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

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

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

December 7, 2010

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

Re: Inquiry on Bed Rail Type Products

Dear Ms. Black:

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

CPSC Mission/Recall Authority/Procedures for Analyzing Death Reports

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

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

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

CPSC Strategies/Decision Making Policy

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

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

Manufacturer/Importer/Distributor/ Retailer Reporting Obligations

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

Medical Examiner Reporting Obligations

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

CPSC/FDA Bed Rail Jurisdictional Questions

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

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

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

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

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

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

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

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

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

CPSC Bed Rail Death and Injury Statistics/Agency Coordination

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

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

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

Activities on Bed Rail Entrapments to Adults

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

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

CPSC Activities on Bed Rail Entrapment Hazards to Children

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

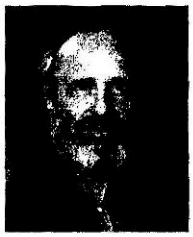
If you would like any additional information or need further clarification on these issues, please feel free to contact me at (301) 504-7546 or at rkhanna@cpsc.gov.

Sincerely,

Rohit Khanna

Bed-rail entrapments still a serious problem

William A. Hyman
July 24, 2008



More In Guest columns

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

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

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

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

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

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

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

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

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

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

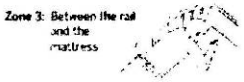
What is the problem?

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

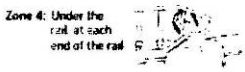
Zone 1: Within (between) the bars of the rails

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

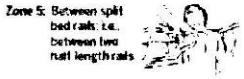
Zone 3: In the gap between the rails and the mattress



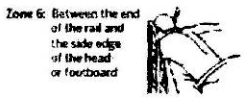
Zone 4: Under the rail and between the rail and the mattress at the outside edge of the rail



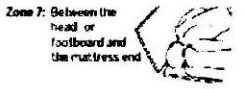
Zone 5: Between split rails



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



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



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

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

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

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

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

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

What are the real solutions?

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

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

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

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

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

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

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

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

Explaining the death that occurs

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

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

The current situation

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

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

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

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

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

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

5

References

1. FDA Safety Alert, Entrapment Hazards with Hospital Bed Side Rails, dated August 23, 1995, http://www.fda.gov/cdrh/bedrails.html.

2. FDA, FDA Issues Warning about Hospital Bed Side Rails, FDA Consumer, 29, December, 1995.

3. Todd, J., Ruhl, C., & Gross, T., Injury and Death Associated with Hospital Bed Side-Rails: Reports to the U.S. Food and Drug Administration from 1985 to 1995, American Journal of Public Health 87 (10): 1675-1677, 1997.

4. Parker, K., Miles, SH., Deaths caused by bed rails. Journal of the American Geriatrics Society, 45:797-802, 1997.

5. FDA, Hospital Bed Safety Workgroup, http://www.fda.gov/cdrh/beds/.

6. Miles, S., Deaths between bedrails and air pressure mattresses. Journal of the American Geriatrics Society, 50, 1124-1125, 2002.

7. FDA, Hospital Bed Safety Workgroup, dated, Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities and Home Care Settings, http://www.ute.kendal.org/learning/documents/clinicalguidance_SideRails.pdf, April, 2003.

8. The Joint Commission, Bed rail-related entrapment deaths, dated September 6, 2002, http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_27.htm.

9. Veterans Administration, National Center for Patient Safety, Bed Rail Entrapment, http://www.va.gov/ncps/alerts.html, July 12, 2001.

10. Shapiro, J., Bedrails Can Cause Death in Frail Elderly, National Public Radio, http://www.npr.org/templates/story/story.php?storyId=5519589, June 29, 2006.

11. FDA bed safety guidance: Mitigating risk: Interviews with Larry Kessler and Marc Bruley, Nursing Homes, May, 2006, Available on line at http://www.nursinghomesmagazine.com/ME2/Default.asp.

12. FDA, Hospital Bed Safety Workgroup, Hospital Bed System Dimensional and http://www.fda.gov/cdrh/beds/guidance/1537.html Assessment Guidance to Reduce Entrapment - Guidance for Industry and FDA Staff, dated March 10, 2006.

Comments (2) Login

Sort by: Date Rating Last Activity

DuWayne E Kramer, Jr 0

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

Reply

William A Hyman [illegible] 0

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

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

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

Reply

Post a new comment

Comment as a Guest, or login:

Name Email Website (optional)

Subscribe to None Submit Comment

McKnight's encourages reader feedback on news stories, Guest Columns and blog entries. We reserve the right to remove comments with profanity, personal attacks or other inappropriate material. Also, comments that include product solicitations may be subject to removal from www.mcknights.com. For further questions, please contact Web Editor Liza Berger at liza.berger@mcknights.com.

Comments by

(3)

The New York Times
The New Old Age
Caring and Coping

MARCH 10, 2010, 12:29 PM

Safe in Bed?

By PAULA SPAN

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

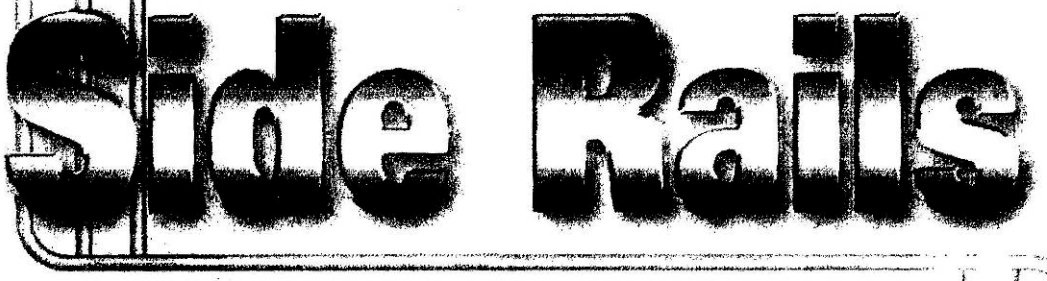
The ultimate solution would be to establish manufacturing standards so that no bed has a dangerous gap between mattress and rail, just as one can no longer buy a crib that could entrap an infant. "We value babies more than elderly nursing home patients," Dr. Miles observed.

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

(4)

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

Myths and Facts About Side Rails



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

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

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

Karen A. Talerico is an assistant professor and scientist in the Department of Population-Based Nursing at Oregon Health and Sciences University in Portland. Elizabeth Capezuti is an associate professor and the Independence Foundation Wesley Woods Chair of Gerontologic Nursing at Emory University's Nell Hodgson Woodruff School of Nursing in Atlanta.

Resource

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

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

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

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

MYTH: Side rails are not restraints.

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

HCFA offers a functional definition of restraints for both nursing homes and hospitals: any device that restricts a patient's voluntary movement or access to his body and that can't easily be removed by the patient constitutes a restraint.[3,5] The Food and Drug Administration (FDA) offers a narrower definition; it considers restraints to be devices that attach to a patient's body and that are intended for such use by the manufacturer, according to labeling or promotional materials.[6] Neither does the Joint Commission on Accreditation of Healthcare Organizations consider side rails to be restraints.[7] Because side rail use is associated with significant risks to patients, and because facilities rely on federal monies through the Medicare and Medicaid programs, we believe it wisest to practice in accordance with HCFA's definition.

