Summary

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

D. Potential Small Business Impact

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

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

E. Effective Date of Final Rule

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

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

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

IV. ENVIRONMENTAL CONSIDERATIONS

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

V. STAFF RECOMMENDATION

The NPR for portable bed rails proposed:

- Incorporating by reference ASTM F2085–10, *Standard Consumer Safety Specification for Portable Bed Rails*, with the following modifications:
    1. Revisions to scope to include inflatable and foam-type bed rail products;
    2. New performance requirements, and associated test methods to address fatal entrapment incidents related to misassembly of portable bed rails;
    3. New performance requirement and warning label to address the potential for fatal entrapment incidents related to misinstallation of portable bed rails; and
    4. Revised warning label to specify intended user age for portable bed rails.

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

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

TAB A: Comments to NPR

TAB A

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

PUBLIC SUBMISSION

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

Submitter Information

Name: Drew Goldsmith

General Comment

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

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

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

PUBLIC SUBMISSION

Tracking No. 80c35e0b
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-2011-0019-0004
Comment from Jennifer Davis

Submitter Information

Name: Jennifer Davis

General Comment

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

PUBLIC SUBMISSION

Tracking No. 80c3d530
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-2011-0019-0005
Comment from Laura Myers

Submitter Information

Name: Laura Myers

General Comment

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

PUBLIC SUBMISSION

Tracking No. 80c40111
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-2011-0019-0006
Comment from Ken Walsh

Submitter Information

Name: Ken Walsh

General Comment

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

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

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

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

PUBLIC SUBMISSION

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

Submitter Information

Name: Fredlisha Lansana

General Comment

To Whom it May Concern:

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

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

Thank You,

Fredlisha Lansana

PUBLIC SUBMISSION

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

Submitter Information

Name: Brian Rainey

General Comment

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

PUBLIC SUBMISSION

Tracking No. 80e349bd
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-2011-0019-0009
Comment from Dawneen Huckins

Submitter Information

Name: Dawneen Huckins

General Comment

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

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

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

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

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

PUBLIC SUBMISSION

Tracking No. 80e51481
Comments Due: June 27, 2011
Docket: CPSC-2011-0019
Safety Standard for Portable Bed Rails: Notice of Proposed Rulemaking (NPR)
Comment On: CPSC-2011-0019-0001
Safety Standard for Portable Bed Rails
Document: CPSC-2011-0019-0010
Comment from Michael Coons

Submitter Information

Name: Michael Coons

General Comment

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

PUBLIC SUBMISSION

Tracking No. 80eb41af
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-2011-0019-0011
Comment from Carla Silver

Submitter Information

Name: Carla Silver

General Comment

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

PUBLIC SUBMISSION

Tracking No. 80eb41ec
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-2011-0019-0012
Comment from Janet Wells

Submitter Information

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

General Comment

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

John Weir, President
Sarah F. Wells, Executive Director

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www.theconsumervoice.org

June 27, 2011

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

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

Dear Ms. Tenenbaum:

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

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

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

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

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

Proposed Changes to ASTM F2085-10a

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

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

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

The Consumer Voice makes the following recommendations:

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

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

Sincerely,

Sarah F. Wells
Executive Director

The Myth of Benign Bed Rails: A Consumer Protection Issue

By Omoniyi Adekanmbi

Contents:

The National Consumer Voice for Quality Long-Term Care
1001 Connecticut Avenue NW, Suite 425, Washington, DC 20036
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2. Use of Restraints in Medical Facilities: Who Is Restrained? How and Why?

