bed rail partially disengaged into a "V" shape where it snaps together. For further details on these cases refer to TAB A

3. Incidents with No Injury

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

4. Compliance Data

The Office of Compliance received 30 reports of entrapment and hanging incidents (no deaths) from various manufacturers' of portable bed rails. 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 portable bed rail and the bed/mattress. The other two involved the child getting caught or stuck in the rails of the product.

5. Falls from Beds

CPSC staff also reviewed data³ for children 0-5 years old involving falls from beds and incidents occurring on the wall side of the bed that resulted in fatalities.

There were 47 deaths involving children 1 month to 2 years old from January 1, 1990 to May 17, 2000 involving a fall from a bed⁴. The great majority (38) were under a year old. Most of the children died when they fell into or onto an object (a bucket or bag of clothes for example).

Bunk beds were not included in this data.

³ The databases searched were the Indepth Investigation file, the Injury or Potential Injury file, the Death Certificate file and NEISS from January 1, 1990 to May 17, 2000. The search was limited to children under 6 years of age.

Incidents of death due to blunt force trauma from the fall were rare with only 2 or 3 cases reported. About 70% of the children died from asphyxia/suffocation/drowning.

There were 271 deaths involving children 1 month to 5 years old from January 1, 1990 to May 17, 2000 involving an incident on the wall side of the bed⁵. The deaths on the wall side included entrapments between the wall and bed/mattress; incidents between the wall and bed/mattress where entrapment was not indicated; and falls from the bed/mattress out of a window.

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

B. Societal Cost and Product/Market Information (TAB B)

The Directorate for Economic Analysis (EC) notes that the average number of fatalities per year (about 1.17) results in societal costs of about \$5.85 million (assuming a statistical value of life of \$5 million). Based on sales of over 700,000 annually, EC estimates that there are about 1.5 million to 3 million portable bed rails in use, depending on whether the expected useful life is 2 years or 4 years, respectively. As shown in TAB B, the societal costs per portable bed rail is about \$8 over the life of the product. Thus, it could be cost effective to spend up to \$8 per portable bed rail for a remedial strategy that would eliminate the hazard if the fix were 100% effective.

C. Portable Bed Rails Performance Criteria (TAB C)

All of the portable bed rail products 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 bed rail is held under the mattress by a variety of slip resistant knobs, pads or other means intended to provide resistance.

The friction created to hold the bed rail in place is dependent on a number of factors. In general, the bed rail arms are designed so that they may be easily slipped between the mattress and the mattress support. The design of many portable bed rails tends to make insertion easy and removal somewhat more difficult.

Once installed, a portable bed rail can only be moved outwardly away from the mattress by a force applied in the outward direction. That outward force may originate from activity of the child in the bed, asleep or awake. It should be noted that the bed rail need not be moved out in one continuous motion to produce a hazardous situation. A series of moderate taps could produce the same effect at lower force levels.

⁵ This data did not include bunk beds or incidents that happened at the headboard or footboard of a bed.

The amount of force applied to push out the bed rail depends on the child's strength (which generally increases with age), the motivation to apply a force, and the orientation of the force with respect to the plane of the bed rail

Human Factors (HF) reviewed anthropometric dimensions of children and their various strengths and concluded that portable bed rails should withstand an outwardly directed force of 50 pounds to simulate the maximum potential force that could possibly be applied. Since this performance level is near or at the 95th percentile strength capability of a five-year old (the oldest likely occupant), a reasonable degree of safety is achieved. In addition, the 50-lb requirement assures that the bed rail will serve its purpose for all children in the age range for which it is intended. In other words, even a strong 5 year-old child should not be able to move the bed rail enough so that they fall out of bed.

The applied force required should not result in significant movement of the bed rail. Significant movement could produce a gap, which would allow passage of the torso of the smallest expected occupant. The two critical anthropometric dimensions would be the chest depth and the buttock depth. Both of these dimensions can be pictured by viewing the body in profile. Whichever of these two dimensions is the smallest at the 5th percentile should establish the maximum permissible movement of the bed rail.

At least six of the victims were between 3 and 7 months of age. To consider the younger victims and provide a margin of safety in view of the potential consequence of a larger gap, Human Factors looked at data for children approximately three months of age. Based on a review of the dimensions for the 5th percentile three-month-old for chest depth, hip depth, and buttock depth and discussions with industry, Human Factors recommends that the maximum opening permissible should be 2 9 inches.

It was stated earlier that the force needs to be applied in an outward direction for testing purposes, perpendicular to the plane of the bed rail. Further, since the occupant of the bed must apply the force, the point of application must be above the mattress surface. How far above the mattress surface is a matter of judgement and in individual cases, depends on the compressibility of the mattress, the height of the mattress, and the weight of the person. For testing purposes, Human Factors recommends that the point of application be located at the mattress level to avoid confusion and permit consistent results between testing facilities. Testing at this level will be slightly different from the real-life situation.

Finally, it is recommended that a weight of 33 pounds be applied to the mattress to simulate the weight of a five-year-old occupant. The range in weight of expected occupants is about 12 to 41 pounds. The selected weight of 33 pounds is the 5th percentile for a five year old.

D. Labeling Issues (TAB C)

In the available data, it has been noted that there are incidences of these portable bed rails being used on beds for which the manufacture did not intend. They have been placed on bunk beds, toddler beds or other situations that set up the conditions for an incident. Human Factors

suggests that the proper use applications for these products be prominently displayed on the retail carton. Such text viewed before purchase would serve multiple purposes: 1) they would educate the consumer about subtle hazards associated with these portable bed rails; 2) they would alert the consumer that the application he has in mind may be inappropriate and potentially injurious; and 3) they would alert the consumer that the portable bed rails are only appropriate for a certain age range of children and that children outside of that age range may be exposed to hazards

Human Factors suggests that these pre-purchase warnings fall into three categories; 1) Age, Height and Weight restrictions, 2) types and sizes of beds appropriate for the particular model of portable bed rail and 3) a specific warning prohibiting use on bunk beds.

After reviewing the instruction sheets for 16 different models, Human Factors has found there is no consistency in age recommendations. The composite range across various manufacturers is about 6 months to five years of age. One manufacturer places a weight limit of 150 pounds without stating any age.

To bring some consistency to the market and prevent confusion, Human Factors recommends that portable bed rails be labeled for children age 2 years to 5 years with appropriate height and weight limitations. This would at least alert (assure) consumers that they were purchasing a product that was appropriate for their child. Further, there should be short and simple descriptions of the types of beds that this product should not be used on Finally, there needs to be a strong warning regarding the unacceptability of this product's use on bunk beds. At least two fatalities were associated with the use on a bunk bed.

Labeling may reduce the number of under age users, but it is not a preventative measure. Based on incident data, it is obvious that these products are being used for infants. Therefore, manufacturers should consider the anthropometric dimensions of infants for the design and performance testing of the product.

E. Voluntary Standards Activities (TAB D)

In February 1998, CPSC staff requested that ASTM develop a provisional standard and the ASTM F-15 Executive Committee endorsed the CPSC request A month later, the Juvenile Products Manufacturer's Association (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 (TAB E). 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 portable bed rails 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 portable bed rail 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 portable bed rail design concepts that may address entrapment hazards Subcommittee members explained why they disagreed with the CPSC staff proposed requirements and rationale. 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. Several manufacturer members of the Subcommittee believe that the proposed CPSC requirements are too severe and lack adequate rationale Some manufacturers contend that incidents involving infants represent a misuse of the product and that standard requirements should not be based on these cases. Further, some Subcommittee members contend that the resulting performance criteria are unreasonably severe when the anthropometric data of infants and the strength data for five-year-olds are combined.