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

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

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

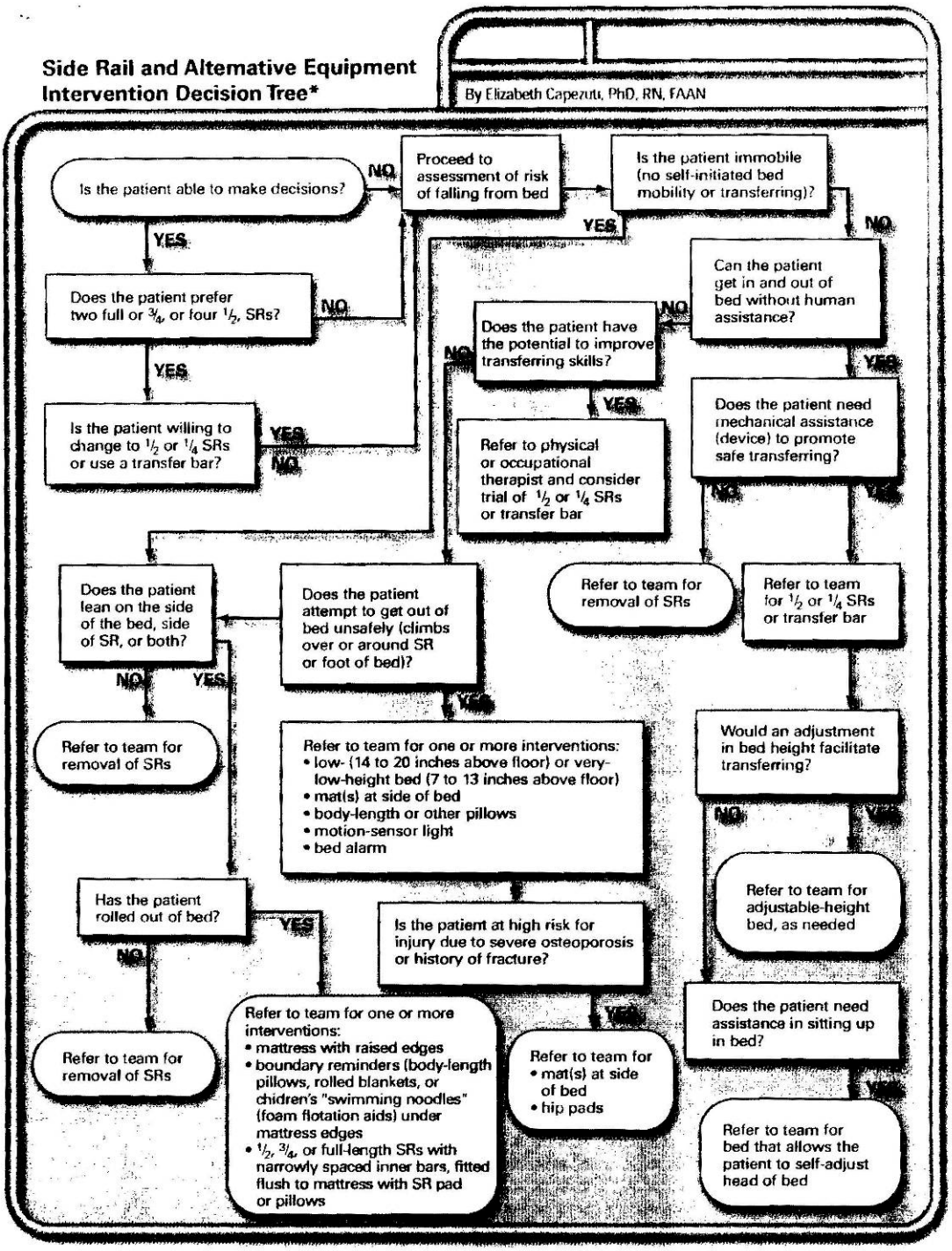
MYTH: The use of side rails poses no risk to the patient.

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

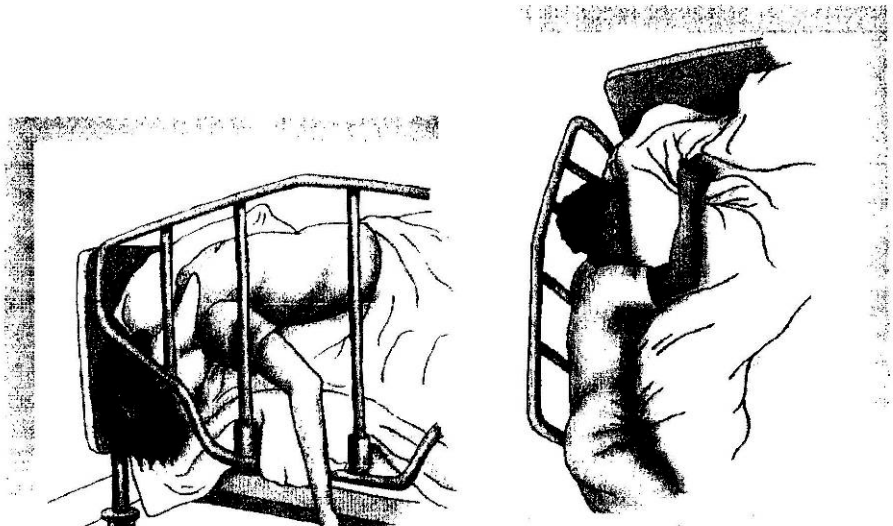
- increased incidence of incontinence.[14]
- increased likelihood of serious injury resulting from a fall from a height greater than that of the

Side Rail and Alternative Equipment Intervention Decision Tree*

By Elizabeth Capezuti, PhD, RN, FAAN



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



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

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

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

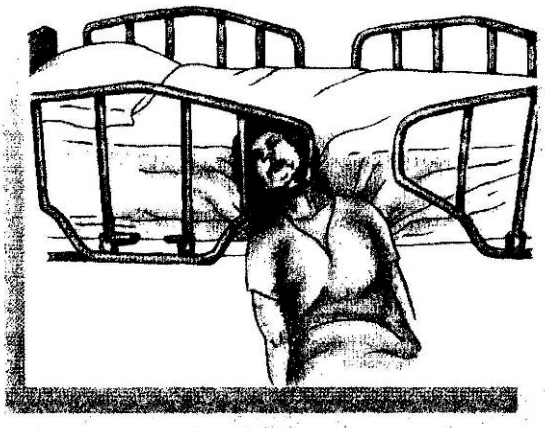
Because side rail surfaces may serve as potential reservoirs for pathogens such as vancomycin-resistant enterococci and *Clostridium difficile*, they've been implicated in nosocomial transmission.[17, 18]

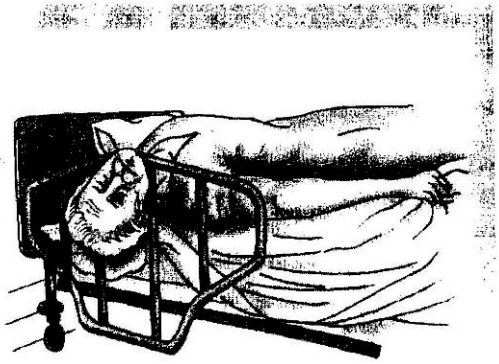
Deaths related to the use of side rails may occur even when the side rails are both installed and used as directed by the manufacturer. Parker and Miles studied 74 deaths reported to the U.S. Product Safety Commission between 1993 and 1996 and found that 69% of them occurred in people older than age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