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

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

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

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

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

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

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

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

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

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

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

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

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

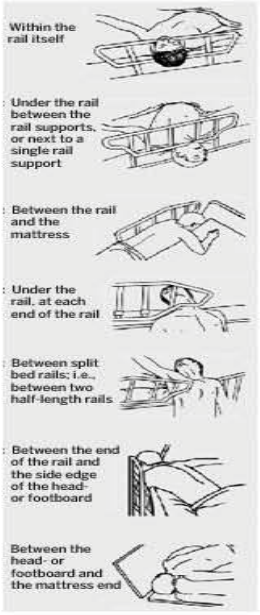

Figure 1. *Common forms of bed rail entrapment.* Source: Hyman, 2008, *Bed Rail Entrapments Still A Serious Problem.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7. *State Ombudsmen Perspectives*

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

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

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

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

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

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

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

8. ***Conclusions***

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

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PUBLIC SUBMISSION

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

Submitter Information

Name: Robert Waller
Organization: Juvenile Products Manufacturers Association

General Comment

June 27, 2011

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

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

Safety Standard for Portable Bed Rails: 16 CFR Part 1224

CPSC DOCKET Number: 2011-0019

Dear Mr. Stevenson:

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

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

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

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

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

Incident Data Conclusions

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

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

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

It is also notable that because 11 of the 13 deaths involved children under 2 years old, the CPSC Health Sciences Staff concludes that portable bed rails, which are meant to be installed on an adult bed, are not intended for this age group. Placing a railing on the side of an adult bed does not make the adult bed safe for infants (i.e. convert an adult bed into a crib). Despite the current warning label cautioning against the use of this product with

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

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

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

While all 13 incidents reported some sort of entrapment of the child between the bed rail and the mattress, no additional product – or scenario-specific information was available for five of the reports. Understandably any conclusion on the data can, at best, be implied and not validated due to the inability to recreate the circumstances at the immediate time of the incident. Reported experience suggests that secondhand or used product may be involved.

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

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

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

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

Engineering Assessment

The CPSC staff comment includes *"For bed rails that are assembled and installed in accordance with the manufacturer's instructions, staff believes that the requirements to address structural integrity and to prevent displacement from the mattress are adequate. However, if the bed rail is misassembled or misinstalled on the bed, it could present an entrapment hazard."*

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

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

ASTM standards have evolved with the intent of including performance testing and product warnings as evidenced by the following cautionary statement:

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

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

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

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

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

Critical Assembly Components

The NPR defines 3.1.12 *Critical Assembly Component* as –"Any component of the portable bed rail that requires consumer assembly in order to meet the performance requirements of sections 6.1 Structural Integrity, 6.3 Enclosed Openings, 6.4 Openings Created by Portable Bedrails Displacement of adjacent Style Portable Bedrails, 6.5 Openings Created by Displacement of Mattress-Top Portable Bedrails, and 6.6, Openings Created by Displacement of Portable Bed Rails Intended for Use on Specific Manufacturers Beds of ASTMF2085-10A. As referenced in Appendix B of the NPR the concerns outlined in the task group proposal remain the same. All the products on the market now require that most all components be assembled in order to meet section 6.4, essentially making all components critical and consequently diluting the importance of calling out these components. The definition of a critical assembly component essentially requires that the technician evaluate the product via process of elimination which is not a practical approach to testing to determine which components would be classified as critical safety components.

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

- *The portable bed rail can be assembled without any critical assembly component*
- *The portable bed rail can be assembled without the supplied fasteners, such as screws, nuts, or bolts that are not captive to a critical assembly component like the frame.*

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

- *The portable bed rail's fabric cover or mesh can be placed over the rigid frame structure without engaging critical parts of the frame as intended in final assembly.*
- *The portable bed rail can be assembled by improper placement of any critical component, such as an inverted or an interchanged part, without permanent deformation or breakage.*