The CPSC staff agrees that portable bed rails 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 portable bed rails with infants is reasonably foreseeable. It is therefore appropriate to base performance requirements on infant anthropometry. Further, the CPSC staff believes that it is necessary to combine anthropometric data for a 3-month-old with the strength capabilities of older users in order to achieve an adequate factor of safety to sufficiently reduce the risk of entrapment-related fatalities.

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 present an equal or greater risk of entrapment than current bed rails on the market. The basis for their concern is that new bed rails designed to meet the CPSC staff draft requirements would be more complex than current designs. The increased complexity could increase the possibility that consumers will install them incorrectly or perhaps make modifications to the bed rails. Either action could defeat the safety features on the bed rail, and possibly even increase the possibility of entrapment. Manufacturers

reinforced this message at the most recent Subcommittee meeting held at CPSC offices on April 12, 2000.

At the Subcommittee meeting, the group discussed various bed rail design concepts that could possibly conform to the CPSC staff draft test requirements. One idea included a bed rail that would have an anchor to the opposite side of the bed so as to prevent the unit from sliding out away from the mattress on the "rail side" of the bed. Two anchor designs were mentioned. One anchor was formed from the bed rail tubing that slides between the mattress and box springs. At the opposite side of the bed, the tubing bends 90 degrees downward so that it hooks around the edge of the box spring. A second anchor concept was a large disk that would be positioned at the opposite side of the bed and pulled up snug against portions of the mattress and box spring.

With regard to the status of the standard proposed by CPSC, 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 has not been able to reach agreement on this draft standard so that it may be sent to ballot. The next Subcommittee meeting is scheduled for October 2000. The Subcommittee Chairman recommended a working group phone conference prior to the full Subcommittee meeting so that work on a performance standard can continue The phone conference is not yet scheduled.

F. Performance Evaluation and Prototype Development (TAB F)

Staff from the Division of Engineering in the Directorate for Laboratory Sciences (LSE) tested 13 portable bed rails representing the products of 7 manufacturers. Details of the testing and results can be found in TAB F. The tests measured the forces to move the bed rail approximately 90 mm (3.5 in) away from the mattress. The test methods and data from these tests, along with a set of proposed performance criteria from Human Factors (HF) staff, formed the basis for the draft standard presented to ASTM The test matrix consists of all possible combinations of the variables in the test for each bed rail. The test variables were:

- (1) 2 bed sets
- (2) 3 test masses
- (3) 5 measurement locations

The test data showed general trends. As expected, the addition of mass to the mattress generally increases the force needed to move the bed rail relative to the mattress. A similar effect is usually seen when the different bed sets are used – heavier mattresses require greater forces to move a bed rail. This latter result may be partially due to the differences in "texture" of the interface of the box spring and the interface's interaction with the bed rail's legs.

Other characteristics of the data are the amount of scatter and the occasional inconsistency. Much of it is due to the different interactions of the bed rail with the mattress and box spring surfaces, and the leverage (moments) produced when testing the bed rails at the upper corners of the bed rails.

Based on the testing, none of the tested portable bed rails would meet the proposed performance criteria. The forces to move the bed rails beyond the recommended gap of 2 9 inches, with a mass of 40 pounds added to a foam mattress, were well below the force requirement of 50 lb_f. With a 15 kg (33-lb_m) mass on the mattress, the force to move the bed rail will be somewhat lower.

After the testing, LSE staff was tasked to develop a prototype portable bed rail that would meet the proposed performance criteria and not create an entrapment hazard or gap between the bed rail and the bed.

In designing the portable bed rail, an approach was taken to place the bed rail on top of the mattress instead of next to the mattress, which is more typical. Placing the rail on top of the mattress eliminates a gap that might exist between the portable bed rail and the side of the mattress. A triangle shape was selected for the main body of the portable bed rail. The inclined slope faces toward the inside of the bed. The overall length is approximately 48 inches (1.2 m) and it is approximately 6 inches (150 mm) high with a 6-inch (150-mm) wide base. The rail is attached to the mattress by a framework made of ¾-inch (19-mm) hollow tubing. The tubing is bent to right angles and attached to the back of the bed rail. The tubing extends under the mattress and connects to three cross members made of the same tubing. The length of this framework is approximately 29 inches (740 mm) and extends under the mattress approximately 15 inches (380 mm). Both the portable bed rail base and the framework have non-slip abrasive tape applied to their surfaces. The portable bed rail also clamps to the mattress using the framework. The portable bed rail is pushed down against the mattress and then secured to the framework via U-shaped clamps. Testing indicated that this design meets the proposed test criteria.

The important features of this portable bed rail design are:

- 1. It withstands the 50 lb_f (220 N) tension force and stays attached to the mattress.
- 2. Since the portable bed rail is on top of the mattress, no gap exists between the bed rail and the mattress sides.
- 3. The 45-degree inclined plane faces the bed occupant and presents no hazard.
- 4. The clamping force of the bed rail, coupled with the abrasive surfaces, provides an excellent method for securing the bed rail to the mattress.

This particular concept design has only been tested in a laboratory setting. There are other designs that CPSC staff can envision to meet the proposed requirements of the standard. However, to move from concept through prototype and production stages of manufacturing requires consideration of the human factors issues associated with the practical and safe use of the particular product design.

G. Compliance Activities (TAB G)

The Office of Compliance staff investigation of portable bed rails was prompted by a fatal incident involving a 19 month old male who became entrapped between the mattress and bed rail. During the staff's investigation, it discovered that all of the portable bed rails manufactured and sold to consumers had a similar design and held a potential for entrapment. Further, almost all of the manufacturers' records listed incidents involving entrapment incidents. As a result, Compliance opened cases with a total of eight firms whose portable bed rails had been involved in incidents of child entrapment. Beginning in November 1997, eight manufacturers were notified of the staff's preliminary determination of a substantial product hazard in this matter.

In April 1998, the staff met with the portable bed rail manufacturers to discuss the entrapment issue. At that time, the manufacturers were reluctant to develop a retrofit or new design program out of concerns that improving the fit of the rail to the side of the mattress could present an even greater risk of serious injury for all age groups, including the 2 to 5 year age group considered by the staff as the appropriate age group for the product.

In November 1998, one of the eight manufacturers took the initiative to pursue the concept of a new product design, and hired an outside design expert to review the issues surrounding an improved portable bed rail. As a result of the independent expert review, the manufacturer reiterated the initial conclusion that any attempt to improve the fit or affix the rail to the mattress increased the potential for entrapment for all age groups. The basis for their concern is that new bed rail designs would be more complex than current designs. The increased complexity could increase the possibility that consumers will install them incorrectly or make modifications to the bed rails, defeating any gained safety advantages. Further, the increased cost of producing a new product could result in the manufacturer "out pricing" itself from the market, which was of great concern to the manufacturer.

After a careful review of the staff's concerns, and an evaluation of the complexity of issues raised in conjunction with design modifications to the product, the Compliance staff decided to close the eight cases and refer the matter to the Office of Hazard Identification and Reduction staff for consideration in developing a voluntary standard that would address all of the design issues surrounding the portable bed rails. Accordingly, by memorandum dated September 29, 1999, the matter was closed by Compliance.

H. Discussion Summary

The basic issue involved with the entrapment/hanging hazard is whether or not this product 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. Even though the manufacturers have not recommended the product for infants and the staff agrees with this position, it is apparent from the data that bed rails are being used for infants and that these children are the ones most likely to suffer an entrapment/hanging fatality or injury. In addition, the data associated with children falling out of bed clearly show that this age group is also the most susceptible to fatalities. Therefore, with or without a bed rail present, parents and caretakers are putting infants to sleep in adult beds and deaths are occurring.