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

Legal implications. In 1995, the FDA issued a Safety Alert concerning hazards associated with side rail use and informing clinicians that use of side rails may not be benign practice.[13] Elizabeth Capezuti (an author of this article) and colleagues are completing an ongoing study of legal cases involving side rails and falls from bed; preliminary findings indicate a significant increase in the number of hospitals and nursing homes sued for injuries and deaths related to side rail entrapment in the last five years. While many of these cases are still in litigation, the majority of them have involved suits against a facility rather than a nurse

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





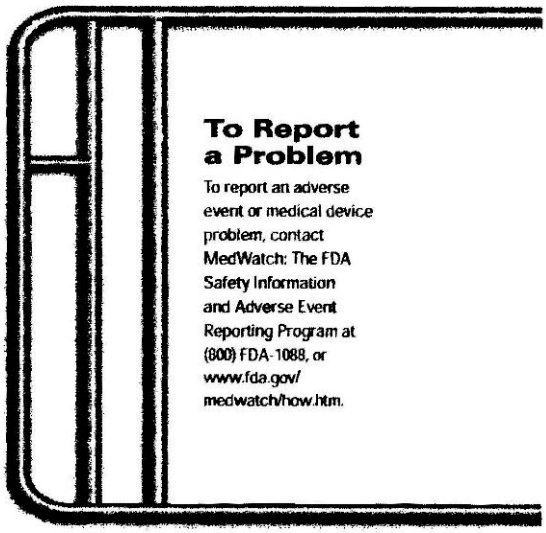
Rail and in-bed entrapment:
Most of the patient's body is on the bed, and the airway is occluded by the rail as a result of side rail latch failure.

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

MYTH: Safe alternatives to side rails do not exist.

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

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



To Report a Problem

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

Alternatives to Side Rails

Low-height beds have been employed successfully at health care facilities during the last five years.[6] They usually have short (quarter-length) upper rails instead of full-length ones (that is, fully enclosing). Nonadjustable low-height or platform beds may cause injury to staff members as a result of the necessity of bending when assisting patients. We suggest the use of a bed which can be electronically adjusted from a maximum height of 26 to 30 in. to a minimum height of 7 to 15 in. as measured from floor to top of mattress with the patient on it. Manufacturers include*:

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

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

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

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

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

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

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

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

REFERENCES

1. Health Care Financing Administration. Quality of care—standards. Hospital conditions of participation for patients' rights: interpretive guidelines. 2000 Jun. http://www.hcfa.gov/quality/4b2.htm.
2. Braun JA, Capezuti E. Siderail use and legal liability issues in nursing homes. *Illinois Bar J* 2000;88:324-6, 8-9, 32, 34.
3. Ludlam JE. Bedrails: up or down? *Am J Nurs* 1957;75(11):1439-40.
4. Barbee GC. More about bedrails and the nurse. *Am J Nurs* 1957;57(11):1441-2.
5. Health Care Financing Administration. *State operation manual. Transmittal 274: interpretive guidelines.* Washington (DC): The Administration; 1995 Jun.
6. Westmoreland TM, Feigal DW. [Letter to Cathy Morris, President of the AHFSA, regarding difference between the Food and Drug Administration's and the Health Care Financing Administration's interpretation of a physical restraint]. *HCFA Long Term Care Survey Protocol Information Site.* 2000 Aug 1. http://www.hcfa.gov/medicaid/ltcsp/q&a/t18-8100.htm.
7. Joint Commission on Accreditation of Healthcare Organizations. *Comprehensive accreditation manual for hospitals: the official handbook.* Oakbrook Terrace (IL): The Commission; 2001.
8. Capezuti E, et al. The effect of a low-height bed intervention on nighttfalls among frail nursing home residents [abstract]. *Gerontologist* 1999;39(Special issue 1):196.
9. Hanger HC, et al. An analysis of falls in the hospital: can we do without bedrails? *J Am Geriatr Soc* 1999;47(5):529-31.
10. Si M, et al. Removal of bedrails on a short-term nursing home rehabilitation unit. *Gerontologist* 1999;39(5):611-4.
11. Food and Drug Administration. *FDA safety alert: entrapment hazards with hospital bed side rails.* Rockville (MD): Department of Health and Human Services; 1995.
12. Parker K, Miles SH. Deaths caused by bedrails. *J Am Geriatr Soc* 1997;45(7):797-802.
13. Todd JF, et al. Injury and death associated with hospital bed side rails: reports to the US Food and Drug Administration from 1985 to 1995. *Am J Public Health* 1997;87(10):1675-7.
14. Brandeis GH, et al. The prevalence of potentially remediable urinary incontinence in frail older people: a study using the Minimum Data Set. *J Am Geriatr Soc* 1997;45(2):179-84.
15. Capezuti E, et al. Individualized interventions to prevent bed-related falls and reduce siderail use. *J Gerontol Nurs* 1999;25(11):26-34; 52-3.
16. Donius M, Rader J. Use of siderails: rethinking a standard of practice. *J Gerontol Nurs* 1994;20(11):23-7.
17. Catalano M, et al. Survival of *Acinetobacter baumannii* on bed rails during an outbreak and during sporadic cases. *J Hosp Infect* 1999;42(1):27-35.
18. Noskin GA, et al. Recovery of vancomycin-resistant enterococci on fingertips and environmental surfaces. *Infect Control Hosp Epidemiol* 1995;16(10):577-81.
19. Capezuti E, et al. Individualized assessment and intervention in bilateral siderail use. *Geriatr Nurs* 1998;19(6):322-30.
20. Sullivan-Marx EM. Psychological responses to physical restraint use in older adults. *J Psychosoc Nurs Ment Health Serv* 1995;33(6):20-5.
21. Hammond M, Levine JM. Bedrails: choosing the best alternative. *Geriatr Nurs* 1999;20(6):297-301.
22. Mosley A, et al. Initiation and evaluation of a research-based fall prevention program. *J Nurs Care Qual* 1998;13(2):38-44.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date: June 7, 2000

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

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

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

FROM : Joyce McDonald
Program Analyst
Division of Hazard Analysis

SUBJECT : Portable Youth Bed Rail Entrapments and Hangings

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

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

Table 1: Portable Youth Bed Rail Entrapment and Hanging Incidents

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

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

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

[3] These 16 incidents shown in Table 1 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 data[5] for children 0-5 years old involving falls from beds and incidents occurring on the wall side of the bed that resulted in fatalities.

Falls

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

---

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

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

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

Wall Side Incidents

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

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

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

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

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

PUBLIC SUBMISSION

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

Submitter Information

Name: Kenneth J. Walsh
Organization: Bureau Veritas

General Comment

To Whom It May Concern

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

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

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

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

Sincerely Yours,
Kenneth J. Walsh

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

TAB B

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

Memorandum

Date: January 4, 2012

TO : Rohit Khanna
Project Manager, Portable Bed Rails

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

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

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

I. BACKGROUND

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

II. DISCUSSION

A. ASTM Activity (November 2010–January 2012)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

FIG. 10 Examples of Fail Conditions.