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

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

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

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

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

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

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

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

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

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

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

Critical Installation Components

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

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

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

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

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

Impact on Business both Large and Small

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

Implementation

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

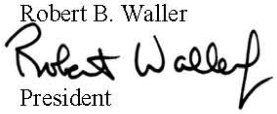
Figure 1

Conclusion

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

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

Sincerely,
Robert B. Waller



President

PUBLIC SUBMISSION

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

Submitter Information

Name: Nancy Cowles
Organization: Kids in Danger

General Comment

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June 27, 2011

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

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

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

Introduction

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

Background

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

Recommendations

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

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

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

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

Conclusion

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

Respectfully submitted,

Nancy A. Cowles

Nancy Cowles
Executive Director

PUBLIC SUBMISSION

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

Submitter Information

Name: Donald Mays
Organization: Consumers Union

General Comment

Consumers Union
NONPROFIT PUBLISHER OF CONSUMER REPORTS

June 27, 2011

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

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

Docket No. CPSC– 2011–0019

Introduction

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

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

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

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (''CPSIA'') requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

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

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

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

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

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

Consumers Union also supports the Commission's proposed test methods for determining the acceptability of the vertical structure of a misassembled/function portable bed rail, as well as the test method for determining fabric sag acceptability of a misassembled/functional portable bed rail. We agree that these tests would provide a method for testing laboratories to determine if a misassembled portable bed rail lacks sufficient vertical structure and also determine the sufficiency of visual cues for portable bed misassembly.

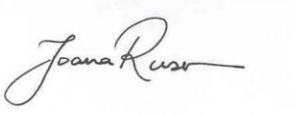
In addition, we are pleased with the proposed rule's requirements for clear, permanently affixed labeling or graphics in order to address potential consumer misassembly of the product. As noted in the CPSC notice, installation of a portable bed rail onto a bed can require complex or physically demanding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

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

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

Respectfully submitted,

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



Ioana Rusu
Staff Policy Assistant
Consumers Union

PUBLIC SUBMISSION

Tracking No. 80eb7daf
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-2011-0019-0016
Comment from Rachel Weintraub

Submitter Information

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Organization: Consumer Federation of America

General Comment

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June 30, 2011

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Via: tstevenson@cpsc.gov

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

Docket No. CPSC– 2011–0019

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

Section 104(b) of the Consumer Product Safety Improvement Act of 2008 (''CPSIA'') requires the Commission to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be "substantially the same as" applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

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

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

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

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

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

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

Third, Consumer Federation of America also supports the Commission's proposed test methods for determining the acceptability of the vertical structure of a misassembled/function portable bed rail, as well as the test method for determining fabric sag acceptability of a misassembled/functional portable bed rail. We agree that these tests would provide a method for testing laboratories to determine if a misassembled portable bed rail lacks sufficient vertical structure and also determine the sufficiency of visual cues for portable bed misassembly.

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

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

PUBLIC SUBMISSION

Tracking No. 80ec1416
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-2011-0019-0017
Comment from Gloria Black

Submitter Information

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General Comment

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June 2, 2011

COMMENTS

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

To Whom It May Concern:

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

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

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

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

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

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

THE EXTENSIVE REPORTS ON DEATHS BY BEDRAILS

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

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

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

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

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

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

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

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

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

DO BED RAILS MAKE PEOPLE 'SAFER'?

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

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

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

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

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

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

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

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

Statements such as the following are made in the docket:

"...we are proposing some modifications to strengthen the standard because these more stringent requirements would further reduce the risk of injury associated with portable bed rails. ..."

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

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

"...These standards are to be 'substantially the same as' applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirement would further reduce the risk of injury associated with the product. ... "

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

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

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

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

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

THE NEED FOR RECALLS AND/OR BANS

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

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

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

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

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

"For portable bed rails that are assembled and installed in accordance with the manufacturer's instructions, we believe that the requirements to address structural integrity and prevent displacement from the mattress are adequate."

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

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

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

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

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

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

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

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

RECOMMENDATIONS REGARDING WARNINGS OF RISK OF ASPHYXIATION

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

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

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

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

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

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

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

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

SUMMARY OF PROPOSED SOLUTIONS

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

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

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

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

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

Respectfully,

Gloria Black

Gloria Black

(cont. on next page)

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

ENDNOTES

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

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

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

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

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

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