Currently, bed rails that are properly installed are not adequately designed to prevent young children from becoming entrapped. Industry representatives have expressed concern that a redesign of the product may make them more difficult to install and therefore increase the likelihood that they may not be properly installed in the future. The staff believes that it is unacceptable to modify the designs in a way that would make them more difficult to install. These products must be designed to take into account several important criteria: 1) they shall be capable of being properly installed on a wide variety of bed and mattress types; 2) they shall be designed to minimize the potential for incorrect installation that could result in hazardous spaces between the bed rail and mattress; and 3) when properly installed, they shall resist movement by a young child that would create an entrapment hazard.

III. OPTIONS

Options for remedial efforts in this area include:

- 1. Initiate a rulemaking proceeding to develop mandatory performance requirements addressing the hazards posed by portable bed rails or to ban the sale and distribution of portable bed rails by publishing an Advance Notice of Proposed Rulemaking (ANPR).
- 2. Direct the staff to continue to work with ASTM to develop a performance standard that will adequately address the portable bed rail hazards
- 3. Take no further action to address portable bed rail hazards at this time

IV. CONCLUSIONS AND RECOMMENDATIONS

The staff concludes that current bed rail designs are inadequate to prevent the entrapment deaths of young children, even when the product is properly installed. These safety devices marketed for use by children between the ages of 2-5 years of age are intended to prevent injuries from falling out of bed Yet, Commission data indicates that the risk of death from a fall from a bed is overwhelmingly to children under the age of two years. Bed rails, because of their current design are inadequate to prevent these young children from becoming entrapped between the rail and the mattress. Therefore, the staff recommends that the commission initiate a rulemaking proceeding to address the risk of entrapment from bed rails A copy of a draft ANPR is attached at TAB H.

TAB A



Memorandum

Date:

June 7, 2000

TO

: Patricia Hackett

Division of Mechnical Engineering
Directorate for Engineering Sciences

THROUGH:

Susan Ahmed, Ph.D, AED

Directorate for Epidemiology

Russell Roegner, Ph D., Director 721

Division of Hazard Analysis

FROM

: Joyce McDonald

Program Analyst

Division of Hazard Analysis

SUBJECT:

Portable Youth Bed Rail Entrapments and Hangings

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

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

Table 1: Portable Youth Bed Rail Entrapment and Hanging Incidents

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

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

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

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

CPSC Reports

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

Deaths

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

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

Incidents with Injury

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

Incidents with No Injury

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

Comments

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

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

Compliance Reports

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

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

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

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

Deaths from Falls from Bed and Wall Side Incidents

CPSC staff also reviewed data⁵ for children 0-5 years old involving falls from beds and incidents occurring on the wall side of the bed that resulted in fatalities.

Falls

There were 47 deaths involving children 1 month to 2 years old from January 1, 1990 to May 17, 2000 involving a fall from a bed⁶. The great majority (38) were under a year old. Most of the children died when they fell into or onto an object (a bucket or bag of clothes, for example). Incidents of death due to blunt force trauma from the fall were rare with only 2 cases reported. In another case a massive intracerebral hemorrhage resulted from the fall out of the bed and this may have been a death due to blunt force trauma also. About 70% of the children died from asphyxia/suffocation/drowning. (See Appendix C.)

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

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

Bunk beds were not included in this data

Wall Side Incidents

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

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

271
233
30
8

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

This data did not include bunk beds or incidents that happened at the headboard or footboard of a bed.

Many incidents indicated an entrapment between a mattress and a wall or mentioned the mattress and not a bed specifically. Where it clearly stated that the mattress was on the floor, the case was not used in the count.

Appendix A

Portable Youth Bed Rail Entrapments and Hangings Deaths and Near-Misses 1/1/1990 to 3/14/2000

	9	V 20 0	C. L. (Otala)	N-1
Document #	Date	Age/Sex	City/State	Narrative
1 900209HCC2155 03/06/1990 7 MO M	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 08/02/19913 MO M	08/02/1991	3 MO M	Clarksville, VA	Child's head became entrapped between the
9151029634				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
	1	-		asphyxia
3 91112HCC1470	10/31/1991 15 MO F	15 MO F	Newark, NJ	Child was found hanging half out of the bed
X91B0438A1				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 11/10/1991 14 MO M	11/10/1991	14 MO M	Lancaster, CA	Child was found hanging by his shirt collar
X9231206A1				which caught on a metal clip with a small
9106192347				metal tab on the extenor of a portable bed
				rail on a single size bed Cause of death
				was ligature strangulation

Document #	Date	Age/Sex	City/State	Narrative
5 940110HCC1085 06/23/1993 2 YR F	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	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
7960215HCC5012 12/08/1995,2 5 YR F X961288A 9555036345 X9611117A X9772446A	12/08/1995	2 5 YR F	North Fond du Lac, W	North Fond du Lac, 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 03/07/1996 5 MO M 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.

لتے	Document #	Date	Age/Sex	City/State	Narrative
8	9 970127 CCN0290 01/15/1997 19 MO M	01/15/1997	M OM 61	Chicago, IL	Child became trapped between a portable
_	G9710223A				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
5	10 980327HCC3723	03/18/1998 4 YR M	4 YR M	Bothell, WA	Mentally retarded boy became trapped
- 1	X9832550A				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
1	11 990317HCC0349	08/17/1998 7 MO M	MOM 7	Waynesville, NC	Child became trapped in a toddler bed with a
	9837042368				youth guardrail His head was entrapped
					between the bed's headboard and the youth
_					bed rail The cause of death was asphyxia
	000000000000000000000000000000000000000	000717077		014	
7	12 990/1ZHCC05/9 11/0//1998 5 MO F	8661/10/LL	J OM c	Kaleign, NC	Child was round stuck between the mattress
 -	9837061207				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

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-	1 900706HWE5005 06/22/1990 23 MO M	06/22/1990		San Francisco, CA	San Francisco, CA Child became entrapped between bed and
	F9075005A				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	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
က	3 H9560295A	05/00/1995 6 MO M	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 Crty/State		Narrative
4 H9660068A	9661/60/90	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 01/04/1999 9 MO F	01/04/1999	9 MO F	Easley, SC	The product involved was a metal-framed
H9910102A				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

Document #	Date	Age/Sex	City/State	Narrative
2 920325CNE5107	V1992		Riverdale, NY	Head got caught between a portable bed rail
N9230050				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 07/15/1993 3 YR M	07/15/1993	3 YR M	Churubusco, IN	Child was in an adult size double bed with a
C9530032A1				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	35 YR M	Mannette, WI	Got head and upper body caught in a space
				between the guard rail and the side of 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 05/19/1995 2 YR F	05/19/1995	2 YR F	Sharpsburg, PA	Child became entrapped between the
N560002A				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	08/27/1995 2 YR F	2 YR F	Orlando, FL	Child became entrapped between the bed
N95A0002A				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

Docu	Document #	Date	Age/Sex	City/State	Narrative
7 H9650180A	0180A	05/14/1996 23 MO M	23 MO M	Webster Grove,	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
8 H9690202A	0202A	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	0001A	09/30/1996 19 MO M	ŀ	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 97032	10 970327CCC1051	02/17/1997/2 5 YR M	2 5 YR M	Boca Raton, FL	Parents purchased a wooden bed rail with
<u>.</u>					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
		ļ			was sustained
11 H9770106A	0106A	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

