



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

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 approved and signed.

BALLOT VOTE SHEET

DATE: April 23, 2014

TO: The Commission
 Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
 Elliot F. Kaye, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
 Hyun S. Kim, Attorney, OGC

SUBJECT: Petition CP 13-1; Request for Ban or Standard for Adult Portable Bed Rails

BALLOT VOTE Due: April 29, 2014

The CPSC received, in the form of separate petitions, two requests to initiate proceedings under the Consumer Product Safety Act (CPSA) to address an unreasonable risk of injury associated with adult portable bed rails (APBR). Gloria Black, the National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (the Consumer Group) filed one petition; Public Citizen Health Research Group (Public Citizen) filed the other petition. The Consumer Group and Public Citizen collectively are referred to as petitioners. The CPSC has docketed the requests as a single petition under Petition CP13-1, Petition Requesting a Ban or Standard on APBR. On June 4, 2013, the Commission published notice of the petition for comment (78 Fed. Reg. 33393). CPSC staff prepared the attached briefing package in response to the petitioners.

Please indicate your vote below:

I. Grant the petition.

 (Signature)

 (Date)

II. Defer the petition.

(Signature)

(Date)

III. Deny the petition.

(Signature)

(Date)

IV. Take other action (please specify).

(Signature)

(Date)

Attachment: CPSC staff briefing package: Petition CP13-1 Requesting a Ban or Standard for Adult Portable Bed Rails



STAFF BRIEFING PACKAGE

PETITION CP-13-1
REQUESTING A BAN OR STANDARD FOR ADULT PORTABLE BED RAILS

April 23, 2014

For further information, contact:

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EXECUTIVE SUMMARY

The U.S. Consumer Product Safety Commission (CPSC, Commission) received two requests to initiate proceedings under the Consumer Product Safety Act (CPSA) to address an unreasonable risk of injury presented by adult portable bed rails (APBR). Gloria Black, The National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (the Consumer Group) made one request; Public Citizen Health Research Group (Public Citizen) made the other request. The Consumer Group and Public Citizen are collectively referred to as “petitioners.” The petitioners request that the CPSC initiate proceedings under section 8 of the CPSA to ban all adult portable bed rails because the product presents an unreasonable risk of injury. Public Citizen contends that no mandatory standard or warnings could be developed that would adequately protect against the hazards presented by APBR.

The Consumer Group states that if the CPSC does not pursue a ban, the Commission should initiate a rulemaking to promulgate mandatory standards under section 9 of the CPSA to reduce the unreasonable risk of asphyxiation and the entrapment hazards posed by APBR and to include warning labels in the standards. The Consumer Group also requests action under section 27(e) of the CPSA to require manufacturers of APBR to provide performance and technical data regarding the safety of their products to the Commission.

The CPSC has docketed the two requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. On June 4, 2013, the Commission published a *Federal Register* (FR) notice requesting public comments on the petition (78 Fed. Reg. 33393). CPSC received 99 comments in response to the FR notice. Out of 99 comments, 86 comments request rulemaking on APBR; six comments request a ban on APBR; and seven comments request that CPSC take no action on APBR.

Voluntary standard development is currently ongoing. ASTM is coordinating the development of a new performance standard to address the hazards associated with currently available APBR products. ASTM has formed a subcommittee to develop the standard, and three task groups have been formed to address the scope, performance requirements, and marking and labeling requirements for APBR. CPSC staff actively participates in all three of these task groups.

CPSC staff has prepared this briefing package in response to the petition. The briefing package provides the Commission with information relevant to the petition, including a review of the public comments received in response to the *Federal Register* notice and a discussion of possible options the Commission could take to respond to the petition. Staff recommends that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard has been developed and evaluated by staff.



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

This document has been electronically
approved and signed.

Memorandum

Date: February 26, 2013

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director

FROM : George A. Borlase, Assistant Executive Director
Office of Hazard Identification and Reduction

Richard McCallion, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Staff Recommendation to Petition CP-13-1 Requesting a Ban/Mandatory
Standards for Adult Portable Bed Rails

I. Introduction

The U.S. Consumer Product Safety Commission (CPSC, Commission) received two requests to initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails (APBR) pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. Gloria Black, The National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (the Consumer Group) made one request; Public Citizen Health Research Group (Public Citizen) made the other request. The Consumer Group and Public Citizen collectively are referred to as “petitioners.” Though there are differences in their requests of the Commission, the CPSC has docketed the requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on APBR. On June 4, 2013, the Commission published a *Federal Register* notice requesting public comments on the petition (*see* TAB A).

II. Petitioners’ Requests

The petitioners assert that APBR currently on the market are responsible for many injuries and deaths among users, particularly the elderly and frail. Additionally, the petitioners state that many of these deaths result from asphyxiation caused by entrapment within openings of the rail or between the rail and the mattress or bed frame. The petitioners also claim that individuals who attempt to climb over bed rails may be at greater risk of injury or death than they would be if no bed rail were used at all. In support of their request, the petitioners cite a CPSC staff memorandum dated October 11, 2012, “Adult Portable Bed Rail-Related Deaths, Injuries, and

Potential Injuries: January 2003 to September 2012¹.” The petitioners note that the CPSC staff’s data showed that there were 155 fatalities during the period from January 2003 to September 2012, of which 129 involved victims ages 60 years and over; most of the fatalities related to rail entrapment. In addition, petitioners state that the CPSC staff found that an estimated 36,900 APBR-related injuries were treated in U.S. hospital emergency departments from January 2003 to December 2011².

The petitioners request that the CPSC initiate proceedings under section 8 of the CPSA to ban all adult portable bed rails because, they assert, the product presents an unreasonable risk of injury, and no feasible consumer product safety standard would adequately protect the public from these products. Public Citizen contends that no mandatory standard or warnings could be developed that would adequately protect against the hazards presented by APBR.

The Consumer Group states that if the CPSC does not pursue a ban, the Commission should initiate a rulemaking to promulgate mandatory standards under section 9 of the CPSA to reduce the unreasonable risk of asphyxiation and the entrapment hazards posed by APBR and to include warning labels in the standards. The Consumer Group also requests action under section 27(e) of the CPSA to require manufacturers of APBR to provide performance and technical data regarding the safety of their products to the Commission.

III. Product Description

In general, bed rails attach to, or are installed on, the side of a bed to help keep the occupant in bed or to provide assistance when one gets in or out of bed. Many types of bed rails are available. One key distinction is that some bed rails are medical “devices” under the authority of the U.S. Food and Drug Administration (FDA), and other bed rails fall under the CPSC’s authority.

The FDA regulates adjustable hospital beds used for medical purposes. *See* 21 C.F.R. §§ 880.5100, 880.5110, 880.5120. Bed rails that are an accessory or an appurtenance to regulated hospital beds are considered by the FDA to have a medical purpose and to be “devices” subject to FDA jurisdiction³. FDA regulations do not reference “bed rails” or “bed handles”; rather, FDA regulations refer to “movable and latchable side rails.” *See* 21 C.F.R. §§ 880.5100, 880.5110, 880.5120. In addition, bed rails that are considered by FDA to have a medical purpose and may be classified as a medical device would fall under FDA’s jurisdiction as medical “devices.”

¹ The full version of this memorandum is available at: <http://www.cpsc.gov/PageFiles/133466/adultbedrail.pdf>.

² CPSC reporting times for NEISS and deaths are different. NEISS reports are finalized annually while it can take up to 2-3 years to receive incident data for fatalities.

³Information on Adult Bed rails under FDA jurisdiction is available at www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BedRailSafety/ucm362832.htm

In contrast, bed rails intended for use with a non-FDA-regulated bed, and that are not considered by the FDA to have a medical purpose and are not medical devices, would fall under the CPSC's jurisdiction. Accordingly, such bed rails fall within the CPSC's jurisdiction, irrespective of where the bed is used (long-term care facility, residence), if they are not regulated by the FDA.

For bed rails not regulated by the FDA, CPSC staff considers an APBR to include any portable rail not designed by the manufacturer as part of the bed, which is installed on or used along the side of a bed by consumers older than 5 years of age and is intended to:

- (1) reduce the risk of falling from the bed;
- (2) assist the consumer in repositioning in the bed; or
- (3) assist the consumer in transitioning into or out of the bed.

The term "bed rails" may include products such as side rails, split rails, half rails, bed handles, full-length rails, and bed canes. CPSC staff used the following definitions in the evaluation of APBR:

- *Full Length* - Bedside product that is intended to extend the full length of the bed and is generally constructed from tubular metal and rectangular in shape. A full-length APBR is one continuous piece, commonly attached to the side of the bed between the mattress and box spring. A floor support or mattress top-supported design is possible. Full-length APBR may adjust to conform to varying bed sizes and mattress heights. This product is intended to keep consumers from falling from bed and with repositioning themselves in the bed.



Full-Length Bed Rail

- *Half Length* - Bedside product that is intended to extend approximately half the length of the bed and is generally constructed from tubular metal and rectangular in shape. A half-length APBR is commonly attached to the side of the bed between the mattress and box spring and may be used in conjunction with another APBR. A floor support or mattress top-supported design is possible. Half length APBR may adjust to conform to varying bed sizes and mattress heights. This product is intended to keep consumers from falling from bed and assist consumers with repositioning themselves in the bed. Half-length APBR also may be used to assist the consumer when entering and exiting the bed.



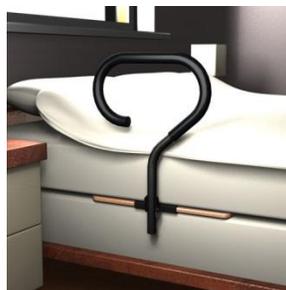
Half Rail

- *Bed Handle* - Bedside product that is generally constructed from tubular metal and available in various shapes and sizes. A bed handle is commonly attached to the side of the bed between the mattress and box spring or may be freestanding. Bed Handles may adjust to conform to varying bed sizes and mattress heights. This product is intended to assist consumers with repositioning themselves in the bed. A bed handle also may be used to assist the consumer when entering and exiting the bed but is not designed to keep the consumer from falling from the bed. A bed handle has the same basic purpose as a bed cane, in CPSC staff's opinion.