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

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

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

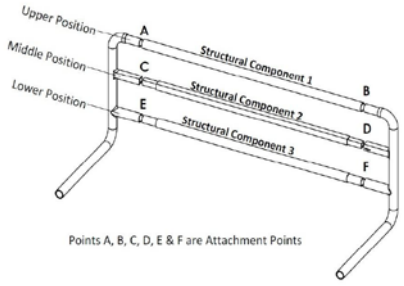


FIG. 12 Example of Tube Inverted or Interchanged

Figure 4. Example of inverted or interchanged parts

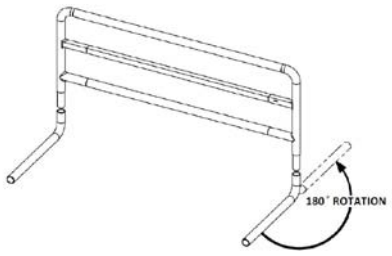


FIG. 13 Example of Test for Unidirectional Arm

Figure 5. Example of testing the arm orientation

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

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

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

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

IV. Staff Recommendations for Final Rule

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

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

Appendix A: Comparison of NPR and ASTM F2085-12

I. Introduction

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

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

II. Comparison of Scope - NPR vs. ASTM

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

Table 1. Revision to Section 1. Scope

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature.	N/A - The NPR did not address toddler beds.		The ASTM scope was revised to clarify that the standard does not apply to guardrails attached to toddler beds. New language, shown underlined, was added.	1. Scope 1.1 This consumer safety specification establishes requirements for the performance of portable bed rails. It also contains requirements for labeling and instructional literature. This consumer safety specification does not cover guardrails that fall under the scope of Consumer Safety Specification F1821 or guardrails that are designed for a specific model of bed and which attaches at the headboard or footboard.
N/A – non-rigid bed rails are not included in the 2010 ASTM standard.	The NPR would revise ASTM F2085-10a to include inflatable and foam bed rails to the scope. Staff recommends that only the General Requirements of section 5, the performance requirement of subsection 6.3, Enclosed Openings, and the warning requirement of subsection 9.3.1 of Section 9, Marking and Labeling requirements apply to foam and inflatable portable bed rails products.	1.5 *Foam* and *inflatable* bed rails need only meet the General Requirements of section 5, the performance requirement of 6.3 Enclosed Openings, and the warning requirement of 9.3.1.	ASTM adds non-rigid bed rails in the section 5 General Requirements	5.5 Non-rigid bed rails need only meet the general requirements of Section 5, the performance requirement of 6.3, and the warning requirements of 9.3.

III. Comparison of Terminology - NPR vs. ASTM

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

Table 2. Revision to Section 3. Terminology

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
N/A – *captive hardware* is not included in the 2010 ASTM standard.	N/A - NPR did not define *captive hardware.*		ASTM adds terminology for *captive hardware*	3.1.4 *captive hardware*, *n*—fasteners that remain attached to their respective components before normal assembly and after normal disassembly (See Fig 1).
N/A – following terms are not in the 2010 standard: • *Foam bed rail* • *Inflatable bed rail* • *Critical assembly component* • *Critical installation component* • *Misassembled/-functional bed rail*	The NPR would revise the terminology in section 3 of ASTM F 2085–10a by creating new terms for: • *Foam bed rail* • *Inflatable bed rail* • *Critical assembly component* • *Critical installation component* • *Misassembled/-functional bed rail*	3.1.10 *foam bed rail*, n— portable bed rail constructed primarily of non-rigid materials, such as fabric or foam.	ASTM adopts the terminology from the NPR but combines foam and inflatable bed rails into a single term, "*non-rigid bed rail.*"	3.1.12 *non-rigid bed rail*, *n*—portable bed rail constructed of non-rigid materials, including but not limited to fabric or foam, or that requires air be inflated into the product to achieve structure.
		3.1.11 *Inflatable bed rail*, n— a portable bed rail constructed primarily of non-rigid material that requires air be inflated into the product to achieve structure.		
		3.1.12 *critical assembly component*, *n* —any component of the bed rail that requires consumer assembly in order to meet the performance requirements of sections 6.1 *Structural Integrity*, 6.3 *Enclosed Openings,* 6.4 *Openings Created by Bed Rail Displacement of Adjacent Style Portable Bed Rails,* 6.5 *Openings Created by Displacement of Mattress-Top Portable Bed Rails and* 6.6 *Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers' Beds.*	ASTM does not add terminology for critical assembly components because the subcommittee determines that all bed rail components are critical to safety.	
		3.1.13 *critical installation component, n* — any component of the bed rail that is used to attach the bed rail onto the bed.	ASTM creates a new definition for *installation component* that is similar to the NPR's definition for *critical installation component*.	3.1.8 *installation component, n* — component of the bedrail that is specifically designed to attach the bedrail to the bed and typically located under the mattress when in the manufacturer's recommended use position.

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

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

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

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

IV. Comparison of General Requirements NPR vs. ASTM

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

Table 3. Revision to Section 5. General Requirements

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

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

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

V. Comparison of Performance Requirements NPR vs. ASTM

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

Table 4. Revision to Section 6. Performance Requirements

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

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
N/A - the 2010 ASTM standard did not address misassembly or captive hardware.	NPR would create a new section in ASTM F2085–10a to require that fasteners, such as nuts and bolts, be attached or captive to the frame to prevent loss or non-use.	6.9.2 - The bed rail can be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component, such as the frame.	ASTM creates new section 5.8, which requires that all fasteners are captive or attached to the component. This is equivalent to section 6.9.2 of the NPR.	5.8 For products requiring consumer assembly, supplied hardware used for assembly of the bed rail such as screws, nuts or bolts shall be captive hardware to their respective components.
N/A - the 2010 standard does not have requirements to determine if a misassembled bed rail is acceptable.	NPR would create a new section in ASTM F2085–10a to determine the acceptability of a misassembled/functional portable bed rail. These new sections would provide the criteria for testing laboratories to determine the sufficiency of visual cues for misassembly.	6.10 *Determining Acceptability of Misassembled/functional bed rail misassembled/functional bed rails* shall meet 6.10.1, 6.10.2, 6.10.3, or 6.10.4. 6.10.1 The bed-rail shall not remain upright or the vertical height shall decrease by 6 inches at any point along the top rail when tested to 8.7. 6. 10.2 The fabric cover or mesh shall have a permanent sag a minimum of 3 inches after tested in accordance with 8.8. 6.10.3 The fabric cover will not fit over the frame without tearing. 6.10.4 Mating parts must clearly show misassembly by two parts overlapping and creating a minimum of a ½-inch protrusion out of the plane of the rail.	N/A - ASTM F2085-12 does not have requirements to determine whether a misassembled bed rail is acceptable. Instead, a misassembled bed rail fails the standard if it ***appears to be functional.*** A misassembled bed rail that appears to be **nonfunctional** passes the standard. This determination is up to the judgment of the test lab. The definition of misassembly and the figures that show examples of passing and failing bed rails should provide sufficient guidance for a test lab to make a determination.	