A (two 06/00/1998 30 MO M Windsor Locks, CT 06/00/1998 3 5 YR F Coppell, TX A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co two Male	Document #	Date	Age/Sex	Clty/State	Narrative
# (two 06/00/1998 3.5 YR F Coppell, TX	12 980415CNE5131		30 MO M	Windsor Locks, CT	Child pushed his bed rail out from under his
14) 06/00/1998 3.5 YR F Coppell, TX 07/14/1998 2.5 YR F Johnston, IA A 11/22/1998 2.5 YR F Willowgrove, PA (two 00/00/1999 Unk Age Denver, Co 11)	N9840007A (two				twin bed mattress and fell into the space
14) 06/00/1998 3.5 YR F Coppell, TX 07/14/1998 2.5 YR F Johnston, IA 11/22/1998 2.5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co 14)	events of				between the mattress/box spring and bed
06/00/1998 3.5 YR F Coppell, TX 07/14/1998 2.5 YR F Johnston, IA A 11/22/1998 2.5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co tth Male	entrapment)				rail twice. No injury. Bed rail was mesh-
66/00/1998 3.5 YR F Coppell, TX 07/14/1998 2.5 YR F Johnston, IA 11/22/1998 2.5 YR F Willowgrove, PA (two 00/00/1999 Unk Age Denver, Co Male int)					framed and had 2 tubes to place between
06/00/1998 3.5 YR F Coppell, TX 07/14/1998 2.5 YR F Johnston, IA A 11/22/1998 2.5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co Male					the mattress and box spring
A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co Male	13 C9910005	06/00/1998	3 5 YR F	Coppell, TX	Child was found wedged between the
A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA (two 00/00/1999 Unk Age Denver, Co Male					mattress and bed rail due to the flexibility of
07/14/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co Male					the "feet" and rail when leaned against This
A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co Male					created the space There was no slipping of
A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA two 00/00/1999 Unk Age Denver, Co Male					the bed rail involved No injury reported
A 11/22/1998 2 5 YR F Johnston, IA A 11/22/1998 2 5 YR F Willowgrove, PA (two 00/00/1999 Unk Age Denver, Co Male					
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male	14 H980139A	07/14/1998	2 5 YR F	Johnston, IA	Child was found with her head hanging down
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male	-				in the 5-6 inch space between the metal
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male					support of the guard rail and the mattress of
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male		_			her twin bed. No injury. Consumer feels the
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male					4 inch long plastic rubber "stoppers" do not
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male					secure the guard rail to the mattress,
11/22/1998 2 5 YR F Willowgrove, PA 00/00/1999 Unk Age Denver, Co Male	;				causing it to move
00/00/1999 Unk Age Denver, Co Male	15 H98B0215A	11/22/1998	25YRF	Willowgrove, PA	Child was found wedged between the bed
00/00/1999 Unk Age Denver, Co Male					rail and mattress after she pushed against
00/00/1999 Unk Age Denver, Co Male					the bed rail creating a 6-8 inch gap Her arm
00/00/1999 Unk Age Denver, Co Male					and head slipped through the opening The
00/00/1999 Unk Age Denver, Co Male					bed rail is held in place by two bars that slip
00/00/1999 Unk Age Denver, Co Male		_			under the mattress Report does not
00/00/1999 Unk Age Denver, Co Male					mention an injury
Male (16 199B0017 (two	00/00/1999	Unk Age	Denver, Co	Portable bed rail has pulled out a foot from
	events of		Male		the bed and child was found on the floor
week's time It is unknown if the child was injured	entrapment)				twice and wedged twice in less than a
painful					week's time It is unknown if the child was
					injured

	Document # Date Age/Sex City/State	Date	Age/Sex		Narrative
4	17 (199A0008	Between	1.5 YR M	Between 1.5 YR M Reading, PA	Child partially slipped through a mesh net
		26/00/80			bed rail attached to parents' bed. Child was
		and			freed and no injury is mentioned Parent
		10/01/99			now makes sure new bed rail is firmly
					pushed against the bed when in use

Source US Consumer Product Safety Commission, INDP, IPII, DTHS and NEISS

Appendix B

Portable Youth Bed Rail Entrapments and Hangings Incidents Reported to Compliance by Firms

Salar Salar Charles and the Control	Presidential	I PILLO TANA	Notice of Laboratory	V. C.
1 Firm Information	Unknown	22 MOS	No injury reported	Child found with head stuck between rail
				with feet sticking up
2 Firm Information	Unknown	4 MOS	No injury reported	Child caught between bed rail and mattress
				The plastic brace bowed out
3 Firm Information	Unknown	2 5 YRS	No injury reported	Child found wedged between the mattress
				and bed rail
4 Firm Information	Unknown	SOM 6	No injury reported	Child's body fell beneath rail and mattress
				Head wedged between mattress and rail
5 Firm Information	Unknown	2 YRS	Red mark on left side of	Child's head got stuck beside the bottom
			neck	tube due to rail moving outward
6 Firm Information	Unknown	17 MOS	Red mark on right side	Child's head was stuck between bed rail and
			of neck	mattress The rail moved out so body was
				upside down
7 Firm Information	Unknown	23 MOS	No injury reported	Child stuck between bed rail and bed Body
				had sunken between bed and rail and was
				enveloped in blanket
8 Firm Information	Unknown	2 5 YRS	Red marks on face and	Red marks on face and Child found with half body dangling between
			nec k	the bed rail with head between bed and rail
9 Firm Information	Unknown	21 MOS	No injury reported	Child found between bed rail and mattress
10 Firm Information	Unknown	2 5 YRS	No injury reported	Child got stuck between bottom bed rail and
		T	4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
11 Firm Information	2881/62/11	Unknown	Not reported	Mesh pulled away from plastic. Child got caught between mattress and bed rail
12 Firm Information	12/03/1992	3 YRS	Not reported	Child's foot and head caught between
				mattress and bottom rung of rail

		Print Rribbred Approxeciile		Naturosoulnijury	Netrative:
<u>6</u>	13 Firm Information	02/24/1993	Unknown	Not reported	Child fell out of bed and got stuck between bed and rail
4	14 Firm Information	08/26/1993	2 YRS	No injury reported	Rail pushed out from between mattress on bed and child found hanging between mattress and rail
15	5 Firm Information	01/01/1994	25 YRS	No mjury reported	Child fell through bed rail to chest level and got stuck in rail
16	16 Firm Information	11/10/1994	3 YRS	Not reported	Bed rail moved and child was caught between rail and mattress
1	17 Firm Information	11/15/1994	Unknown	Not stated	Bed rail came away from mattress Child hung up between the rail and mattress
<u>8</u>	18 Firm Information	01/26/1995	2 5 YRS	Not reported	Child gets caught between the bed rail and bed on a twin size bed
<u>0</u>	9 Firm Information	05/25/1995	3 YRS	Ring around neck and breathing cut off	Child was between bed rail and mattress
20	20 Firm Information	07/11/1995	7 MOS	Bruised neck	Child slipped between mattress and bed rail
2	21 Firm Information	08/29/1995	2 YRS	None reported	Rail came off allowing the child's head to fall between the edge of the mattress and rail
ัส	22 Firm Information	04/01/1896	2 YRS	Marks from slats	Child's neck caught between bed and rail frame, smashed against slats of bed rail
23	23 Firm Information	08/01/1996	21 MOS	No injury reported	Child rolled over into bed rail. The fabric gave enough for child to fall into frame and fabric.
7	24 Firm Information	09/25/1996	5 YRS	Choking and vomiting	Child got head stuck between bottom bar and mattress
25	25 Firm Information	10/02/1996	2 5 YRS	None reported	Child got stuck in bed rail on full size bed during first time use
92	26 Firm Information	11/18/1996	2 YRS	None reported	Child found with neck and upper body stuck between mattress and bed rail
27	27 Firm Information	12/00/1996	Unknown	Bruised neck	Child's head got caught in bed rail on twin bed

3800 May (3008)	Patrol Refrestition	Age to Child	STREET DEVENDED STREET ADSOLCHIE NATUREO SINIUP PROFILE NATURED	Natrative
28 Firm Information 08/00/1997	08/00/1997	Unknown	Not reported	Child getting caught between bed rail and mattress
29 Firm Information 08/00/1997	08/00/1997	Unknown	Not reported	Child caught between bed rail and mattress hanging from upper body
30 Firm Information 11/00/1997	11/00/1997	Unknown	Not reported	Child sleeping in a queen size bed and rail slid out. Child got caught between rail and mattress.