Bed Handle

- *Bed Cane* - Bedside product that is generally constructed from tubular metal and available in various shapes and sizes. A bed cane is commonly attached to the side of the bed between the mattress and box spring or may be freestanding. A bed cane may adjust to conform to varying bed sizes and mattress heights. This product is intended to assist consumers with repositioning themselves in the bed. A bed cane also may be used to assist the consumer when entering and exiting the bed. A bed cane has the same basic purpose as a bed handle, in CPSC staff's opinion.



Bed Cane

IV. Incident Data⁴ (TAB B)

The CPSC Directorate for Epidemiology staff reviewed the deaths and injuries associated with APBR and characterized the types of hazard patterns occurring from January 2003 to December 2013 based on reports received by CPSC staff. The memorandum also includes the estimated number of emergency department-treated injuries from January 2003 to December 2012. The data did not include complete details of every incident. Accordingly, it is possible that the memorandum may include some products outside of the CPSC’s jurisdiction, although cases known to be outside the CPSC’s jurisdiction were removed. This memorandum updates a prior version dated October 11, 2012, which covered the period from January 2003 to September 2012.

CPSC staff received reports of 180 incidents, with victims ranging in age from 13 to 103 years. There were 174 deaths among the 180 APBR-related incidents. Death certificates were the source of incident reports for 111 of the 174 fatalities. Table 1 shows the number of deaths by year. Six nonfatal APBR-related incidents occurred. Two of the non-fatal incidents involved rail entrapment, and two incidents related to rail failure. The remaining two incidents were categorized as “miscellaneous incidents.” No injury was reported for any of the nonfatal incidents.

Table 1: APBR-Related Deaths by Year

Year of Incident*	Fatalities
2003	17
2004	25
2005	20
2006	26
2007	19
2008	19
2009	9
2010	11
2011	11
2012	10
2013	7
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS)

* If the date of incident or injury is not reported, the date reported is used.

⁴ The CPSC databases searched were those of Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to adult portable bed rails.

Note: Data in italics indicates reporting is ongoing for 2010–2013. Two new incidents that occurred in 2004 and 2009 were reported to CPSC in 2013.

One hundred sixty-one of the 174 deaths associated with APBR were related to rail entrapment. Twelve deaths were related to falls on the bed rail. The details of one death were not available. One hundred and forty-five decedents were over the age of 60, while 28 were under the age of 60 (Table 2).

Table 2: APBR-Related Deaths by Age

Age	Fatalities
13 to 29 years	7
30 to 59 years	21
60 to 69 years	11
70 to 79 years	20
80 to 89 years	69
90 years and over	45
Not reported*	1
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

Approximately one-half of the reported 174 deaths involved victims that had an underlying medical condition, including cardiovascular disease, Alzheimer’s disease, dementia, mental limitations, seizure, mobility limitations, Parkinson’s disease, drug medicated, cerebral palsy, multiple sclerosis, pulmonary disease, or other condition (Table 3). The majority of the incidents occurred in the home of the victim or caregiver. The remaining incidents occurred at nursing homes, assisted living facilities, hospice facilities, or other locations (Table 4).

Table 3: APBR-Related Deaths by Medical Conditions

Medical Conditions	Fatalities
Cardiovascular disease	22
Alzheimer’s/dementia/mental	23
Seizure	5
Mobility/paralysis	8
Parkinson	5
Drug medicated	4
Cerebral palsy	4
Multiple sclerosis	3
Multiple conditions	4
Pulmonary disease	3

Other	7
No medical condition reported	86
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

* Other included tracheotomy and G-tube, severe burn, post hip surgery, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, cancer hospice, and muscular dystrophy.

Table 4: Distribution of Reported Fatal APBR-Related Incidents by Injury Location (1/1/2003 to 12/31/2013)

Injury Location	Fatalities
Home	104
Nursing home	28
Assistant living facility	18
Hospice	3
Other*	9
Unknown	12
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

*Other included a care home, a foster home, a group home, a hotel, a retirement center, town/country manor, rehab center, and an adult family home.

CPSC staff reviewed all 180 incidents to identify hazard patterns associated with APBR and grouped the incidents into four categories (Table 5). The categories are listed from the highest frequency to the lowest:

- A. *Rail entrapment*: There were 163 incidents related to rail entrapment. This category included incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and a bed rail, between the floor and a bed rail, or between the headboard and a bed rail. The most frequent injuries were to the neck and head. Most of these incidents (161 out of 163) resulted in death.
- B. *Falls*: There were 12 incidents related to falls. This includes incidents in which the victim fell off the bed rail, climbed over the bed rail, fell and hit the bed rail, or fell due to an un-raised bed rail. All incidents resulted in a fatality.
- C. *Miscellaneous*: There were three miscellaneous reports, including one incident where the victim’s head hit the rail. The other two reports were determined to be inquiries and did not describe an incident; one was an inquiry regarding a misleading label, and the second was an inquiry regarding a recalled bed rail. There was one death and no other reported injuries.

D. *Structural integrity*: There were two incidents involving structural component failure. In one incident, screws pulled through the wooden side rail. In the second incident, the bed rail cracked while the victim was sitting on the bed. No injuries were reported.

Table 5: APBR-Related Incidents by Hazard

Hazards	Counts
Rail entrapment	163
Falls	12
Miscellaneous	3
Structural integrity	2
Total	180

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

Based on NEISS data, overall, there were an estimated 39,600 APBR-related injuries treated in U.S. hospital emergency departments from January 2003 to December 2012 (Table 6).

Table 6: APBR Injury Estimates by Year

Year	Cases	Estimates
2003	104	4,600
2004	87	3,800
2005	97	3,900
2006	73	3,500
2007	102	4,500
2008	110	4,400
2009	105	3,900
2010	103	4,200
2011	100	4,100
2012	71	2,700

Source: National Electronic Injury Surveillance System (NEISS)

The data indicated that victims were between the ages of 13 to 101 years old. Forty percent were 60 years and older; 34 percent were between 30 and 59 years old; and 26 percent were younger than 30 years old. Most of the injuries (92%) were treated and released from the hospital emergency department. The head, lower legs, and feet were the body parts most often injured, and injuries generally were contusions/abrasions, lacerations, or fractures.

V. Market for APBR (TAB C)

The CPSC Directorate for Economic Analysis provided information on the market for APBR. Staff is aware of 16 suppliers of APBR marketing their products in the United States. Collectively, these entities supply approximately 74 models of APBR. This estimate attempts to exclude products listed as medical devices, as available information allowed. Of these suppliers, 15 are domestic manufacturers, and one is a foreign manufacturer who exports directly to the United States via Internet sales. Of those for whom publicly accessible data were available, three appear to be small manufacturers based on U.S. Small Business Administration guidelines (500 or fewer employees for a domestic manufacturer in this industry sector), nine are large manufacturers, and the size of the remaining four are unknown.

Sales data, expressed either in product units or monetary value, are not available. There are no known trade associations tracking APBR sales, and manufacturers did not respond to staff requests for such information. Additionally, data providing the number of APBR in use are not available.

Typically, APBR are available: (1) directly from the manufacturers, (2) through retailers such as Walgreens, CVS, and Wal-Mart, (3) through trade shows, and (4) from home medical device retailers. These products range in price from approximately \$30 for some assists and handles, to more than \$200 for larger, more complex bed rails, with prices typically around \$125 for most products marketed as bed rails.

The consumer market for APBR consists primarily of elderly and/or disabled users.

VI. Preliminary Estimates of Societal Costs (TAB C)

The Directorate for Economic Analysis provided preliminary information on the societal costs of injuries and deaths involving APBR. The societal costs of nonfatal injuries are based on estimates from the CPSC's Injury Cost Model (ICM). The ICM is fully integrated with NEISS and provides estimates of the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between injuries treated in hospital emergency departments and injuries medically treated in other settings, the ICM also estimates the number and societal costs of injuries medically treated in other settings (such as doctors' offices, emergency clinics, etc). Based on the ICM, there was an average of about 11,000 medically attended injuries involving APBR annually, from 2003 through 2012 (including about 3,960 treated in hospital EDs and another 7,040 treated in other settings). According to the ICM, the societal costs of these injuries amounted to about \$250 million annually. Medical costs and work losses accounted for about 26 percent of total costs. The remainder of societal costs consisted of the intangible costs associated with pain and suffering (72 percent) and product liability costs (2 percent).

In addition to the nonfatal injuries, there were 174 reported deaths involving APBR between 2003 and 2013, or about 16 annually. Commission staff does not ascribe a value to life. If, however, we assign a cost of \$5 million for each death, which is generally consistent with

willingness-to-pay estimates of the value of a statistical life (VSL),⁵ the societal costs associated with these deaths would amount to about \$80 million. When combined with the estimated societal costs resulting from nonfatal injuries, aggregate societal costs amount to about \$330 million annually.

In developing injury and death estimates, the Directorate for Epidemiology attempted to eliminate cases known to involve bedrails under FDA jurisdiction (by excluding cases involving hospital beds and incidents occurring in hospitals). However, it is possible that some cases involving FDA-regulated APBR remain. Consequently, the total of \$330 million in societal costs may be an overestimate of the societal costs associated with the adult bed rails of interest.

Additionally, adult bed rails under CPSC jurisdiction are used as safety products, much as helmets are safety products for bicyclists. This analysis of societal costs does not attempt to evaluate the reduction in societal costs (*i.e.*, benefits) that result because of the use of adult bed rails because available data and information are insufficient to support such an evaluation.

V. Health Sciences Discussion of Injuries and Incident Data (TAB D)

The Directorate for Health Sciences (HS) staff provided information on the injuries associated with APBR and the role that APBR may have on the injuries. Entrapment between the side rail and mattress was the most common hazard pattern and accounted for 161 incidents (93 percent). Analysis by HS staff revealed that the head or neck was the part of the body most frequently entrapped, with positional asphyxia the most common cause of death.

Staff evaluated the possible role that bedrails may have played in entrapment deaths and found that there are a number of factors to consider. The vast majority of the incidents involving APBR entrapment were adults 60 years and older. This is a potentially vulnerable population associated with an overall progressive decline in muscle strength, balance, and cognitive abilities who are also increasingly susceptible to a variety of ailments prevalent among the elderly. In addition to these age-related issues, more than half of the entrapment victims had a diagnosed condition commonly known to cause cognitive impairment, as well as other physical and/or neurological conditions that would have increased their vulnerability and risk of entrapment and falls.