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

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

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

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

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

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

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

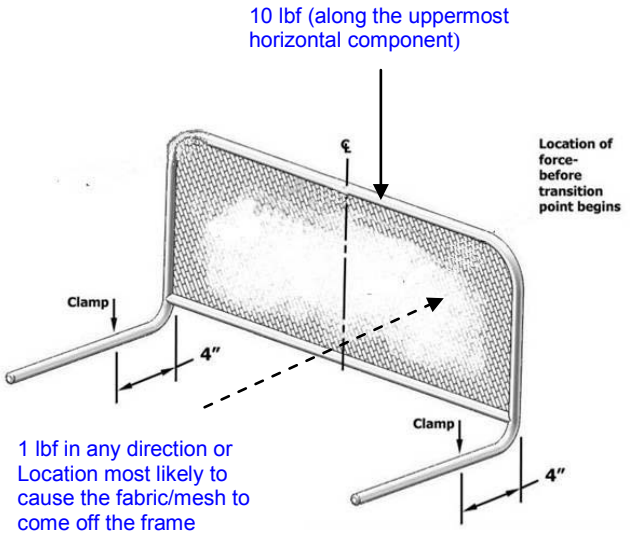
The difference between the ASTM requirements and the NPR requirements is that ASTM does not have a physical test that establishes pass and fail criteria to determine whether a misassembled bed rail appears to be functional. Determination of whether a misassembled bed rail *appears to be functional* (failing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

VI. Comparison of Test Methods - NPR vs. ASTM

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

Table 5. Revision to Section 8. Test Methods

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
N/A – the 2010 standard does not have test requirements to determine if a misassembled bed rail is acceptable.	NPR would create a new section in ASTM F2085–10a to provide test criteria to determine the acceptability of a misassembled/functional portable bed rail	8.7 *Test Method for Determining Acceptability of Vertical Structure of a misassembled/functional bed rail:* 8.7.1 If possible, attempt to assemble the bed rail in a misassembled configuration(s), as defined in 6.9 *Determining Misassembled/functional bed rail* 8.7.2 Firmly secure the misassembled bed rail on a table top or other stationary flat surface, using clamps. The clamps should be located 4 to 6 inches from the intersection of the bed rail legs to the vertical plane (see Figure 8). 8.7.3 Gradually apply a force of 10 lbs, using a ½-inch disc to the uppermost horizontal component of the rail in a downward direction at a location along the horizontal component to most likely vertically deform the bed rail (see Figure 8). Apply the force over a period of 5 seconds; hold the force for 10 seconds, and release. 8.7.4 Repeat 8.7.1 through 8.7.3 for all misassembly configurations discovered in 6.9. 8.8 *Test Method for Determining Fabric Sag Acceptability of a misassembled/functional bed rail:* 8.8.1 If possible, attempt to assemble the bed rail in a misassembled configuration(s), as defined in 6.9 *Determining Misassembled/functional bed rail.* 8.8.2 Gradually apply a force of 1 lb, using a ½-inch disc on the fabric/mesh in any direction or location along the fabric/mesh that is most likely to cause it to come off of the frame (see Figure 8). Apply the force over a period of 5 seconds, hold for an additional 10 seconds and release. 8.8.3 Repeat 8.8.1through 8.8.2 for all misassembly configurations discovered in 6.9.	N/A - ASTM F2085-12 does not have test requirements to determine if a misassembled bed rail is acceptable.	

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

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

VII. Revisions to the Test Equipment Section in ASTM

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

Table 6. Revisions to Section 7. Test Equipment

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

ASTM F2085-10a	NPR rationale	NPR	ASTM F2085-12 rationale	ASTM F2085-12
recommended quantity of a commercial detergent, and dried in an automatic home tumble dryer. 7.1.2.2 *Mattress Performance*—The foam shall have an Indentation Load Deflection (ILD)4 of between 28 and 33 when tested in accordance with Test Methods D3574, method B1.				
No change	The addition of the force gage specification would help clarify the manner in which the force will be applied under the proposed test methods discussed in section (vii).	Proposed section 1224.2(b)(5)(i) would state that a force gauge must have a minimum range of 0 to 50 lb (222N) with a maximum tolerance of±0.25 lb (1.11N), as set forth under a new section7.6 of ASTM F 2085–10a.	ASTM added the force gage specification from the NPR.	7.6 *Force Gauge*—Gauge shall have a minimum range of 0 to 50 lb (222 N) with a maximum tolerance of 60.25 lb (1.11 N).

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

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

Table 7. Revisions to Section 9. Marking and Labeling

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

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer. 9.3.2.5 For manufacturers' specific bed rails: *(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	require critical installation components to be labeled with the entrapment hazard warning for portable bed rail use to warn of issues related to misinstallation of portable bed rails	labeled with the entrapment hazard warning in 9.4.1. The entrapment hazard warning must be in contrasting colors, permanent, conspicuous, and sans serif-style font. In the entrapment hazard warning statement the safety alert symbol "⚠" and the words ''WARNING – ENTRAPMENT HAZARD'' must not be less than 0.20 in. (5 mm) high. The remainder of the text must be characters whose upper case must be at least 0.10 in. (2.5 mm) high. 9.4.1 The warning must including the following, exactly as stated below: ⚠WARNING – ENTRAPMENT HAZARD NEVER use portable bed rail without installing this part onto bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death	on installation components. This requirement is similar to the NPR	entrapment hazard warning in 9.4.1. The entrapment hazard warning shall be in contrasting colors, permanent, conspicuous, and sans serif style font. In the entrapment hazard warning statement the safety alert symbol "⚠" and the words "WARNING – ENTRAPMENT HAZARD" shall not be less than 0.20 in. (5 mm) high. The remainder of the text shall be characters whose upper case shall be at least 0.10 in. (2.5 mm) high. 9.4.1 The following warning shall be addressed: ⚠WARNING – ENTRAPMENT HAZARD NEVER use bed rail without properly securing bed rail to bed. Incorrect installation can allow bed rail to move away from mattress, which can lead to entrapment and death. NOTE 2—Addressed means that verbiage other than what is shown can be used as long as the intent is the same or information that is product-specific is presented.

Table 8. Revisions to Section 11. Instructional Literature

ASTM F2085-10a	NPR rationale	NPR	ASTM 2085-12 rationale	ASTM 2085-12
11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, maintenance, cleaning, operating, and adjustment instruction and warnings, where applicable, shall be included. 11.1.1 The instructions shall contain the warning statements required by 9.3.1 in the same exact format and shall address the statements in 9.3.2. In addition, instructions shall address the following: Discontinue use if damaged, broken, or if parts are missing	NPR would revise the language in section 11.1 of ASTM F2085–10a to add the word ''installation'' among the topics in the instructional literature. This requirement would add clear instructional literature for installation components to provide consumers easy-to-understand information for securing portable bed rails on beds.	11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, shall be included.	ASTM adopts the language recommended in the NPR and clarifies the use of warning statements in the instructions.	11.1 Instructions shall be provided with the bed rail and shall be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instruction and warnings, where applicable, shall be included. 11.1.1 The instructions shall contain the warning statements required by 9.3.1 , and, where applicable, shall address the statements in 9.3.2. In addition, instructions shall address the following: 11.1.1.1 Discontinue use if damaged, broken or if parts are missing.