Appendix C

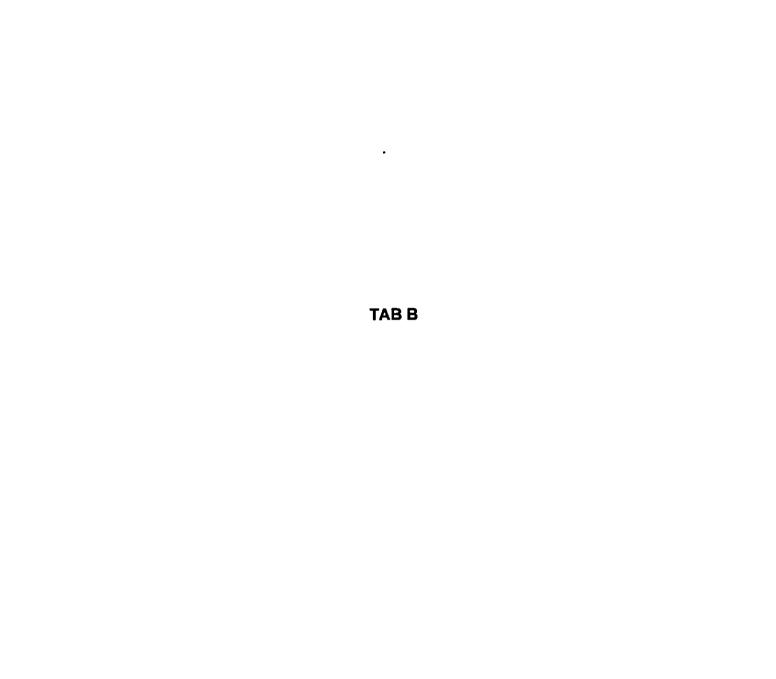
Fall Deaths from Beds (Excluding Bunk Beds and Wall Side Incidents) 1/1/90-5/17/00 Children Ages 0-5 Years of Age

1	Document #	Date	Age/Sex	City/State	Narrative
1	900305HCN1141	02/02/1990	13 MO M	St Louis, MO	Drowned after he apparently fell off a bed
	G9020343A	'		[and into a bucket of water and cleaning
2	910730HCC2244	02/16/1990	4 MO M	Jackson, MS	solution Fell out of bed into a pan of water
4	9028003112	02/10/1990		Jackson, IVIS	Asphyxia by immersion
3	9016001163	02/19/1990	4 MO M	Boise, ID	Rolled off bed, landing face down in a
	X9176109A				plastic bag and a pile of bed clothing
j	91708HCC0267		[[Asphyxia
	X9176170A				
	NEISS	03/25/1990	12 MO F	Unknown	Found in full arrest Child fell out of bed
5	920205HCC1545	04/16/1990	6 MO F	Bronx, NY	Rolled off a day bed and was smothered
	9036023118	0.45044000	4 4 4 0 1 4	N-t	by a plastic bag containing drapes
6	9006059332	04/29/1990	1 MO M	National City, CA	Asphyxiated when fell from the bed and wedged between clothing-filled plastic
Ì	l	1	1		trash bags
7	P9720216A	06/26/1990	8 MO M	Cincinnati, OH	Fell off bed into a plastic bag full of
Ì					clothes
8	910123HCC1114	06/27/1990	7 MO F	Norfolk, VA	Left on a full size bed and found later
	9051024487			[entangled in bedding and a plastic bag of
					laundry on the floor The child apparently
	1			ļ	rolled off the bed and smothered with the
۵	910225HCC0149	08/07/1990	3 MO F	Portland, OR	plastic over her face Fell from a bed into plastic material
9	9041015138	00/07/1880	13 MIC F	Fordand, ON	Asphyxia
10	X90C0964A	12/15/1990	15 MO F	Stoneville, NC	Died when she rolled off a bed hitting her
				_	head on a magazine rack
11	910503HCC1237	03/07/1991	12 MO M	Salem, NC	Drowned after falling out of his parents'
	X9154785A	ł			bed into a bucket filled with 4.5 inches of
					rain water from a leaking roof.
12	9106079292	04/29/1991	4 MO F	Escondido, CA	Asphyxiated when she rolled off bed with
12	9118022058	05/18/1991	9 MO F	Indianapolis, IN	face in plastic bag. In bed with mother and fell off bed, landing
13	9110022030	00/10/1991) WIC I	Indianaposis, ii4	on a pile of clothes. Positional asphyxia.
				ļ	on a pilo of oloulos. I osizonal copriyata.
14	9113036326	09/11/1991	6 MO M	Americus, GA	Fell off bed into trash can, suffocating.
15	NEISS	10/06/1991	5 MO M	Unknown	Fell off parents' bed into a trash can
					containing a plastic liner Suffocation.
16	9137051864	11/17/1991	4 MO M	Jacksonville, NC	Rolled off bed and face contacted plastic
4	V02659454	00/0040/00	10.140.0	Somto Acc Ot	laundry bag Asphyxia
1/	X9365815A	00/0019/92	8 MO ?	Santa Ana, CA	Died following a fall from a bed onto an
j		ł	ł	ł	open drawer

I	Document #	Date	Age/Sex	City/State	Narrative
	X9252642A	03/06/1992	7 WK M	Falcing Waters, WV	Died after rolling off a bed onto plastic bags filled with clothing Possible asphyxiation or SIDS (?)
19	N92A0004A	09/08/1992	4 MO F	Mıamı, FL	Found unresponsive after falling out of a twin bed earlier
20	F92C0137A	11/09/1992	5 MO M	Marmaduke, AR	Died after he fell off a bed and into a clothes hamper
21	9336008595	02/07/1993	2 YR M	Rochester, NY	Fell from bed, landing on an upright knifeblade. Stab wound to anterior right ventricle.
22	N9470179A	06/23/1994	5 MO F	Winter Haven, FL	Died after touching bare wires from an extension cord when she fell out of bed.
23	9415005004	08/09/1994	6 MO F	Waimea, HI	Apparently rolled off bed head first into plastic bag-lined container Asphyxia
24	9429204218	08/26/1994	6 MO M	St Louis, MO	Fall from bed to asphyxiating position
25	9455027831	10/03/1994	6 MO M	Monroe, WI	Rolled from bed into plastic-lined wastebasket Entrapped head in a downward position/asphyxia
26	9566012927	02/22/1995	8 MO F	Brooklyn, NY	Rolled off bed into plastic bag containing clothes Smothering
27	9537024230	05/22/1995	5 MO M	Winston-Salem, NC	Fell off bed onto plastic bag Asphyxia
28	NEISS	12/25/1995	7 MO F	Unknown	Fell off bed and hit a jar of pennies sustaining cardiopulmonary arrest
29	X9652561A	02/16/1996	8 MO F	Ft Myers, FL	Drowned in a bucket adjacent to a bed she rolled off of
30	9626030458	05/19/1996	10 MO M	Kentwood, MI	Rolled off bed, landing in plastic bag in a plastic container Asphyxia
31	961101HCC7078 9649005889	07/17/1996	3 MO F	Grantsville, UT	Fatally injured when she pressed her face against a plastic bag of clothes and suffocated. She had been left on an adult bed and fell off hitting her head on the floor.
32	X9694034A	07 <i>1</i> 24/1996	3 MO F	Philadelphia, PA	Died of SIDS (?) when she fell from a bed onto a floor mat near a plastic bag of dirty clothes
33	X98B0828C	00/00/1997	4 MO M	Sacramento, CA	Died of suffocation when he fell from a bed into a pile of clothing.
34	G9710179A	01/05/1997	16 MO M	Creston, IA	Suffocated when he rolled out of his father's bed into wastebasket with a plastic liner
35	9748092910	06/16/1997	5 MO M	Waco, TX	Fell from a bed onto a child's walker with neck in a position that obstructed airway.
36	9712135242	11/19/1997	2 YR F	Gainesville, FL	Fell out of bed Massive intracerebral hemorrhage.