Some APBR products function as rails and handles. Side rails and grab bars are similar in design and overall shape and are secured to the side of the bed by a set of two bent base rails that slide between the mattress and box springs. Because of the similarity in design and mechanism of attachment to the side of the bed, both products pose the same potential entrapment hazards.

⁵ According to OMB's 2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act, willingness-to-pay estimates of the value of a statistical life (VSL) generally vary from about \$1.2 to \$12.2 million in 2010 dollars. Available at: http://www.whitehouse.gov/sites/default/files/omb/inforg/2013_cb/draft_2013_cost_benefit_report.pdf. Accessed on February 5, 2014.

HS staff has identified three sites where entrapments have occurred: (1) in gaps between the mattress and side rail; (2) in openings within the horizontal bars of the side rail; and (3) in the space between the headboard or footboard and vertical end bar of the side rail. Upper body entrapment between the mattress and rail can lead to positional asphyxia by chest or neck compression.

VI. Human Factors Discussion of the Incident Data and Behavior (TAB E)

The Directorate for Human Factors (HF) staff provided a discussion regarding the effectiveness of warning labels on APBR. According to staff, warnings are less effective than designing a hazard out of the product or guarding the consumer from a hazard. When older adults are at risk, controlling hazards through design or guarding, rather than warnings, is especially important. Age-related declines in physical skills and abilities may limit the ability of older adults to avoid or remove themselves from warned-about hazardous situations. Some elderly individuals may suffer from forms of dementia that prevent them from being able to appraise a hazard, appreciate the consequences of their own actions, or determine how to avoid hazards. Moreover, age-related deficits in vision are likely to limit the extent to which older consumers can read and process a warning. Even the caregivers of older adults may be older adults and suffer from similar age-related deficits. Thus, improved warnings on APBR are likely to have a limited positive effect on fatalities.

Nevertheless, warnings might offer some benefit as a supplemental safety measure, if the risk cannot be eliminated through design. Currently, the warnings provided with APBR vary greatly. Some APBR lack any on-product warnings; while others rely on the same warning mandated for children's portable bed rails, which emphasizes the dangers to children younger than 2 years old but says nothing about the dangers to older adults. Still other APBR warnings instruct consumers to keep the product against, or at least close to, a mattress, without describing the potential hazard and hazard's consequences. In addition, the warnings on these products do not seem to be formatted with older adults as the target audience. CPSC staff has been working with a newly formed ASTM subcommittee to develop requirements intended to address the concerns of the petition; and HF staff, in particular, has been working with the marking and labeling task group to strengthen the warnings about the hazards associated with APBR. This work is ongoing.

VII. Review of Existing Standards (TAB F)

Currently, there are no CPSC regulations or voluntary standards pertaining to APBR. ASTM International developed a voluntary standard for children's portable bed rails: ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed Rails*. In 2012, the Commission issued a mandatory standard for children's portable bedrails that incorporates by reference ASTM F2085-12. 16 C.F.R. part 1224. The scope of ASTM F2085-12 (and CPSC's mandatory standard) is limited to portable bed rails intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2 to 5 years of age).

The hazard patterns and some APBR designs are similar to children's portable bed rails and ASTM F2085 is being used as a framework for APBR standard development. Entrapments between rail and mattress and within the rail are the greatest hazard for both. Structural integrity is a concern for both but for different reasons. Children are more likely to climb over the rail, while adults are more likely to use a rail for support when standing or attempting to stand. Finally, when becoming entrapped, children may not have the strength or mental acuity to self-extricate, similar to older adults or adults with underlying medical conditions. Other sources that ASTM is aware and may use to develop the voluntary standard on APBR include FDA's 2006 guidance for industry on "Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment." Although the guidance does not cover all APBR because the guidance is intended for hospital beds some of the information could be used to develop performance requirements for APBR. For example, the anthropometric data sources in the guidance may be useful in making recommendations in an ASTM APBR standard. Other resources that could provide valuable information for developing an ASTM adult bedrail standard include:

- European standard, BS EN 60601-2-52:2010, *Medical Electrical Equipment – Particular Requirements for Basic Safety and Essential Performance of Medical Beds available for development of an adult bedrail standard*; and
- *Safe Use of Bed Rails* bulletin, published in December 2013 by the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA), provides guidelines for the safe use of bed rails aimed at all users, caregivers, and staff with the responsibility for the provision, prescription, use, maintenance, and fitting of bed rails.

ASTM is developing a performance standard to address the hazards associated with currently available APBR products based on the ASTM F2085-12 requirements, but the standard would also identify and address any additional hazards specific to APBR. ASTM F2085-12 contains the performance requirements that address known bed rail hazards for children, such as requirements addressing structural integrity, openings, protrusions, misassembly, sharp points and edges, small parts, assembly components and hardware, lead limits, wooden parts, labeling and warnings, and instructional literature requirements.

For APBR, ASTM has formed a subcommittee to develop the standard, and three task groups have been formed to address the scope, performance requirements, and marking and labeling requirements. CPSC staff has actively participated in the meetings of all three of these task groups to assist in the development of requirements to address the hazards identified with APBR. Although staff anticipates that ASTM will issue a completed standard that will address the hazards identified in CPSC's data, the exact timeframe for completion of this standard is not known. However, fully developing a new voluntary standard within the ASTM process will likely take more than a year.

VIII. Staff Response to Public Comments (TAB G)

On June 6, 2013, a notice of the petition requesting comments was published in the *Federal Register*. The comment period ended on August 5, 2013. The Commission received a total of 99

comments; 92 supported the petition (86 commenters supported regulation by CPSC; six commenters supported a ban on APBR). The remaining seven comments opposed taking any action on APBR. Overall, commenters included family members of victims, ombudsmen, health care professionals and facilities, safety advocacy groups, and other individuals. Specific comments are addressed in TAB G.

IX. Discussion

Staff performed a product review of APBR to develop potential options for CPSC action on petition CP13-01. The review included an in-depth analysis of CPSC incident data, including injuries and deaths, hazards, existing regulations, standards, and guidance associated with APBR.

Staff has determined that the senior population and consumers with underlying medical conditions are more at risk of death or injury from the hazards when using APBR products. Staff review of incident data has shown consumers over age 60, where age-related deficits appear to be a factor, are at the greatest risk of injury. Additionally, underlying medical conditions increase the risk to consumers over age 60. Entrapment is the greatest risk APBR pose to consumers in this age population, with falls and structural integrity the next largest hazard. Staff believes better product design, based on minimum performance requirements, could substantially reduce the risk associated with using APBR.

Currently, there are no voluntary or mandatory standards for APBR. There are guidelines and standards for similar products from other organizations, including the FDA guidelines for hospital beds and an ASTM standard on portable bed rails for children. CPSC staff performed a preliminary evaluation of a small sample of APBR using requirements in ASTM 2085-12 and the FDA guidelines for hospital beds. The testing performed on the samples included structural testing, measuring openings, and testing gaps between the mattress and rail. Staff performed additional testing to evaluate the rail attachment systems, such as straps and bed frame clamps. During testing, staff re-created scenarios similar to reported incidents on each of the samples selected, except on a sample bed cane. Staff used the FDA entrapment hazard probe and the ASTM 2085-12 probes in this evaluation to determine how the failures occurred. The FDA probe is designed based on adult anthropometrics; however, the tests for ASTM are designed for products used by children.

Staff's preliminary testing on the sample APBR shows that the FDA guidelines for hospital beds and ASTM F2085-12 provide a basis for individual tests that could be used to evaluate rail strength, performance, and entrapment hazards in APBR. Both the FDA guidelines and ASTM F2085 have been developed for other products and would need to be modified to apply to APBR. Staff's review of the APBR samples showed that effective performance requirements could be developed to increase the safety of APBR with additional testing and development of performance requirements, labeling requirements, and warnings. This should include performance requirements to address potential gaps between the APBR and mattress; retention systems intended to secure the APBR to the bed; bounded openings within the APBR; and gaps between APBR and bed components, such as the headboard or footboard. Staff believes that

warnings and labeling requirements should require specific language to inform consumers of potential hazards, specify label placement, and provide improved instructions for use and installation.

The ASTM subcommittee on APBR is composed of all interested stakeholders. Participants in the standard development process include Ms. Gloria Black, FDA, APBR manufacturers, consumer groups, testing laboratories, and other consumer product experts. A new voluntary standard has the potential to reduce the risk of injury or death to consumers who use APBR. A standard may be developed to provide warnings, instructions, design, and performance requirements for APBR. CPSC staff's review showed that the types of incidents associated with both child and adult portable bed rail product categories are similar. Entrapments between rail and mattress and within the rail are the greatest hazard for both. Structural integrity is a concern for both but for different reasons. Based on the similarities of hazards and risks associated with portable bed rails, staff believes the prior work and expertise developed from the children's portable bed rail standard by the CPSC would be useful in the development of any performance requirements for APBR. Staff has provided available information regarding children's portable bed rails to ASTM. In exchange, the work performed by ASTM to develop the voluntary standard would provide CPSC staff with additional product information, design information, and expert opinions on APBR.

CPSC staff is actively participating in the subcommittee to assist ASTM in the development of a voluntary standard that will address the hazards identified in the CPSC incident data. The information from the subcommittee will be used by staff to provide future recommendations on APBR to the Commission.

I. Recommendations

In response to the petition the Commission may:

1. Grant petition CP13-01 and direct staff to initiate rulemaking;
2. Deny petition CP13-01; or
3. Defer decision on petition CP13-01 to allow the voluntary standards process to continue APBR standard development.

Staff recommends that the Commission defer a decision on the petition, CP13-01, to allow the APBR voluntary standard process to continue with CPSC participation. The effectiveness of the voluntary standard will be evaluated by staff as part of a comprehensive product review. Development of this voluntary standard provides additional information that would be used for rulemaking if a completed voluntary standard is determined to be ineffective in reducing the risk of death and injuries to consumers. Staff will provide information to the Commission in 12 months about the status of the voluntary standard development.