IX. **Conclusion**:

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

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

Appendix B – ESME Staff Response to NPR Comments

Public Comments to NPR Recommendations

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

Comments concerning proposed misassembly and misinstallation requirements

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

Juvenile Products Manufacturers Association (JPMA) Comments

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

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

Kenneth Walsh, Bureau Veritas Comment

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

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

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

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

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

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

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

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

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

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

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

Comments concerning Foam and Inflatable Bed Rails

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

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

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

Comments Concerning Test Platform

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

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

Miscellaneous comments

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

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

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

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

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

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

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

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

DATE: February 1, 2012

DATE: January 13, 2012

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

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

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

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

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

BACKGROUND

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

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

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

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

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

ASTM F2085–10a	NPR
9.3.1.1 Suffocation and Strangulation Hazard	9.3.1.1 ⚠WARNING: Suffocation and Strangulation Hazard
9.3.1.3 Infants who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place infants in adult beds with or without a bed rail.	9.3.1.3 Children who cannot get in and out of an adult bed without help can be trapped between a mattress and a wall and suffocate. NEVER place children younger than 2 years old in adult beds with or without a portable bed rail.

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

DISCUSSION

PUBLIC COMMENTS

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

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

Warning Language Revisions

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

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

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

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

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

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

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

Warning Graphics or Symbols

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

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

Warning Visibility

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

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

Other Labeling Issues

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

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

ASTM SUBCOMMITTEE ACTIVITIES

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

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

ASTM F2085–10a	NPR	ASTM F2085–12
9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib.	9.3.2.1 Use only for children who have outgrown a crib. NEVER use in place of crib.	Use only on (*manufacturer insert applicable bed and mattress/platform information*).
9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up).	9.3.2.2 Use only with children who can get in and out of adult bed without help (typically 2 years and up).	
9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard.	9.3.2.3 ALWAYS keep bed rail pushed firmly against mattress and at least 9 in. from headboard and footboard.	
9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	9.3.2.4 NEVER use on toddler bed, bunk bed, water bed, or bed with inflatable mattress. Use only on adult bed with mattress and mattress support as defined by the manufacturer.	
9.3.2.5 For manufacturers' specific bed rails:	9.3.2.5 For manufacturers' specific bed rails:	
(1) Use only on (*manufacturer insert applicable bed and mattress/platform information*).	*(1)* Use only on (*manufacturer insert applicable bed and mattress/platform information*).	

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

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

slightly lower grade level than the NPR warning language,[4] which means that people who read the warning may be more likely to understand it.

CONCLUSIONS

ESHF staff suggests revisions to the proposed warning requirements to address public comments received in response to the NPR for portable bed rails and to clarify the warning statements. These revisions appear in the latest version of the voluntary standard, ASTM F2085–12. ESHF staff believes that they are superior to the requirements in the prior version of the voluntary standard and the NPR.

[4] The Flesch-Kincaid grade level of the revised warning language is 5.4, whereas, the reading level of the NPR warning language is 6.7, assuming that the warning statements that were required to be "addressed" were written in the exact language used in the standard.

REFERENCES

Johnson, D. A. (2006). Practical aspects of graphics related to safety instructions and warnings. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 463–476). Mahwah, NJ: Lawrence Erlbaum Associates.

Wogalter, M. S., Silver, N. C., Leonard, S. D., & Zaikina, H. (2006). Warning symbols. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 159–176). Mahwah, NJ: Lawrence Erlbaum Associates.

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

TAB D

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

Memorandum

Date: December 9, 2011

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

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Risana T. Chowdhury
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011.

Introduction

The incident data presented in the Portable Bed Rail NPR briefing package in March 2011[1] was extracted on April 1, 2010. This memorandum includes portable bed rail-related incident data reported to CPSC staff from April 1, 2010 through November 9, 2011. The reports of emergency department-treated injuries (none of which were fatal) were ambiguous in the product descriptions, and hence, are excluded from this analysis.

Portable Bed Rail NPR incident data

The proposed rule summarized the data for incidents related to portable bed rails from January 1, 2000 through March 31, 2010. For that period, CPSC received reports of a total of 132 incidents related to portable bed rails. Among the 132 reported incidents, there were 13 fatalities, 40 nonfatal injuries, and 79 non-injury incidents. Of the 13 child fatalities reported involving portable bed rails, most children (9 out of 13) were under 1-year-old; two were between 1 and 2 years old; and two children, both physically handicapped, were 6 years old. Of the 13 fatalities, there were 2 deaths that resulted from portable bed rail displacement, when the portable bed rail partially pushed away from underneath the mattress and allowed the child to fall into the opening and get trapped. There were 3 cases of portable bed rail misassembly. In 3 additional fatal incidents, the contributing factor(s) that led to the hazardous entrapment scenario could not be determined. The beds used in all 8 cases

[1] http://www.cpsc.gov/library/foia/foia11/brief/bedrailNPR.pdf.

were adult size. The remaining 5 (of the 13) fatal incidents had no product or scenario-specific information.

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

New Incident Data[2] on Portable Bed Rails

A search of the CPSC epidemiological databases showed that there were 23 new portable bed rail-related incidents reported between April 1, 2010 and November 9, 2011. These incidents reportedly occurred between 2009 and 2011. Four of the 23 incidents were fatal, and 19 were nonfatal incidents, 8 of which reported an injury. In addition, CPSC staff has received additional information, through in-depth follow-up investigations, on 4 deaths that were listed has having insufficient information at the time of the publication of the NPR.

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

A. Fatalities

Among the newly reported incidents, there were 4 fatalities. One resulted from a misinstalled bed rail (document number X1190536A), where the decedent was strangled by the straps of the reinforced anchor system. The second fatality (document number I1170672A) occurred when the infant slipped through the torn section of the mesh and got caught when the bed rail flipped down and caught him at the neck. The remaining 2 fatalities (document numbers 0906085374 and 0948097318) lack any information on the product or scenario-specific details.

B. Nonfatal Incidents

Among the newly reported incidents, there were 19 nonfatal incidents, 8 of which resulted in injuries.

---

[2] The CPSC databases searched were the In-Depth Investigations (INDP) file, the Injury or Potential Injury Incidents (IPII) file, and the Death Certificates (DTHS) file. These reported deaths and incidents are neither a complete count of all that occurred during this time period, nor are they a sample of known probability of selection. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to portable bed rails.

Date of extraction for reported incident data on portable bed rails was November 9, 2011. All data coded with product code 4075 and age as 6 years or younger (to accommodate any physically disabled children) were extracted. Upon careful joint review with the CPSC's Directorate for Engineering Sciences staff, some cases (adult bed rails, for example) were excluded.

The 8 injuries sustained were mostly bumps and bruises; one case reported laceration that was severe enough to require multiple stitches, and another reported a fractured collarbone. None of the injuries required hospitalization.

C. Hazard Pattern Identification

The hazard patterns identified among the 23 incident reports are grouped in descending order of frequency of incidents, as follows:

- *Hinge-lock failure:* There were 8 incidents, including 4 injuries and 1 fatality, where the hinge-lock mechanism failed to keep the side panel in an upright position. The hazard in the fatality was a combination of hinge-lock failure and torn mesh panel (see below).

- *Displacement of bed rail*: There were 7 incidents, including 3 injuries, where the bed rail pushed out from underneath the mattress and created an opening between the mattress and the rail.

- *Sharp surfaces:* There were 3 incidents, including 1 injury, due to sharp surfaces on the bed rail.

- *Worn or poor quality fabric on mesh panel:* There was 1 fatal incident that was attributable, in part, to the torn mesh panel and, in part, to the hinge-lock failure of the bed rail (see above).