1	Document#	Date	Age/Sex	City/State	Narrative
37	980811HCC3945 9748140237	12/13/1997	10 MO F	Houston, TX	Died of positional asphyxia when she fell from mother's full size bed onto the frame of a child size bed
38	980921HCC0725 X9895102A	12/23/1997	9 MO M	Hampton, VA	Found head down and unconscious in 5 gallon bucket beside her bed. Bucket was placed by bed for use by victim and other siblings who were sick. Died 16 days later.
39	9839105375	09/11/1998	5 MO F	Urbana, OH	Rolled off of bed head first into a trash can Asphyxia
40	X98B0797A	09/22/1998	7 MO M	Washington, DC	Died of blunt force head injury received in a fall from a bed to the floor, hitting his head on a space heater
41	9813060639	10/29/1998	4 MO F	West Point, GA	Fell off bed at home Positional and mechanical asphyxia
42	9854019832	12/03/1998	4 MO M	Princeton, WV	Rolled off bed next to heater. Hyperthermia and body burns
43	9812155537	12/23/1998	6 MO M	N Miami Beach, FL	Fell between bed and nightstand Positional asphyxia
44	9934005509	01/17/1999	2 YR M	Newark, NJ	Fell off bed while playing at home Blunt force trauma to head and neck
45	990316HCC0344 N9930098A	02/18/1999	10 MO M	Tampa, FL	Placed on mother's bed and left alone Found face down in a 5 gallon bucket filled with about 4 5 inches of water Drowning
46	991124HNE5363 N99B0238A	11/23/1999	11 MO M	Old Bridge, NY	Child drowned after she rolled off a bed and fell headfirst into a diaper pail of 6 inches of water and cleaner
47	NEISS	01/22/2000	2 YR F	Unknown	On the middle of 2 twin beds pushed together and fell off onto the floor Cardiac arrest

Source INDP, IPII, DTHS and NEISS





Memorandum

Date:

June 29, 2000

TO

Patricia Hackett, ESME_

FROM

Mary Donaldson, EC

Terrance Karels, EC

SUBJECT: Societal Costs of Portable Bedrails

Portable bedrails are designed to attach to the side of a bed, usually the mattress, to protect young children from falls. The societal costs of injuries and deaths represent the potential benefits. Consequently, they represent the amount that can justifiably be spent to make bedrails safer, under the assumption that the deaths and injuries would be eliminated.

For the purposes of this analysis, we have used a statistical value of life of five million dollars, which is consistent with current economic literature. Over the period 1990 through March 14, 2000, the Directorate of Epidemiology reported that it was aware of 12 deaths of children that could be directly attributed to portable guardrails or an average of 1.17 deaths per year over that period. Thus, the aggregate cost to society of these deaths would be \$5.85 million dollars annually (\$5 million x 1.17). Injuries have been categorized as few and minor; thus, the costs associated with these injuries are not considered in this estimate.

According to the Office of Compliance, eleven firms produced a total of about 7.7 million bedrails during the time period January 1988 to July 14, 1998. Compliance staff reported that subsequent sales (1998 and 1999) were stable. Thus, based on available information, about 733,000 units were sold per year.

No information is available on the average product life of a bedrail. Human Factors staff estimated that, for the period of first use, an expected useful life of 2 years would be appropriate. HF staff also cautioned that some units would see use with subsequent children, and that 4 years may be considered an upper bound for the expected useful life of portable bedrails. However, in this case (as will be shown), the average product life does not affect the estimates of expected societal costs over the life of the product.

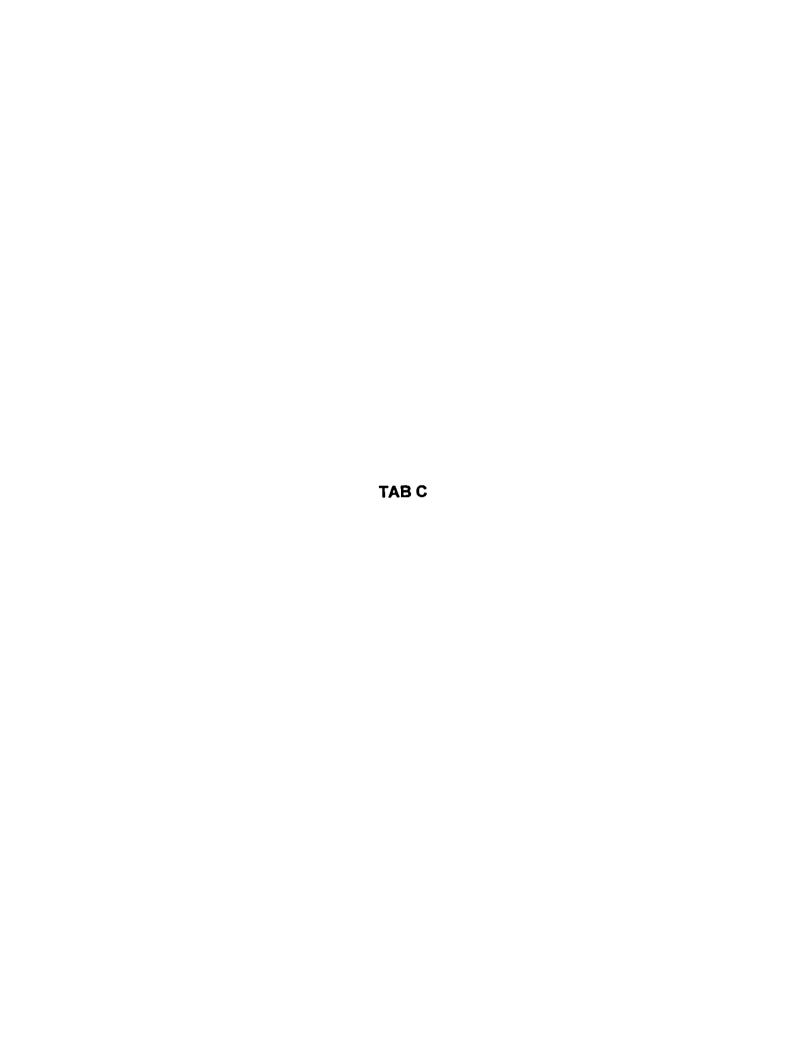
If we assume an average product life of 2 years, there would be about 1.5 million bedrails in use at any give time (733,000 bedrails X 2 years), and, with 1.17 deaths per year, the risk of death would be about .8 per million. The expected cost of these deaths would be about \$4 per bedrail per year (.8 x \$5 million +1 million bedrails). Over its expected useful life, the expected societal costs per bedrail would be \$8 (\$4 x 2 years).

If we assume that bedrails remain in use (on average) for four years, there would be about 3 million bedrails in use at any given time $(733,000 \times 4 \text{ years})$. Because there is an average of 1.17 deaths per year, the risk of death is about .4 per million bedrails. Using a statistical value of life of \$5 million, the expected costs of the deaths per bedrail in use is about \$2 per year $(.4 \times $5 \text{ million} \div 1 \text{ million})$. If the bedrails last 4 years, the expected societal costs over the life of a bedrail would be about \$8 (\$2 x 4 years).

Thus, based on available information, we preliminarily estimate that the expected costs to society presented by portable bedrail entrapments would be about \$8 per bedrail over its useful life. Hence, if improvements to the products were 100% effective in preventing these deaths, the cost of these improvements could be as much as \$8 per bedrail and be economically justifiable. (The \$8 in societal costs represents as much as 50% of the retail price of portable bed rails.) Or, on the other hand, if the improved bedrails prevented only about 75% of the deaths, the cost of the improvement could be as much as \$6 per unit and still be economically justified.