TAB A

**In the United States of America
Before the U.S. Consumer Product Safety Commission**

In the Matter of the Petition of

**Gloria Black, The National Consumer
Voice for Quality Long-Term Care
(Consumer Voice), Consumer
Federation of America and 60
Other organizations, To Ban Adult
Portable Bed Rails, To Issue Mandatory
Standards for Adult Portable
Bed Rails, To Require Warning
Labels and to Recall Potentially
Hazardous Products**

Pursuant to the Administrative Procedures Act, 5 U.S.C. section 553 (e) and regulations of the Consumer Product Safety Commission (CPSC), 16 C.F.R. Part 1051, Gloria Black, The National Consumer Voice for Long-Term Care (Consumer Voice), Consumer Federation of America and 60 other organizations hereby petition CPSC to determine, under section 8 of the Consumer Product Safety Act (CPSA), 15 U.S.C. section 2057, that all currently marketed adult portable bed rails pose an unreasonable risk of injury, that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with adult bed rails, that the Commission shall, in accordance with section 9 of the CPSA, 15 U.S.C. § 2058, promulgate a rule declaring all currently marketed adult bed rails to be a banned hazardous product, and that a mandatory standard, promulgated under section 9 of the CPSA, 15 U.S.C. §2058, should be issued to adequately address the asphyxiation and entrapment hazard caused by the use of adult bed rails; that a mandatory standard should also require an adequate label to warn of the hazard. The groups further urge the CPSC, under section 27(e) of the CPSA, 15 U.S.C. § 2076(e) to promulgate a rule requiring any manufacturer of an adult bed rail to provide performance and technical data related to performance and safety of such products to the Commission. The Groups also petition CPSC to exercise its authority under section 15 of the CPSA, 15 U.S.C. section 2064 to require adult bed rail manufacturers to issue a public recall notice and offer a refund for all adult portable bed rails.

I. Interest of Petitioners

This petition is brought by Gloria Black, as an individual, and by Consumer Federation of America, Consumer Voice, and 60 other organizations on behalf of their members and their families affected by adult portable bed rails.

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.

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) is a national non-profit organization that advocates for quality care on behalf of long-term care consumers across all care settings. The membership of Consumer Voice consists primarily of consumers of long-term services and supports, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. Consumer Voice has over 37 years' experience advocating for quality care.

The Georgia Office of the State Long-Term Care Ombudsman seeks to improve the quality of life for residents of long-term care facilities (nursing homes, intermediate care facilities for the mentally retarded, personal care homes, and community living arrangements). The State Office certifies and trains community ombudsmen who work to resolve concerns of long-term care facility residents statewide and emphasize residents' wishes in assisting to resolve problems.¹

The Resident Councils of Washington (RCW) is a partnership of residents living in long term care facilities, family members and friends, healthcare professionals and educators who recognize that disability and/or chronic illness does not mean inability, but rather to focus on the strengths of individuals to live their lives as fully as possible. RCW is the only independent consumer-based statewide organization in the USA which is governed for and by residents (citizens) living in LTC residential settings.²

Since 1983, California Advocates for Nursing Home Reform (CANHR), a statewide nonprofit 501(c)(3) advocacy organization, has been dedicated to improving the choices, care and quality of life for California's long term care consumers. Through direct advocacy, community education, legislation and litigation it has been CANHR's

¹ <http://www.georgiaombudsman.org/>

² <http://volunteer.truist.com/uwkc/org/10333804619.html>

goal to educate and support long term care consumers and advocates regarding the rights and remedies under the law, and to create a united voice for long term care reform and humane alternatives to institutionalization.³

Ombudsman Services of San Mateo County in California is a non-profit organization that investigates complaints and brings resolution to those complaints on behalf of residents in long-term care facilities and their family members.⁴

The Delaware Office of the State Long-Term Care Ombudsman advocates for residents who live in long-term care facilities, and those who live in the community and receive home and community-based services from providers. The Ombudsman program investigates and resolves complaints on behalf of these residents.⁵

Centralina Area Agency on Aging in North Carolina strives to support and enhance the capacity of service and advocacy systems to promote independence, preserve dignity and advocate for the rights of older and disabled adults and their families.⁶

Senior Care Cooperative in Pennsylvania is a Naturally Occurring Retirement Community, which is a community that naturally evolves over time to include a relatively large concentration of senior residents.

The Regional Long-Term Care Ombudsman Program housed within the Area Agency on Aging, PSA 3 in Ohio provides a voice for consumers of long-term care services in nursing homes, assisted living facilities, adult care facilities, adult foster homes, county homes and in private residences. Ombudsman staff seeks to identify, verify and resolve concerns regarding quality of life and quality of care in the above settings.⁷

The Barren River Long-Term Care Ombudsman Program in Kentucky accepts complaints from anyone regarding a problem affecting someone residing in a long term care facility. The goal of the program is to resolve problems on behalf of individual residents and groups of residents.⁸

³ <http://www.canhr.org/about/index.html>

⁴ <http://www.ossmc.org/html/ossmchome.htm>

⁵ <http://dhss.delaware.gov/dhss/main/litcop.html>

⁶ <http://www.centralina.org/centralina-area-agency-on-aging-home/about-us/>

⁷ <http://www.aaa3.org/longtermcareombudsmanprogram.aspx>

⁸ <http://www.klaid.org/ombudsman/default.aspx>

The Council on Aging-Orange County in California promotes the independence, health and dignity of older adults through compassion, education and advocacy. It was founded in 1973 by a group of skilled professionals, civic leaders, and committed citizens who recognized a need to define and address community concerns regarding aging. Originally named the Orange County Council on Aging, COA-OC was the first agency in Orange County formed to address the needs of older adults.⁹

The District 9 Long-Term Care Ombudsman program in Tennessee advocates for residents of long-term care facilities, including nursing homes, assisted-living facilities, and residential care homes. Through regular visits to facilities by staff and specially trained volunteers, the program investigates and mediates complaints, monitors residents' care and quality of life, and provides public education for clients and families.¹⁰

The San Francisco Long-Term Care Ombudsman Program in California works to improve the quality of life and quality of care of people living in nursing homes, residential care homes and assisted living facilities. The Ombudsman Program receives, responds to and investigates complaints made by residents, family members and anybody else concerned about the well being of a resident. In addition, the Ombudsman Program provides consultation and education to the residents and the public regarding resident rights and good care practices.¹¹

The Alliance for Better Long Term Care in Rhode Island promotes the quality of life and care of residents of nursing homes and other long-term care institutions. The Alliance provides information and support to family members and residents. In addition, this grassroots agency works to support a more caring industry and to educate healthcare providers and staff as well as society to be more sensitive and compassionate to nursing home residents. The Alliance is the designated office of the Rhode Island State Ombudsman for Long Term Care.¹²

The Maryland Office of the State Long-Term Care Ombudsman seeks to improve the quality of life for residents of long-term care facilities (nursing homes, and assisted living). The State Office certifies and trains community ombudsmen who work to resolve concerns of long-

⁹ <http://www.coaoc.org/about-us/mission-and-history.aspx>

¹⁰ <http://www.mifa.org/ombudsman>

¹¹ <http://www.sanfranciscoltcombudsman.org/about.html>

¹² <http://alliancebltc.com/>

term care facility residents statewide. We emphasize residents' wishes in assisting to resolve problems.¹³

The Center for Advocacy for the Rights and Interests of the Elderly (CARIE) in Pennsylvania is a non-profit organization, based in Philadelphia, dedicated to improving the quality of life for vulnerable older people.¹⁴

The Rainbow Connection Community ("RCC") in Virginia is a 501(c)3 tax-exempt not-for-profit organization created to meet the needs of America's senior citizens with a truly innovative approach to elder care. RCC is not a medical model. RCC is a model of empowerment.¹⁵

The Michigan Campaign for Quality Care is a non-partisan, grassroots group seeking better care, better quality of life, and better choices for Michigan's long term care consumers. The campaign is a non-profit organization.¹⁶

The King George Department of Social Services in Virginia promotes and enhances the quality of life for the residents of the County through locally administered State/Federal/Local/Private programs designed to support the economic and social self-sufficiency of families and to safeguard vulnerable children, the disabled and our elderly residents.¹⁷

The Catherine Hunt Foundation in South Carolina is a non-profit transportation company that provides nursing home residents with convenient, low or no cost transportation to allow them to maintain their ties to their communities.

The Advocates for Basic Legal Equality's (ABLE) Ombudsman Program provides services to more than 9,000 individuals who reside in 1,000 nursing homes, located in the program's 10 county service area in northwest, Ohio.

Kansas Advocates for Better Care (KABC) works to promote quality long-term care for residents of licensed adult care homes. KABC is a 501(c) (3) non-profit organization, funded by members, contributors and grants for special purposes.¹⁸

¹³ <http://www.aging.maryland.gov/Ombudsman.html>

¹⁴ <http://www.carie.org/about/>

¹⁵ <http://www.rainbow-cc.org/>

¹⁶ <http://www.michigancampaignforqualitycare.org/>

¹⁷ <http://www.king-george.va.us/county-offices/department-of-social-services/social-services.php>

¹⁸ <http://www.kabc.org/history.html>

The Family Council of Ellicott City Health and Rehabilitation Center is an independent group of families and friends of nursing home residents at the Ellicott City Health & Rehabilitation Center, a larger-sized nursing home facility in Ellicott City, Maryland.¹⁹

NICHE (Nurses Improving Care for Healthsystem Elders) in Pennsylvania is the leading nurse driven program designed to help hospitals improve the care of older adults. The vision of NICHE is for all patients 65-and-over to be given sensitive and exemplary care. The mission of NICHE is to provide principles and tools to stimulate a change in the culture of healthcare facilities to achieve patient-centered care for older adults.²⁰

The Detroit Area Agency on Aging in Michigan has the mission to educate, advocate and promote health aging to enable people to make choices about home and community-based services and long term care that will improve their quality of life.²¹

The Indiana Association of Adult Day Services (IAADS) is the leading voice of the adult day service (ADS) industry in Indiana, and the state focal point for adult day service providers. IAADS is committed to providing its members with effective advocacy, educational and networking opportunities, technical assistance, research and communication services.²²

The Massachusetts Advocates for Nursing Home Reform ("MANHR") is a network of long-term care consumers, their family and friends, and citizen advocates. MANHR's mission is to improve the quality of care and ensure the dignity and quality of life for Massachusetts long-term care residents.²³