- *Misinstallation:* One strangulation fatality on the straps of the reinforced anchor system of the bed rail was due to the improper installation of the bed rail.

- *Miscellaneous or unknown issues:* There were 4 incidents, including 2 fatalities with insufficient information on the product or scenario. Of the 2 nonfatal incidents, 1 reported hazards from broken screws, while the other reported design issues with the bed rail.

Conclusion

The hazard patterns identified among the 23 incident reports were similar to the hazard patterns identified in the data included in the NPR. Among the newly reported incidents, there were 4 fatalities. In addition, CPSC staff conducted follow-up investigations on 4 deaths that were listed as having insufficient information at the time of publication of the NPR; 2 of them are now known to be unrelated to the use of a portable bed rail.

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

TAB E

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

Memorandum

Date: January 6, 2012

TO : Rohit Khanna
Project Manager, Portable Bed Rails

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

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

FROM : Samantha Li
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of Draft Final Rule for Portable Bed Rails

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104 of the CPSIA requires that the U.S. Consumer Product Safety Commission (CPSC) evaluate the current existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. While portable bed rails are not explicitly mentioned in section 104, they are a durable toddler product of longstanding interest to the agency.

In March 2011, the CPSC proposed adopting the voluntary ASTM International (formerly known as the American Society for Testing and Materials) standard for portable bed rails (F2085–10a *Standard Consumer Specification for Portable Bed Rails*) with a few modifications. Staff recommended that portable bed rails meet additional performance requirements to address fatal incidents resulting from misassembly and potentially fatal incidents that resulted from misinstalled portable bed rails. In response to injury data supplied by CPSC staff, ASTM revised the voluntary standard to reduce entrapment hazards by incorporating requirements for misassembled and misinstalled portable bed rails similar to those recommended by CSPC staff.[1] In November 2011, ASTM balloted a revision to the standard ASTM F2085-10a that contained

[1] Memorandum from Mark Kumagai, Mechanical Engineering, dated January 4, 2012, Subject: Comparison of ASTM 2085-12 Standard Consumer Specification for Portable Bed Rails with the Proposed Requirements in the NPR Docket # CPSC- 2011-0019.

the additional requirements and also included an expanded scope to cover non-rigid portable bed rails. They published a revised standard on January 1, 2012. The current version of the voluntary standard is F2085–12. Staff now recommends adopting the current voluntary standard without changes.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that CPSC staff prepare a final regulatory flexibility analysis when the Commission promulgates a final rule. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

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

The Product

As specified in the current ASTM standard (F2085–12), a portable bed rail is a device intended to be installed on the side of an adult bed and/or on the mattress surface to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2 to 5 years old). They include bed rails that have a vertical plane that presses against the side of the mattress but does not extend over it (referred to as "adjacent type bed rails"), as well as bed rails that extend over the sleeping surface of the mattress (called "mattress-top bed rails"). Portable bed rails constructed primarily from nonrigid materials, such as fabric, foam, or an inflatable device, are also covered by the voluntary standard.

Both portable bed rails, made for a specific manufacturer's adult-size beds, and "universal" portable bed rails, which can attach to any adult-size bed, are included under the voluntary standard. However, guardrails, which are used with crib mattresses on toddler beds, are not covered under the voluntary standard. They are covered by the CPSC's standard for toddler beds,[2] as opposed to the voluntary standard for portable bed rails.[3]

[2] The rule became effective on October 20, 2011.
[3] Guard rails are: (1) sold with a crib, or (2) can be purchased separately to convert a crib to a toddler bed.

Other products not covered by the voluntary standard include:

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

The Market for Portable Bed Rails

Typically, portable bed rails are produced and/or marketed by juvenile product manufacturers and distributors or by furniture manufacturers and distributors. Currently, there are at least 17 known manufacturers or importers supplying bed rails to the U.S. market. Thirteen are domestic manufacturers (76 percent), and three are domestic importers (18 percent). The remaining firm has an unknown supply source, and there is no publically available information regarding its size.

Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of portable bed rails is small if it has 500 or fewer employees; an importer is considered small if it has 100 or fewer employees. Based on these guidelines, 12 of the domestic manufacturers and three of the domestic importers known to be supplying portable bed rails to the U.S. market are small. There may be additional unknown small manufacturers and importers operating in the U.S. market as well.

The Juvenile Products Manufacturers Association (JPMA), the major U.S. trade association that represents juvenile product manufacturers and importers, runs a voluntary Certification Program for several juvenile products.[4] Five manufacturers supply bed rails to the U.S. market that are compliant with the ASTM standard F2085–10a (the previous voluntary standard). Among them, 4 are JPMA-certified as compliant with the ASTM standard F2085–10a, and 1 firm claims compliance. Of the 3 importers, 1 firm is JPMA-certified as ASTM compliant with F2085–10a, and 1 firm claims to be in compliance. All 7 firms, which are either JPMA-certified or claim compliance with the ASTM standard F2085–10a, are small. However, none of these firms meet the current voluntary standard requirements (F2085–12).

JPMA estimates that current annual sales of portable bed rails are approximately 750,000 units, and retail sales is approximately $20 million. No information is available about the average product life of bed rails; but if, for example, bed rail sales are assumed to have remained constant in recent years, and bed rails remain in use for 3 to 5 years, then currently, there might be 2.25 million to 3.75 million bed rails in use.

[4] Since 1976, JPMA has run a voluntary Certification Program for several juvenile products, beginning with high chairs. Products voluntarily submitted by manufacturers are tested against the appropriate ASTM standard and only passing products are allowed to display JPMA's Certification Seal. See http://www.jpma.org/content/safety/overview for more information.

National estimates of bed rail product-related injuries are not available because the National Electronic Injury Surveillance System (NEISS) data does not allow for clear identification of youth bed rails. Therefore, the risk of injury associated with the number of products in use cannot be calculated.[5]

Reason for Agency Action and Legal Basis for the Draft Final Rule

Under Section 104 of the CPSIA, the CPSC can promulgate a mandatory standard for portable bed rails that is substantially the same as, or more stringent than, the voluntary standard. The current voluntary standard (F2085-12) has four modifications from F2085-10a. The first two changes specify test procedures for determining when bed rails are considered to be misassembled and misinstalled. The third change requires different warning labels and makes the warning statements more concise. The last change includes non-rigid portable bed rails under the scope of the voluntary standard and specifies performance requirements. CPSC staff recommends adopting the current voluntary standard with no changes.

Compliance Requirements of the Draft Final Rule

CPSC staff recommends adopting the current voluntary ASTM standard (F2085–12) with no modifications. Key components of F2085–12 include:

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

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

Portable bed rails constructed primarily of non-rigid materials or foam and inflatable bed rails are also covered by the voluntary standard, but the requirements for misinstallation and misassembly do not apply to non-rigid products.

[5] Memorandum from Risana T. Chowdhury, dated December 9, 2011, Subject: Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries Reported Between April 1, 2010 and November 9, 2011.