Conclusion

Based upon best available sales estimates and the reported average number of fatalities per year, it would be cost effective to spend up to \$8 per unit to eliminate the hazard of entrapment in portable bedrails if the fix were 100 % effective. If a fix were less than 100% effective, the amount that would be economically justifiable to address the hazard would be proportionate to the level of effectiveness. However, it is also possible that the number of fatalities known to the Commission staff is underreported, and the extent of that underreporting would also bear on the amount that could be spent on improvements to portable bedrails.





Memorandum

Date:

May 5, 2000

TO

: Patty Hackett, ESME

THROUGH:

Robert B. Ochsman, Ph.I.

Director, HF

Jacqueline Elder Deputy AED, EXHR

FROM

Terry Van Houten, HF T. The Manual

SUBJECT:

Portable Bed Rails, Performance Criteria and Labeling Rationale

This memo addresses human factors performance criteria and labeling issues related to portable bed rails.

Background

The epidemiological memorandum of May 3, 2000, Portable Youth Bed Rail Entrapments and Hangings provides data for 12 fatalities, 9 incidents resulting in injury and 31 incidents with no resulting injury.

The ages of the victims described in the incident reports ranged from about 3 months up to 5 years. The majority of the victims were less than 3 years old.

In 8 of the 12 fatalities, the bed rail was reported to have been pushed away from the side of the mattress a sufficient distance to allow passage of either the torso but not the head or the head but not the torso. In these scenarios, a horizontal member of the bed rail and part of the mattress or bed structure entrapped the victim. A number of cases contained comments describing the bed rail as having moved partially away from the bed.

With the exception of the in-depth investigation (IDI) reports, information in the reports was limited. While much specific data was not available, it was clear that the entrapment incidents fell into two distinct categories: 1) incidents, and 2) fatalities. However, the incidents

appeared to be potentially serious. In most of these incidents, the victim was physically removed from the entrapment situation preventing a more serious outcome.

Development of Performance Criteria

The reported incidents and complaints were the result of several characteristics of both the product and the individual coming together at a time when the child is intentionally unmonitored and presumed safe by the nature of the product's intended purpose.

All of these portable bed rail products follow a general design theme. They consist of a vertical rail about 13-17 inches in height and 3-5 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 bed rail is held under the mattress by a variety of slip resistant knobs, pads or other means intended to provide resistance.

The friction created to hold the bed rail in place is dependent on a number of factors most notable of which are: 1) the number of arms between the mattress and mattress support, 2) the surface texture of each arm, 3) the amount of surface area each arm exposes to the mattress/mattress support surfaces, 4) the texture of the fabric(s) on the mattress and the mattress support, (5) the weight of the mattress and distribution of that weight with respect to the location of each of the bed rail arms, and (6) the weight of the occupant and the location of the occupant on the bed with respect to each of the bed rail arms.

In general, the bed rail arms are designed so that they can be easily slipped between the mattress and the mattress support. The design of many tends to make insertion easy and removal somewhat more difficult.

Once installed, the bed rail can only be moved outwardly away from the mattress by a force applied in the outward direction. That outward force may originate from the activity of the child in the bed, asleep or awake. The application of any force to move out the bed rail may be expected to occur at any point or points on the bed rail and may be applied multiple times. It should be noted that the bed rail need not be moved out in one continuous motion to produce a hazardous situation. A series of moderate taps can produce the same effect at lower force levels.

The amount of force applied to push out the bed rail depends of the child's strength (which generally increases with age), the motivation to apply a force, and the orientation of the force with respect to the plane of the bed rail.

The incident reports did not contain any detail to quantify the forces that resulted in the bed rail moving. Therefore, Human Factors (HF) had to rely on published data to establish performance levels.

Human Characteristics Associated with the Potential Hazard

The human characteristics associated with the present issue fall into two general categories: body size and strength. Each will be treated separately. Before discussing these topics, the ages of the typical users need to be defined.

In the incident reports, the age of the victims ranged from 3 months to 5 years. Whether this age range is that of the intended user was not considered. For whatever reasons, these are the ages of the children who were placed in these beds and need to be included in safety considerations.

For the purposes of the following discussion, HF will use anthropometric dimensions at the extremes of the age range of 3 months to 5 years and will use strength measurements typical of five-year-olds. In view of the epidemiology data which show fatal consequences in some cases if the bed rail moves beyond a certain distance, HF concludes that using data representative of children ages 3 months to 5 years will reflect the typical user population for these products.

There have been a number of strength studies conducted over the years. The ones most applicable to the issue under discussion are those conducted by Brown et.al., 1973, and de Winter, 1994. Several cautionary notes should be made about any child strength study.

Such studies are difficult to perform in terms of both instrumentation and cooperation of test subjects. For the most part strength studies measure the force at one body position which may not be applicable to another body position that is close to the first but not exact. The definition of strength has also been a persistent difficulty. Special attention must be given to the investigator's criteria for strength such as whether it is a sustained effort for a specified time duration or a peak value lasting only a fraction of a second. The situation under investigation will govern what type of data is applicable.

Within the two studies previously mentioned, the push task is of most interest. Brown et. al., showed that children age 5 years are capable of exerting pushing forces of 60 pounds at the 95th percentile level and about 40 pounds on the average. DeWinter corroborated these values in a subsequent study which obtained pushing capabilities of 245 newtons (equivalent to 59 pounds) for males and 221 newtons (equivalent to 50 pounds) for females. The values from deWinter's study are average values and are not reflective of the upper percentiles of the 5-year-old-age group. Further deWinter's test subjects were sitting at the time of the tests which is closest to the hypothesized incident scenario under consideration.

In view of the above data and information, and in view of the potential consequences of the incidents, Human Factors concludes that portable bed rails should withstand an outwardly directed force of 50 pounds to simulate the upper potential force that may be applied under conditions of reasonably foreseeable use. This performance level is near or at the 95th percentile strength capability of the oldest likely occupant. Human Factors concludes that this performance level provides an increasing safety factor for progressively younger toddlers. Parents purchase these products to solve a perceived hazard and have the expectation that the product will provide a safe environment, particularly for young children. Further, the 50 pound

performance level ensures that the product will perform its safety function of preventing children from falling out of beds as expected by consumers. The recommended performance level ensures that a high safety factor is applied to the youngest expected occupant. While this safety factor decreases as the child matures, it is sufficient to prevent older children from falling off a bed.

The applied force should not result in significant movement of the bed rail. Human Factors suggests that significant movement would produce a gap, which could allow passage of the torso of the smallest expected occupant. Many of the fatalities involved passage of the body but not the head through the gap (it is unclear in some cases). This resulted in the victim being solely supported by the neck.

If the maximum allowable gap is smaller than the minimum dimension of the torso, then the body cannot slip through the opening. The two critical anthropometric dimensions are the chest depth and the buttock depth. Both of these dimensions can be pictured by viewing the body in profile. Whichever of these two dimensions is the smallest at the 5th percentile should establish the maximum permissible movement of the bed rail. If the larger of the two measurements is used, then the smaller portion of the body would be allowed to slip through the opening. This might allow a significant portion of the body (and hence, weight) to exert additional force on the bed rail and force it out a distance which could accommodate the torso but not the head. Because this is an unacceptable situation, the smaller dimension is used.

Five of the victims were 4 to 6 months of age. To consider the younger victims and provide a margin of safety in view of the potential consequence of a larger gap, Human Factors used data for children approximately three months of age. The dimensions for the 5th percentile 3-month-old for chest depth, and buttock depth are 8.1 and 7.5 centimeters respectively. These are 3.2 and 3.0 inches respectively. In view of the above dimensions and to maintain consistency with other similar standards (full-sized baby cribs), Human Factors recommends that the maximum opening permissible should be 2.9 inches. If the maximum allowable gap is smaller than the minimum dimension of the torso, then the body cannot slip through the opening. A British standard for these same products is currently under development. In the most current draft of the study document, which may be used to support the standard, a maximum gap dimension of 2.3 inches is used and was taken for the British standard for children's cribs.