Our Mother's Voice in South Carolina provides information to families of nursing home residents to empower and equip them to advocate for quality of life and quality of care which goes beyond traditional custodial care to encompass the achievement of maximum physical, spiritual, social, mental, and emotional health for each resident.²⁴

¹⁹

http://www.nursinghomesite.com/ELLICOTT_CITY_HEALTH_%26_REHABILITATION_CENTER_ELLICOTT_CITY_MD

²⁰ <http://www.nicheprogram.org/>

²¹ <http://www.daaa1a.org/DAAA/>

²² <http://iaads.net/>

²³ <http://www.manhr.org/>

²⁴ <http://www.ourmothersvoice.org/about.html#mission>

The New York City Ombudsman Program housed within the New York Foundation for Senior Citizens enhances the lives of residents of New York City's nursing homes, adult homes and assisted living facilities. Ombudsmen actively visit the facilities to talk with residents and help resolve challenging situations they face. Using non-confrontational approaches to problem solving, Ombudsmen monitor and protect residents' rights related to their health, safety and general welfare²⁵

Kentuckians for Nursing Home Reform is a non-profit organization in Kentucky dedicated to making a positive difference in the lives of the 23,000 "Forgotten Kentuckians" in nursing homes by educating the public about the critical need to improve the care of residents in nursing homes and advocating for laws and regulations that will ensure that nursing home residents will be safe and comfortable.²⁶

The Areawide Aging Agency in Oklahoma works to improve the lives of older adults in the community. They work with partners in the community to develop and maintain programs serving the community which keep older adults active and independent.²⁷

The Ohio Office of the State Long-term Care Ombudsman advocates for people receiving home care, assisted living and nursing home care. Paid and volunteer staff work to resolve complaints about services, help people select a provider and offer information about benefits and consumer rights.²⁸

The Ombudsman Program housed within the Alamo Area Agency on Aging in Texas is an oversight agency for elder rights in long-term care certified by the Texas Department of Aging and Disability Services. The program uses specially trained and certified individuals (ombudsmen) to provide advocacy services to residents of long-term care facilities.²⁹

The California Office of the State Long-Term Care Ombudsman investigates and endeavors to resolve complaints made by, or on behalf of, individual residents in long-term care facilities. These facilities include nursing homes, residential care facilities for the elderly, and assisted living facilities.³⁰

²⁵ <http://www.nyfsc.org/services/ombuds.html>

²⁶ <http://www.kynursinghomereform.org/mission.html>

²⁷ <http://www.areawideaging.org/home.html>

²⁸ <http://aging.ohio.gov/services/ombudsman/>

²⁹ <http://www.aacog.com/index.aspx?nid=65>

³⁰ <http://www.aging.ca.gov/programs/LTCOP/>

The Terence Cardinal Cooke Health Care Center in New York is a long term care facility sponsored by the Roman Catholic Archdiocese of New York and conducted in accord with the medical, moral and ethical teachings of the Catholic Church as promulgated by the Archbishop of New York.³¹

The Long-Term Care Community Coalition in New York works to improve care for the elderly and disabled in all settings. It encourages and helps people to speak out on their own, and provide a voice for those who are too frail to advocate for themselves.³²

The Nursing Home Victim Coalition in Texas is a non-profit organization that helps victims of elder abuse in nursing homes.³³

The Pennsylvania Office of the State Long-Term Care Ombudsman Program oversees ombudsmen in the state, who are federally mandated, legally-based and state certified via standardized training to actively advocate and give voice to older consumers of long-term care services, whether delivered in the community or a facility-based setting.³⁴

The New York State Office of Long Term Care Ombudsman protects the health, safety, welfare, and rights of people living in New York's nursing homes and adult care facilities. Hundreds of certified Ombudsmen work in concert with government agencies to fulfill this duty.³⁵

The New Hampshire Office of the Long Term Care Ombudsman receives services, investigates and resolves complaints or problems concerning residents of long-term health care facilities. The program also provides advocacy services to long-term care facility residents, and comments on existing and proposed legislation, regulations and policies affecting long-term care residents.³⁶

Levin & Perconti, located in Chicago, Illinois, is a nationally renowned law firm concentrating in all types of serious injury, medical malpractice, nursing home, and wrongful death litigation. Our Chicago

³¹ <http://www.archcare.org/tcc-mission.html>

³² <http://www.ltccc.org/>

³³ Did not have a website. Used what I could find from other website, however, no mission was located.

³⁴

http://www.aging.state.pa.us/portal/server.pt/community/advocacy_%28ombudsman%29/19389

³⁵ <http://www.ltcombudsman.ny.gov/>

³⁶ <http://www.dhhs.state.nh.us/oltco/index.htm>

personal injury attorneys are committed to protecting and vindicating the rights of people who are seriously injured by the negligence of others.³⁷

Bethany Village Senior Action in Indiana is a senior care community that provides a variety of services including rehabilitation, memory care, skilled nursing, hospice, and respite care.³⁸

The Snohomish County Long Term Care Ombudsman Program in Washington promotes the interests, well-being and rights of vulnerable adults living in long term care facilities. It is part of the Washington State Long Term Care Ombudsman program, a federally mandated program created by the Older Americans Act.³⁹

The DC Coalition on Long Term Care in Washington, DC was formed in 1995 by consumers, advocates and health care providers whose goal was to expand the quality choices of District adults with chronic care needs.⁴⁰

The Legal Assistance Foundation in Illinois works to provide high-quality civil legal services to low- income and disadvantaged people and communities. Through advocacy, education, collaboration and litigation the LAF empowers individuals, protects fundamental rights, strengthens communities, creates opportunities and achieves justice.⁴¹

Friends of Residents in Long-Term Care is a nonprofit charitable organization in North Carolina committed to advancing the quality of life for individuals who receive long-term care services and supports. They advocate for changes in public policy, support families and help build public awareness in North Carolina about issues impacting the long-term care services system.⁴²

Our Mother's Voice in North Carolina provides information to families of nursing home residents to empower and equip them to advocate for quality of life and quality of care which goes beyond traditional

³⁷ <http://www.levinperconti.com/>

³⁸ <http://www.ascseniorcare.com/bethany-village/>

³⁹

http://www1.co.snohomish.wa.us/Departments/Human_Services/Divisions/LongTermCareAging/Ombudsman/

⁴⁰ <http://iona.org/advocacy/dc-coalition-on-long-term-care>

⁴¹ <http://www.lafchicago.org/content/view/1/40/>

⁴² <http://www.forltc.org/cms/>

custodial care to encompass the achievement of maximum physical, spiritual, social, mental, and emotional health for each resident.⁴³

Advocacy, Inc. (formerly Ombudsman/Advocate, Inc.) is an independent non-profit agency serving Santa Cruz and San Benito counties in California, which is comprised of the Long-Term Care Ombudsman Program and the Patients' Rights Advocate Program.⁴⁴

The California Long-Term Care Ombudsman Association (CLTCOA) is a membership organization dedicated to providing leadership and advocacy to the local long-term care ombudsman programs. Since 1979, CLTCOA has been the voice of local Long-Term Care Ombudsman programs in California. It is the mission of CLTCOA to improve the quality and availability of Ombudsman services to elders and vulnerable adults living in long-term care facilities.⁴⁵

The Montgomery County Long Term Care Ombudsman Program in Maryland serves over 7,700 people living in 34 Nursing Homes and 183 Licensed Assisted Living Facilities in its jurisdiction. The program is designated by the Maryland Department on Aging to operate within the Department of Health and Human Services, Aging & Disability Services. The program supports a cadre of volunteer ombudsman representatives which has received national recognition. As advocates for long term care residents, the staff and volunteers seek to resolve problems, replicate best practices, research current issues and trends, and convey relevant information about topics that promote the highest degree of quality of life and care.⁴⁶

The Long-Term Care Ombudsman Program housed within the Central Ohio Area Agency on Aging is an advocacy program for the rights of consumers of long term care. The Long-Term Care Ombudsman works on behalf of individuals receiving services or care from in-home services, nursing homes, adult care facilities, or residential care such as assisted living facilities.⁴⁷

OWL – The Voice of Older and Midlife Women is a national membership organization that addresses social, economic and political concerns of midlife and older women through advocacy, education and empowerment. OWL values older women's independence, self-

⁴³ <http://www.ourmothersvoice.org/about.html#mission>

⁴⁴ <http://www.advocacy-inc.org/about.htm>

⁴⁵ <http://www.cltcoa.org/about.html>

⁴⁶

<http://www6.montgomerycountymd.gov/hhstmpl.asp?url=/content/hhs/ads/Ombudsman.asp>

⁴⁷ <http://www.coaaa.org/programs-long-term.php#ltc>

determination, security, respect, dignity and diversity, and the social contracts to achieve them.⁴⁸

PHI – Quality Care through Quality Jobs is a national organization that works to improve the lives of people who need home or residential care—by improving the lives of the workers who provide that care. PHI’s goal is to ensure caring, stable relationships between consumers and workers, so that both may live with dignity, respect and independence: Quality care through quality jobs.⁴⁹

The National Association of States United for Aging and Disabilities (NASUAD) was founded in 1964 under the name National Association of State Units on Aging (NASUA). In 2010, the organization changed its name to NASUAD in an effort to formally recognize the work that the state agencies were undertaking in the field of disability policy and advocacy. Today, NASUAD represents the nation’s 56 state and territorial agencies on aging and disabilities and supports visionary state leadership, the advancement of state systems innovation and the articulation of national policies that support home and community based services for older adults and individuals with disabilities.⁵⁰

The National Association of State Long-Term Care Ombudsman Programs was formed in 1985. The non-profit organization is composed of state long-term care ombudsmen representing their state programs.⁵¹

The National Senior Citizens Law Center’s principal mission is to protect the rights of low-income older adults. Through advocacy, litigation, and the education and counseling of local advocates, the center seeks to ensure the health and economic security of older adults with limited income and resources. Since 1972, the National Senior Citizens Law Center has worked to promote the independence and well-being of low-income elderly and persons with disabilities, especially women, people of color, and other disadvantaged minorities.⁵²

The Service Employees International Union (SEIU) is a national organization of 2.1 million members united by the belief in the dignity and worth of workers and the services they provide and dedicated to