The current ASTM standard (F2085-12) revises the misassembly and misinstallation performance requirements, removes one performance requirement, and revises the warning statements from F2085-10a: [6]

- Misassembly requirements
    - The current voluntary standard adds illustrations and figures to the misassembly performance requirements to show examples of correctly and incorrectly assembled bed rails. The performance requirements are intended to prevent entrapment.
    - The modified testing requirements will reduce the number of configurations required for testing and allow more consistent evaluation in determining when bed rails are misassembled.
    - The current voluntary standard does not include the CPSC staff–proposed requirement from the notice of proposed rulemaking to use visual cues to determine acceptability of misassembled/functional bed rails as part of the draft final rule. As the performance requirements for misassembly have been revised, the visual cues requirement is replaced with a requirement for testing components.

- Misinstallation requirements:
    - CPSC staff included a performance requirement in the proposed rule that critical installation components [be] affixed to structural components of the bed rail.
    - The current voluntary standard includes a requirement that products which require consumer assembly, use captive hardware. Installation components must be permanently attached to the bed rail. A warning label is also required.

- Warning labels:
    - The current voluntary standard modifies warning labels to identify suffocation and strangulation hazards. The revised warning labels consolidate all of the warning statements required in the voluntary standard and further clarify the hazards. In addition, manufacturers must label applicable bed and mattress and platform information for intended use with the product. At least one installation component must be labeled with the entrapment hazard warning.

- Non-rigid portable bed rails:

    - CPSC staff recommended including non-rigid bed rails in the proposed rule. Foam and inflatable bed rails must meet the general requirements for portable bed rails and the requirement for enclosed openings. Foam and inflatable bed rails must also contain warning label statements.
    - The scope of the current voluntary standard was modified to include nonrigid bed rails. Non-rigid bed rails, including foam or inflatable bed rails, must meet the

[6] Memorandum from Mark Kumagai, Mechanical Engineering, dated January 4. 2012, Subject: Comparison of ASTM 2085-12 Standard Consumer Specification for Portable Bed Rails with the Proposed Requirements in the NPR Docket # CPSC- 2011-0019 and memorandum from Timothy P. Smith, Division of Human Factors, Directorate for Engineering Sciences, dated December 28, 2011, Subject: Human Factors Staff Response to NPR Comments and Revised Warning Requirements for Portable Bed Rails.

general requirements and the requirement for enclosed openings. Non-rigid bed rails must also meet the warning label requirement.

The misinstallation requirement may help prevent entrapment in bed rails. This new requirement ensures that installation components are permanently attached to the bed rail and requires labeling on the installation component. ASTM clarifies that consumer adjusted components such as straps and telescoping rods must be attached to a bed rail component but are not required to be pre-adjusted for proper fit to the bed. In order to bring their bed rails into compliance, manufacturers could preassemble the installation component. Alternatively, manufacturers could opt to redesign their products entirely.

Adding illustrations and figures to the test procedures reduces the likelihood of incorrectly assembling portable bed rails. Similarly, firms would need to revise their current warning statements to include a more concise description of suffocation and strangulation hazards and to clarify the intended age use for the product.

Portable bed rails constructed primarily of non-rigid materials, such as foam and inflatable bed rails, must meet requirements of the voluntary standard. These requirements cover hazardous sharp points and edges, small parts, warning labels, and enclosed openings. The voluntary standard requirements for misassembly and misinstallation do not apply to non-rigid products.

Issues Raised by Public Comments

There were several public comments that resulted in modifications that are reflected in the draft final rule. Other than a slight reduction in testing costs that would be associated with the elimination of the visual cues requirement, none of the modifications affect the final regulatory flexibility analysis for portable bed rails. Commenters raised two issues concerning the initial regulatory flexibility analysis, which are summarized in the appendix. Staff agrees with both comments and both have been acknowledged in the final regulatory flexibility analysis.

Other Federal Rules

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

Since portable bed rails now will be subject to a mandatory standard, they will be subject to the certification requirements of section 14(a)(2) of the CPSA. Moreover, portable bed rails are children's products and are subject to the third-party testing requirements of section 14(d)(2)(A) of the CPSA.

Portable bed rails are also subject to the lead and phthalate limit requirements under sections 101(a) and 108 of the CPSIA. Section 101(a) of the CPSIA limits the amount of lead content in children's products. Section 108 of the CPSIA prohibits certain phthalates in concentration of more than 0.1% in children's toys and child care articles. "Child care articles" are defined as consumer products "designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger, or to help such children with sucking and teething."

Impact on Small Businesses

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

Small Domestic Manufactures

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

The products of seven firms that are not in compliance with F2085-10a may require substantial modifications to meet F2085-12. The costs associated with these modifications could include product redesign, development and marketing staff time, product testing, and focus group expenses. It is possible that some firms may change the type of materials used to make portable bed rails, resulting in some cost increase. Costs may also rise if additional materials are required, or need to be redesigned. The actual costs of product modifications are unknown, but could be significant for some firms. However, the impact of these costs may be mitigated if they are treated as new product expenses and amortized.

The impact on the five firms which produce portable bed rails that are compliant with the voluntary standard F2085-10a may be less significant. Firms already in compliance with F2085-10a may require fewer modifications in order to bring their product into compliance with the current voluntary standard. Some firms may opt to preassemble component(s) rather than redesign their product. If firms decide to preassemble products, then portable bed rails may require larger shipping boxes. Shipping larger boxes is likely to increase shipping costs, and increased shipping costs may be significant in some cases. Larger boxes will also require greater storage space and may cause some retailers to reduce portable bed rails from their shelves and inventories.

All manufacturers will need to modify existing warning labels. Costs associated with the new warning label would be low because no new materials are used. However, eliminating the visual cues and reducing the number of warnings may result in a small reduction in costs.

At least four small manufacturers' product lines consist entirely or primarily of nonrigid portable bed rails. These firms may need to alter the warning label and requirements for enclosed openings, but otherwise are not likely to be affected significantly by the voluntary standard.

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

Small Domestic Importers

All three small domestic importers would need to find an alternate source of portable bed rails if their existing supplier does not come into compliance with the current voluntary standard. The cost to importers may increase; and, in turn, they may pass on some of those increased costs to consumers. Some importers may respond to the rule by discontinuing the import of their portable bed rails. However, the impact of such a decision may be lessened by replacing the noncompliant portable bed rail with a complying product or another juvenile product. Deciding to import an alternative product would be a reasonable and realistic way for most importers to offset any lost revenue, given that most import a variety of products. However, for small importers whose product lines rely largely on bed rails, substituting another product may not be realistic. The impact on these small importers likely would be more significant.[7]

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

Alternatives

Section 104 of the CPSIA requires CPSC to adopt a mandatory standard substantially the same as, or more stringent than, the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury associated with such products. One alternative would be to set an effective date later than the staff-recommended six months. This would allow suppliers (and manufacturers) additional time to modify and/or develop compliant portable bed rails, thereby spreading the associated costs over a longer period of time.

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

Appendix / Public Comments

Shipment costs

One comment (CPSC 2011-0019-0013) stated that the shipping costs are a significant portion of the product's total cost and thus increasing the box size to contain a preassembled product could potentially increase cost to ship the product by 50%.

CPSC staff agrees that preassembling portable bed rails may require larger boxes, and that shipping larger boxes will likely increase shipping costs. It is possible that the increased shipping costs could be significant for some small firms.

Size of Products

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

CPSC staff agrees that, all else equal, larger box sizes for bed rails will require additional space on shelves and in inventories. As a result, some retailers might choose to decrease the number or model types of portable bed rails that they offer to the public which could, in turn, have the effect of reducing sales by manufacturers.