It was stated earlier that the force on the bed rail needs to be applied in an outward direction for testing purposes, perpendicular to the plane of the bed rail. Further, since the occupant of the bed must apply the force, the point of application must be above the mattress surface. How far above the mattress surface is a matter of judgement and in individual cases, depends on the compressibility of the mattress, the height of the mattress, and the weight of the person. For testing purposes, Human Factors recommends that the point of application be located at the mattress level to permit consistent results between testing facilities.

Finally, Human Factors recommends that a weight of 33 pounds be applied to the mattress to simulate the weight of a typical user. The range in weight of expected occupants is about 12 to 41 pounds. Since it is not known what the worst case might be, the 33 pound weight

was selected as a compromise for the extremes in the weights of the users. This weight is approximately the weight of a fifth percentile 5-year-old and a 95th percentile 2-year-old.

Summary of Performance Criteria

In summary, Human Factors recommends the following performance levels:

Applied Force = 50 pounds

Location = at the mattress surface

Allowed opening = 2.9 inches Simulated Weight = 33 pounds

Labeling Issues

There are three basic hazards to be addressed by warnings; 1) entrapment by bed rail movement, 2) entrapment by improper spacing or installation of the bed rail, and 3) entrapment because of flexibility.

In visual examination of multiple models of bed rails, Human Factors has noted the inconsistency in spacing of the horizontal rails which are intended to restrain the occupant. Further, the spacing between the rails does not appear to consider the potential for entrapment if the opening is near the surface of the mattress. For example, if a rail is placed at the surface of the mattress and next rail above it is three inches away, most children under the age of 2 years will be able to slip through the opening up to the head at which point an entrapment situation occurs. The problem is exacerbated by certain mattresses, which vary in thickness or are soft and compress easily under body weight. It is difficult to predict the location of these openings since the designs of the bed rail and the mattress can vary. Further, the weight of each occupant can vary adding to the complexity of the situation. There appears to be no simple solution. To correct the problem, bed rails would need to be designed within specified guidelines, along with multiple warnings to the consumer regarding the thickness of the mattress as well as warnings to be alert to any sagging of the mattress when the bed rail is installed and the occupant is lying next to the rail.

The second entrapment issue occurs as a result of the lengthwise flexibility of the bed rail. Depending on how the bed rail is designed, it may be able to bow out in the center or at the ends when subjected to a large force. Such forces can be developed through a wedging effect starting with a hand or foot and moving to the torso. In some instances, body weight may be sufficient to either bow the rail out and/or move it out until the head is entrapped.

A variation of the bowing phenomenon sometimes occurs at the ends of some bed rails. These models are generally made of a flexible material and have the supporting feet (the part that

slips under the mattress) located away from the bed rail ends. The absence of any reinforcing allows the ends to bend back and forth depending of the direction and amount of force applied to the end. In one fatal incident, the bed rail was installed almost touching the headboard. When the occupant attempted to push the bed rail out, the bed rail end bowed out and permitted the individual's head to move through the opening. When the occupant moved a little further, the bed rail closed around the neck. The individual could not back up since that action closed the opening even more.

General Discussion of Warnings

A warning is intended to alert the consumer to some hazard which is not apparent or common knowledge and the steps that need to be taken to avoid that hazard. The underlying concept is that the consumer has the ability to control the situation. If there is no ability to control the situation, a label is not a workable approach. For example, a warning label may state "Danger - High Voltage. Do Not Touch!" This is a situation under the control of the reader. The instruction to avoid the hazard is simply, do not touch this component. On the other hand, a warning sign that states "Danger - Falling Rock" is not realistically within the control of a driver. If one adds a phrase that states "Do not stop in this area" then one has a somewhat controllable situation. To reiterate, one test for a label is the potential for the consumer to have some control over the situation. That is the basic rule that is followed in the rest of this discussion.

Prepurchase Warnings

In the available epidemiology, it has been noted that there is an indication of these bed rails being used inappropriately. They have been placed on bunk beds, other beds that have no box spring or other situations that set up the conditions for an incident. Human Factors suggests that the proper use applications for these products be prominently displayed on the retail carton Such text viewed before purchase would serve multiple purposes; 1) it would educate the consumer about subtle hazards associated with these bed rails, 2) it would alert the consumer that the application he has in mind may be inappropriate and potentially injurious, and 3) it would alert the consumer that the bed rails are only appropriate for a certain age range of children and that children outside of that age range may be exposed to hazards.

Human Factors suggests that these prepurchase warnings fall into three categories; 1) age, height and weight restrictions, 2) types and sizes of beds appropriate for the particular model of bed rail and 3) a specific warning prohibiting use on bunk beds.

After reviewing the instruction sheets for 16 different models, Human Factors has found there is no consistency in age recommendations. The composite range across various manufacturers is about 6 months to 5 years of age. One manufacturer places a weight limit of 150 pounds without stating any age. Judging from the epidemiology where the age of the victim is stated, the public perception for the application of these products is about the same as the manufacturers'. However, most of the manufacturers do recommend a lower age limit of 2 years.

To bring some consistency to the market and prevent confusion, Human Factors recommends that portable bed rails be labeled for children age 2 years to 5 years with appropriate height and weight limitations if such are applicable. This would at least alert consumers that they were purchasing a product that was appropriate for their child.

Further, there should be short and simple descriptions of the types of beds that this product should not be used on. Finally, there needs to be a strong warning regarding the unacceptability of this product's use on bunk beds and toddler beds. Two fatalities were associated with use on a bunk bed.

Installation Issues

There are a number of instructions that can be given to the consumer to ensure that the bed rail has been installed properly and is performing as intended. The most important of these is to make sure the bed rail is pushed tightly up against the side of the mattress and that the bed rail remains there.

The consumer needs to be instructed on proper bed rail installation, observing end-to-end spacing and the position of any openings with respect to the mattress when the child is on the bed. There needs to be a practical and simple way for the consumer to test whether the bed rail will stay in position and will not creep out if the child pushes or hits against it. A simple tugging or pulling test should be considered as well as some visual cue that will tell the adult with certainty that the situation is acceptable or otherwise. Further, the guidance given should alert the adult to the possibility of gaps existing at either end of the bed rail with respect to the headboard or footboard.

These products appear simple in construction, are inexpensive, and fulfill a straightforward obvious need. There are subtleties, unknown to the consumer, in the structural interaction of the bed rail with the bed. These subtle interactions are the very things that result in the fatalities and which may be minimized through clear communication with the user audience.

Maintenance Issues

The consumer must be repeatedly reminded of several issues. They are: 1) tight fit against mattress each time the rail is installed or the bed made up, 2) checking for broken parts, and 3) checking any locking mechanism for wear or damage. These issues are most amenable to labeling in that they are clear and easily visualized issues, are simple to look for, and may easily be communicated through short sentences or phrases. If space is severely limited on any proposed label and a forced choice is necessary on which messages must appear, it is the opinion of Human Factors that, by far, the first issue is the most important.

In summary, a number of issues have been discussed and some guidance provided to address these issues. By far, the most critical issue is the retention of the bed rail in the bed assembly. Addressing this issue would substantially decrease the number of reported incidents.

References:

Brown, W.C., Buchanan, C.J., and Mandel, J., "A Study of the Strength Capabilities of Children Ages Two through Six", National Bureau of Standards, U.S. Department of Commerce, NBSIR 73-156, August 7, 1973.

de Winter, Peter E., "Pushing and pulling - Loads exerted by Children", TNO Building and Construction Research, The Netherlands, 1994.