⁴⁸ <http://www.owl-national.org/pages/mission>

⁴⁹ <http://phinational.org/quality-care-through-quality-jobs>

⁵⁰ http://www.nasuad.org/about_nasuad/nasuad.html

⁵¹ <http://www.nasop.org/about.htm>

⁵² <http://www.nsclc.org/index.php/about/who-we-are/>

improving the lives of workers and their families and creating a more just and humane society.⁵³

The Direct Care Alliance (DCA) is a nationwide and state-based alliance of direct care workers, employers and people of all ages and disabilities who use long-term services, care and supports. DCA is united to build an empowered and valued professional direct care workforce essential to ensuring high-quality services and a life of dignity, respect, autonomy and opportunity for all to participate in community life.⁵⁴

United Spinal Association is a national organization whose mission is to improve the quality of life of all people living with a spinal cord injury or disease (SCI/D). United Spinal Association believes that despite living with a spinal cord injury or disease, a full, productive, and rewarding life is within the reach of anyone with the strength to believe it and the courage to make it happen.⁵⁵

The Center for Medicare Advocacy, Inc., established in 1986, is a national nonprofit, nonpartisan organization that provides education, advocacy and legal assistance to help older people and people with disabilities obtain fair access to Medicare and necessary health care. The Center is headquartered in Connecticut and Washington, DC with offices throughout the country.⁵⁶

The National Research Center for Women & Families promotes the health and safety of women, children, and families, by using objective, research-based information to encourage new, more effective programs and policies. The Center achieves its mission by gathering and analyzing information and translating that information into clearly presented facts and policy implications that are made widely available to the public, the media and policy makers.⁵⁷

⁵³ <http://www.seiu.org/our-union/>

⁵⁴ <http://www.directcarealliance.org/index.cfm?pageId=495>

⁵⁵ <http://www.unitedspinal.org/>

⁵⁶ <http://www.medicareadvocacy.org/about/>

⁵⁷ http://www.womensorganizations.org/index.php?option=com_content&view=article&id=223:national-research-center-nrc-for-women-a-families&catid=13:member-profiles&Itemid=69

II. The Product

For the purpose of this Petition, portable bed rails shall be considered to be those that are sold and marketed directly to the public, and intended to be used with a home-style bed. This would include those portable bed rails marketed on the Internet, in department stores and other retail outlets, and directly by manufacturers. The scope of this definition also includes bed rails sold in medical supply stores, since no special requirement or prescription is currently needed for the sale or purchase there,⁵⁸ even though such a shop may advertise that it specializes in medical supplies. Portable bed rails sold without reference to a particular bed of a manufacturer would be included in the scope. The exclusion of other bed rail products from the scope in this petition does not mean that such rails are necessarily safe; rather, they are being excluded for jurisdictional reasons. The term “bed rails,” as referenced in this petition, includes, but is not limited to, side rails, split rails, half rails, bed handles, full length rails, and bed canes. If a manufacturer develops another term to define their company’s bed rails, such new terminology should not create an exemption from oversight and regulation as proposed in this petition.

III. Hazards Presented by Portable Bed Rails

Portable bed rails currently on the market are responsible for too many injuries and deaths among users, particularly the elderly and frail. Many of these deaths result from asphyxiation caused by entrapment within openings of the rail or between the rail and the mattress or bed frame. Individuals attempting to climb over bed rails placed on their beds are also victims: research has shown that a fall resulting from an individual attempting to climb over a rail – which can have the effect of increasing the height from which that person may fall – may be at greater risk for injury or death than if no rail were used at all.

To cite one such example, in 2004, on Christmas morning, a 75 year old man was found with his neck entrapped between the mattress or bed frame and a bed rail.⁵⁹ The New York Times blog in which this story was identified includes an important common, but flawed perception of these devices:

⁵⁸ Of major importance for CPSC to note in addressing this Petition is that requirements for prescriptions from doctors to purchase bed rails will not address the fundamental problem of flawed designs in bed rails. Many deaths are documented where doctors recommended purchase of a bed rail, in the misguided belief the bed rail would make the individual “safer,” only to find a person dies instead allegedly from use of the bed rail.

⁵⁹ *The New Old Age* blog, written by reporter Paula Span on March 10, 2010, in which she described the Christmas morning death.

Like a lot of people, I supposed that bed rails were a safety device, analogous to a seat belt in a car, meant to keep, sick, drugged, confused or restless people from falling or climbing out of beds in hospitals and nursing homes.

Dr. Steven Miles of the University of Minnesota found that bed rails are not safety devices, after spending years reviewing bed rail death and injury incidents of elderly people. In the same New York Times blog, he states that, "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."⁶⁰ The incidents take place when "confused or demented patients who try to climb over the rails, instead of falling from a lower level and landing on their knees or legs, are apt to fall face down and strike their heads. But the greater danger is entrapment – patients getting stuck within the rails or between the rail and the mattress."

Portable bed rails are purchased as consumer products by well-meaning family members and then not infrequently are brought into various care facilities where their loved ones are living. Even when their use in said facilities is in violation of state or federal regulations, the facilities, either through ignorance or indifference, allow the portable bed rails to remain on their clients' beds.

In one example of a Department of Health and Human Services Departmental Appeals Board Case,⁶¹ (which was denied), the following statements by an administrative law judge reveal the documented hazards posed by bed rails:

No one disputes that side rails can represent an accident hazard. (P. 4)

Facility policies did not reflect the standard of care, which mandates that: a) side rails be used only where an individualized resident assessment establishes that their potential benefit outweighs safety risks; and b) the facility takes steps to minimize the risk of entrapment whenever side rails are used. (P. 4)

Side rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail. (P. 4)

⁶⁰*The New Old Age* blog, written by Paula Span, March 10, 2010.

⁶¹ May 30, 2008; Docket No. C-07-222; Decision No. CR1796; Laurelwood Care Center, (CCN: 39-5812), Petitioner v. Centers for Medicare & Medicaid Services.

Facilities should begin with the presumption that side rails not be used, and should place the burden on the side rail proponent to demonstrate that their use is appropriate. (P. 5)

Any time a bed rail is purchased for an adult by a consumer, for private use at home or for use while traveling or while in a facility, it is because the consumer has a concern which in all likelihood is related to cognition or a physical weakness of the adult for whom the rail is being purchased. An average consumer is not likely qualified or likely to make the necessary evaluation at the time the bed rail is purchased. Such evaluations should include assessing the actual needs of the intended user of the bed rail, and taking measurements the consumer may ultimately be called upon to make by a manufacturer such as the size of a mattress used at home. Further, most consumers are probably unaware that adult portable bed rails are not required to meet mandatory safety standards, that there is no independent verification of manufacturer claims made for that product, and that use of bed rails has resulted in injuries and deaths.

IV. Bed Rail Deaths and Injuries: Statistics Available

A. CPSC Memo to Gloria Black

In a CPSC memo dated December 7, 2010, in which an answer was provided to Gloria Black's question addressed to the CPSC regarding a breakdown of the CPSC known statistics on bed rail deaths and injuries, the following data were provided:⁶²

CPSC staff is aware of 203 incidents between 1985 and 2009 that involved entrapments, entanglements, or strangulations in bedrails. The sources of these incident reports include consumers reporting via the Internet or hotline, death certificates provided by states, newspaper clippings, medical examiner reports, and reports from a probability sample of hospitals with emergency departments.

Of the 203 reported incidents, 155 resulted in fatalities; 18 resulted in non-fatal injuries; and 30 reports did not mention any injury. The number of incidents and fatalities of which CPSC staff is aware does not likely represent all incidents that occurred in the time period because not all incidents are reported and the reports are not projected nationally. It is also

⁶² It is acknowledged that responses provided in said letter were prepared by CPSC staff, and do not necessarily constitute an official position taken by the CPSC.

possible that some of these incidents may be, or should 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 twin/full/queen/king size bed. The remaining 149 reports did not mention either the bed rail type or the bed. Of the 203 incidents reported to the CPSC between 1985 and 2009, 123 incidents involved individuals older than 60 years of age; 40 incidents involved children younger than 5 years of age; and 31 involved individuals between the ages of 5 and 60. Victim age was not mentioned in 9 of the incidents reported to the CPSC.

B. CPSC Bed Rail Data

In the summer of 2012, the CPSC researched the issue of bed rail injuries and deaths for adults. The resulting findings were reported in the CPSC's October 11, 2012, memo, "Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: January 2003 to September 2012." People aged 13 years and older were included in the analysis. The number of fatalities CPSC uncovered for that approximately nine year period totaled 155. Of the 155 fatalities, 129 were aged 60 years and over. The CPSC found that 94 of the total number of fatalities took place at home, 25 in a nursing home, 15 in an assisted living facility, and 3 in hospice.⁶³ The study further provided that:

- There were 145 incidents related to rail entrapment. This category included incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, or between the headboard and rail. Based on the narrative, the most frequently injured body parts were the neck and head. Most of these incidents (143 out of 145) resulted in fatalities.
- There were an estimated 36,900 adult portable bed rail-related injuries...that were treated in U.S. hospital emergency departments from January 2003 to December 2011.
- The data included an age range from 13 to 101 years old. The injuries were fairly evenly distributed among age groups. Thirty-nine percent were 60 years and over; 34 percent were between 30 and 60 years old; and 27 percent were younger than 30 years old. Most of the injuries (92%) were treated and released. The following injury characteristics occurred more frequently:

⁶³ Page 4 of report.

- *Injured body part – head (14%), lower leg (12%), foot (12%)
- *Injury type – laceration (30%), contusions/abrasions (30%), fracture (14%).

On November 26, 2012, the New York Times ran a front page article on bed rails: “After Dozens of Deaths, an Inquiry into Bed Rails.”⁶⁴ It made public for the first time CPSC’s findings on the nearly 37,000 hospital emergency ward visits due to bed rail related injuries that had taken place over the nine year period.

V. Existing Voluntary Standards are Inadequate to Address the Risks Caused by Portable Bed Rails

a. ASTM Standard

An ASTM standard for bed rails exists but its scope is limited to children’s bed rails. ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails* defines a “portable bed rail” as a device intended to be installed on an adult bed to prevent children from falling out of bed.⁶⁵ CPSC, as required by the CPSIA, has issued a mandatory standard for these products. Given the limited scope of the voluntary standard, it is clear that the voluntary standard is failing to address the hazards posed by adult portable bed rails. Further, given that the hazards posed by adult portable bed rails have persisted and are well documented and that ASTM has failed to write a voluntary standard that adequately addresses these products, reliance upon such a nonexistent voluntary standard would not reduce the product risk.

VI. CPSC Actions Taken to Address Children’s Bed Rails

In 2011, as a result of the passage of the Consumer Product Safety Improvement Act in 2008, which required CPSC to promulgate mandatory standards for infant and toddler durable products, including bed rails, CPSC proposed a rule on children’s portable bed rails.⁶⁶ By 2012, the mandatory standard was finalized, requiring a standard addressing the suffocation hazard of bed rails and a labeling requirement warning of potential hazards posed by children’s portable

⁶⁴ NY Times, front page article, “After Dozens of Deaths, Inquiry into Bed Rails,” Ron Nixon, Nov. 26, 2012, <http://www.nytimes.com/2012/11/26/health/after-dozens-of-deaths-inquiry-into-bed-rails.html>

⁶⁵ <http://www.cpsc.gov/PageFiles/133466/adultbedrail.pdf> at 1.

⁶⁶ CPSC Docket No. CPSC-2011-0019; Safety Standard for Portable Bed Rails.

bed rails. Unfortunately, the CPSC has not taken similar actions to address adult portable bed rails.

The CPSC has also recalled children's bed rails due to suffocation and strangulation hazards. For example, on December 6, 2012,⁶⁷ CPSC conducted a recall of Dream On Me Children's Bed Rails. The hazards identified in their press release announcing the recall are that "the bed rail can separate from the mattress allowing a child's body to become entrapped if it slips between the rail and the mattress. This poses suffocation and strangulation hazards to children." This is the identical hazard posed by portable adult bed rails to adults. The CPSC should similarly recall bed rails when the bed rail poses the risk of strangulation to adults, especially when reports indicate that there have been multiple deaths for the same model bed rail. Regrettably, currently such adult bed rails remain on the market – not recalled, unlabeled and without warning.⁶⁸

VII. Misleading Advertising of Bed Rails and Hazard Warning Labeling

The fact that misleading advertising has been allowed to flourish, allowing consumers to believe that the use of bed rails makes a person "safer," when evidence suggests otherwise, and the fact that we have a growing, aging population make it all the more urgent that this issue be addressed. Appendix A (p. 24) cites research conducted on safety of bed rails. Appendix B, which cites excerpts from adverse event reports of alleged death events involving bed rail use, is found on page 27. A description of death by asphyxiation is included there.

An article published in *Biomedical Safety & Standards* in November of 2012, "Safe Portable Bed Rails – There's no Such Thing (Request to Stop False Advertising Goes to Federal Trade Commission),"⁶⁹ reported on alleged unsubstantiated advertising of bed rails. The article also mentions a letter sent jointly by Public Citizen and the National Consumer Voice for Quality Long-Term Care in September 2012 to the Federal Trade Commission (FTC)(See Appendix F, p. 35).⁷⁰ The two consumer organizations argued that a bed rail for which there allegedly

⁶⁷ <http://www.cpsc.gov/cpsc/pub/prereel/prhtml13/13060.html>

⁶⁸ Public Citizen Petition to FDA; FDA-2011-P-0438. Also, "Safe, Portable Bed Rails: There's No Such Thing (Request to Stop False Advertising Goes to Federal Trade Commission)," Lisa Marshall, *Biomedical Safety & Standards*, Nov. 15, 2011.

⁶⁹ "Safe, Portable Bed Rails: There's No Such Thing (Request to Stop False Advertising Goes to Federal Trade Commission)," Lisa Marshall, *Biomedical Safety & Standards*, Nov. 15, 2011.

⁷⁰ A link to the Public Citizen/National Consumer Voice for Quality Long Term Care letter sent to the FTC in September 2012 is available here: <http://www.citizen.org/hrq2069>, and also appears in Appendix F on page 36 of this petition.

are multiple reports of death in government files does not, as is claimed in its advertising, “make any bed safer,” and hence should not be allowed to continue to make such claims. The FTC’s response to date has been a form letter acknowledging receipt of the letter by the groups.

1. Unsubstantiated and False Advertising of Adult Portable Bed Rails

Numerous claims made in the marketing of portable bed rails are easily found through an Internet search. Many of the promises made include increased safety, and use words to promote the sense that to buy a bed rail for a loved one is to show that you care for their safety. Examples of this advertising are found in Appendix C, page 30, of this petition.

It is important to contrast the advertising of bed rails to what is found in some of the text written in the *CMS (Centers for Medicare and Medicaid Services) State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities*. Excerpts from that document appear in Appendix D, page 32, of this petition. That information underscores a dual standard in bed rail oversight within our government agencies. When an individual purchases a portable bed rail as a consumer product, he may then bring it into a care facility and request it be used by that facility for a loved one. While federal and some state regulations attempt to regulate bed rail use in facilities, those regulations are too frequently not enforced, and caregivers are themselves frequently unaware of the dangers of bed rail use. Hence, if there is a death or injury involved and the rail was used in a facility which receives federal funding, the portable bed rail, most likely initially purchased as a consumer product, may be treated as if it were a medical device, and, the facility that allowed the bed rail use now stands to be fined by the federal government.

2. Hazard Warning Labeling for Adult Bed Rails

Information in advertisements is misleading consumers into thinking that bed rails increase safety, and at the same time, useful information on bed rails warning of documented hazards fails to be visible on bed rails. (See Appendix A, page 24, and Appendix C, page 30.) At a minimum, consumers should have been warned of potential entrapment, strangulation and asphyxiation risks especially for particular populations such as those who may experience confusion. While redesigning the product to eliminate the hazard is the most effective solution, warning labels should be required to be permanently affixed to the packaging as well as the product, visible to caregivers

and those using the bed, and should be readable for the life of the product.

Warnings alone are not the solution to the problem. Without mandatory safety standards that effectively reduce the hazards, warnings are a band-aid approach. William Hyman, Professor Emeritus of the Bio-Medical Engineering Department at the Texas A & M University, author of 'Bed Rail Entrapments – Still a Serious Problem, McKnights, July 24, 2008, stated that

“Warnings are not an appropriate way to ‘fix’ dangerous designs, unless perhaps the warning says ‘Do Not Use This Product.’ Furthermore, effective warnings must not only identify a hazard but instruct on how to avoid it, and in a way that users will be able to understand and implement. The proper use of warnings is for residual risk, i.e., risk that cannot be reasonably eliminated by design, or replacement. Since most entrapment hazards can be eliminated by design (or by not using bed rails at all), there is no acceptable residual risk.”

VI. Action Requested

For the reasons enumerated above, the Petitioners request that the Consumer Product Safety Commission, pursuant to the Administrative Procedures Act, 5 U.S.C. section 553 (e) and regulations of the Consumer Product Safety Commission (CPSC), 16 C.F.R. Part 1051, determine under section 8 of the Consumer Product Safety Act (CPSA), 15 U.S.C. section 2057, that all currently marketed adult portable bed rails pose an unreasonable risk of injury, that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with adult bed rails, that the Commission shall, in accordance with section 9 of the CPSA, 15 U.S.C. § 2058, promulgate a rule declaring all currently marketed adult bed rails to be a banned hazardous product, and that a mandatory standard, promulgated under section 9 of the CPSA, 15 U.S.C. §2058, should be issued to adequately address the asphyxiation and entrapment hazard caused by the use of adult bed rails; that a mandatory standard should also require an adequate label to warn of the hazard. The Petitioners further urge the CPSC, under section 27(e) of the CPSA, 15 U.S.C. § 2076(e) to promulgate a rule requiring any manufacturer of an adult bed rail to provide performance and technical data related to performance and safety of such products to the Commission. The Petitioners also petition

CPSC to exercise its authority under section 15 of the CPSA, 15 U.S.C. section 2064 to require adult bed rail manufacturers to issue a public recall notice and offer a refund for all adult portable bed rails.

Specifically, the Petitioners request that CPSC initiate a rulemaking for a rule that states:

Under the authority of section 8 of the Consumer Product Safety Act the Commission has determined that adult portable bed rails present an unreasonable risk of injury and no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with these products. Therefore such products are banned hazardous products under section 8 of the Act.

If the CPSC determines, in spite of the evidence provided, not to pursue a ban, the petitioners request that CPSC initiate a rulemaking to promulgate mandatory standards under section 9 of the CPSA, as such mandatory standards for adult portable bed rails would be necessary to reduce the unreasonable risk of asphyxiation and entrapment hazard posed by these bed rails.

Further, we request that under the authority of section 15 of the Consumer Product Safety Act, the Commission require manufacturers to issue a public recall notice and offer a refund for portable adult bed rails, as these products pose a substantial product hazard to consumers in that they contain product defects that create a substantial risk of asphyxiation and entrapment hazard to the public.

This Petition requests that, the U.S. Consumer Product Safety Commission:

1. Ban the sale of adult portable bed rails that are sold directly to the public and that are intended to be used with a range of typical home style beds, which would include those beds that, for example, might be found in nursing care and assisted living facilities, as well as beds found in homes.
2. Exercise recall authority and require notices and refunds to consumers for portable bed rails presently on the market that present risk of entrapment, asphyxiation, or other failure that can lead to injury.

If CPSC will not ban adult portable bed rails, we request that the Commission proceed with the following:

3. Promulgate a mandatory safety standard that establishes requirements for the design of adult portable bed rails. Such mandatory standards must include, at a minimum:
 - a. Design standards that substantially reduce the entrapment, strangulation and asphyxiation hazard posed by portable bed rails.
 - b. Set requirements for the verification by an independent third party that new, mandatory safety standards have been met by the manufacturer in question prior to allowing said product to be introduced to the market.
 - c. Set requirements for warning labels alerting users to the risk of asphyxiation and entrapment in large print. Such warnings must remain visible to all users and caregivers for the life of the product.
 - d. Set requirements for permanently affixed manufacturer and model number on the product. Information affixed permanently to the bed rail stating that such product complies with the new, mandatory guidelines that CPSC would establish.
4. Take all necessary action, including coordinating with the Federal Trade Commission (FTC) to prohibit advertising that states or implies that the use of bed rails increases safety.

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Dated: April 25, 2013

Appendices

The following pages contain:

Appendix A: Research on Bed Rail Safety. Excerpts from two different sources which discuss research on safety and bed rail use. P. 24.

Appendix B: Excerpts from adverse event reports describing alleged death events involving bed rails. Followed by a description of asphyxia. P. 27

Appendix C: Samples of Adult Portable Bed Rail Advertising Found on the Internet P. 30

Appendix D: Excerpts from Centers for Medicare and Medicaid Services (CMS) on restraints and bed rail use. P. 32

Appendix E: Consumer Voice Petition and Gathering of Signatures to CPSC and FDA. P. 34

Appendix F: Consumer Voice and Public Citizen letter to the Federal Trade Commission about misleading advertising. P. 35

Bibliography P. 40

APPENDIX A:

Following are excerpts from two different sources which discuss research on safety and bed rail use.

1. *The Myth of Benign Bed Rails: A Consumer Protection Issue*; NCCNHR (now renamed National Consumer Voice for Quality Long-Term Care) *Policy Paper*, Omoniyi Adekanmbi, April 2010.

...One evaluation of patients on a rehabilitation ward found that all patients with dementia, Parkinson's, bone or rheumatologic abnormalities, and epilepsy were restrained. However, there was no relationship between actual history of falling and application of restraints (Gallinagh et al., 2002). It appears that the use of restraints is based more on 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. ...

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. This research has found that use of restraints did not lower fall rates, recurrent fall rates, or injurious fall risk among residents, even residents with impaired cognitive function. Si, Neufeld, & Dunbar (1999) found there were no serious injuries associated with removal of the bed rails and for most residents raised bed rails did not enhance safety. 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 (Capezuti, 2004; Capezuti, Evans, Strumpf, & Maislin, 1996; Capezuti, Maislin, Strumpf, & Evans, 2002; Capezuti, Strumpf, Evans, Grisso, & Maislin, 1998; Capezuti, Wagner, Brush, Boltz, Renz, & Talerico, 2007). 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 (Neufeld, Libow, Foley, Dunbar, Cohen, & Breuer, 1999). (P. 2)

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), van Leeuwen, Bennett, & West (2001) 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. 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 (they) 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 the risk of aggravated injury from a fall, residents are at risk of entrapment in bed rails resulting in serious injury or death by asphyxiation. 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 footboard, side rail, and mattress (Capezuti, 2004, see Figure 1). The head or neck is the most frequently trapped body part (Todd, Ruhl & Gross, 1997). Asphyxiation occurs when the resident is caught between mattress and bed rail, between the headboard and rail, head stuck in rail, or strangled by vest restraint between the rails (JC, 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, 2010). Miles (2002) suggests that air mattresses pose a particular danger to residents. From 1994 and 2000, 35 deaths due to entrapment between bedrails and air mattresses were reported to the FDA. (P. 2)

2. *Myths and Facts about Side Rails*, by Karen A. Talerico and Elizabeth Capezuti, AJN, July 2001, Vol. 101, Issue 7, 43-48.

Myth: Side rails serve as a safe and effective means of preventing patients from falling out of bed. Facts: No research study has demonstrated the efficacy of side rails in the prevention of injuries resulting from falling out of bed. In fact, several studies have shown that raised side rails do not deter older patients from getting out of bed unassisted, and may even lead to more serious falls and injuries(8-10). Si and colleagues studied the effects of a program to reduce side rail use among older residents (mean age, 83 years) on a short-term rehabilitation unit. (10) They found there were 15 falls in the control group and 15 falls in the study group of residents (N=246) and that serious injuries rarely occurred. Similarly, Hanger and colleagues, studying the effects of a significant reduction in side rail use on an Australian rehabilitation unit, found that there was no significant change in rates of falling; they also found that significantly fewer serious injuries occurred.(9) (P. 44)

- (8) *Capezuti, E., et al. The effects of a low-height bed intervention on nightfalls among frail nursing home residents (abstract); Gerontologist 1999, 39, Special issue 1):196.*
- (9) *Hanger, HC, et al. An analysis of falls in the hospital; can we do without bedrails? J Am Geriatr Soc 1999;(5) 47; 529-31.*
- (10) *Si, M, et al. Removal of bedrails on a short-term nursing home rehabilitation unit. Gerontologist 1999;39(5);611-4.*

APPENDIX B
MAUDE ADVERSE EVENT REPORTS
(Followed by a Description of Asphyxia)

The following report is excerpted from the FDA MAUDE database, found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI__ID=2281458. Filing of reports with the FDA or CPSC is not of itself conclusive proof of a given event or of guilt. The sample provided here is done so strictly for academic purposes. It is to provide the CPSC with just one example of an alleged situation for which, had the consumer had prior knowledge of the risks of portable bed rail use, she may have been able to avoid the tragedy she describes surrounding her mother's death.

There are numerous other examples to be found; this particular entry is unique in that most family members of loved ones who have allegedly been killed through bed rail use do not know that they should report these incidents, either to the FDA or to the CPSC. Nor do they know that it is worthwhile to look at websites such as the CPSC [saferproducts.gov](http://www.saferproducts.gov) site or the FDA Maude database *prior* to making their portable bed rail purchase. *Because* the product is on the market, the assumption is, it is 'safe' to use. Indeed, bed rails are manufactured as 'safety' products. In the case of reports made to the FDA, most descriptions of death events lack reference to the role of the portable bed rail consumer, the one who initially makes the fatal purchase.

**DRIVE MEDICAL DESIGN AND MANUFACTURING DRIVE
BED ASSIST RAIL**

[Back to Search Results](#)

Model Number 15064

Event Date 02/05/2011

Event Type Death **Patient Outcome** Death

Event Description

About 2 years ago, i bought a "drive" bedrail (model 15064) at (b)(6) in (b)(6) to assist my elderly mother, (b)(6), in getting in and out of bed. The bedrail is shaped like an "I" with the bottom part of the "I" sliding under the mattress. It is secured to the mattress by a one inch wide strap that goes around the mattress. On (b)(6) of this year, my mother was reaching for the telephone on the bedside table and started to fall out of bed. Instead of keeping her from falling out of the bed, the strap slipped, causing her to fall between the bed and the bedrail. Her neck got caught on the bedrail, strangling her, and she suffocated to death. After her death, i contacted (b)(6), and they immediately removed that model from their shelves, but a bedrail with that kind of strap should not be sold anywhere.

Attention should be brought to the following YouTube video of the product referred to above: https://www.youtube.com/watch?v=QuG_1pHYLtQ.

The following additional excerpts are taken directly from the FDA Manufacturing and User Facility Device Experience (MAUDE) reports on bed rail deaths, from the Event Description.

- * "...with his head between the vertical uprights of a bed side rail. ... and the administrator stated that there was no malfunction of the side rail."
- *"No imminent hazard to public health claimed..."
- *"Kneeling like they were praying, that was how their body was."
- *"Pt contributed to the event."⁷¹
- *"...pupils were fixed and dilated and resident was blue around the mouth..."
- *"...found with her neck caught between the bed frame and side rail."
- *"...found on floor with head between bed rail and mattress."
- *"Resident was alert and responding, 'please help me'."
- *"Resident found laying on left side on floor with head and left arm wedged in mobility bar."
- *"The resident got their head caught in a side rail and fell out of bed. Death by asphyxiation."

Description of Asphyxia in Bed Rails, provided by Dr. Steven Miles, responding to a request for a description of death by bed rail type products.

"The most common manner of death caused by beds equipped with bed rails is by positional asphyxia. Asphyxia refers to death by suffocation. Positional asphyxia means that the suffocation is caused by the position of the body. In this case, the person slides against the rail and partly into a groove between the rail and the mattress. As the person wedges in that groove, the mattress slides toward the opposite side of the bed thereby widening the space between the mattress and the bed rail. The edge of the mattress, bearing the concentrated pressure of the upper body of the patient, compresses and the person's chest or abdomen drops into the space between the rail and the mattress. The person's downward motion is stopped by a variety of means (sometimes the head or an arm caught in the rail, sometimes the rib cage is too large to slide through the space between the rail and the bed frame. The total sequence from starting to move off the bed to entrapment takes a couple of minutes.

Once held and stopped between the rail and the mattress, the person cannot inhale and so they are squeezed to death. Unable to inhale, they are unable to exhale or call for help. They die of suffocation – a painful death; the pain is compounded by the mechanical pressure on the abdomen, chest, or neck. Bruising however is usually minimal. Occasionally and uncommonly, the person will die of a crush injury to the upper throat or even a fracture of the vertebrae in the neck.

Patients who are at a high risk tend to be somewhat small in size, are impulsive and active in bed, and have impaired thinking. The majority of patients have been

⁷¹ This statement was used multiple times by one company for their manufacturer's narrative in multiple FDA reports filed on alleged deaths in their bed rails.

rescued from a nearly lethal entrapment in rails shortly before they did however in such cases, there was no change to the bed environment.”

APPENDIX C

ADVERTISING

Below is a random selection of what was found on the Internet using a search for portable adult bed rails on January 21, 2012. Note the consistent promise of safety through use of portable bed rails in most of the ads.

[Adult Bed Rails, Safety Bed Rails for Elderly & Seniors](#)

www.parentgiving.com/shop/adult-bed-rails-79/c/

Home and hospital *bed rails* keep *adults* with mobility issues safe! Great selection of safety *bedrails* fit any standard sized bed. ... *Portable Bed Rails*. Great for ...

[Bed Rails for Seniors and the Elderly Adult](#)

www.bedrailsforseniors.com/

Bed Rails for Seniors, a specialty store for *bed rails* for the elderly *adult*. We have a wide selection of safety *bed rails*, side *bed rails* and guard *bed rails*.

Bed Safety Rails

Bed Safety Rails offered at great prices. Many styles to choose from to suit different needs and preferences. Our bed rails for elderly help with fall prevention in the elderly. We have name brands and several styles including a travel bed rail. Sizes include queen size bed rails, full size and other. Take a look at our selection for the right bed rail to suit your need.

[Adult Bed Rails| Walgreens](#)

www.walgreens.com/q/adult-bed-rails

Adult bed rails come in a range of sizes and shapes with multiple features to choose from. Some home *bed rails* work on either side of the bed and are *portable* ...

[Portable Side Rails For Adult Beds from Sears.com](#)

www.sears.com/search=portable%20side%20rails%20for%20adult%2...

Items 1 - 21 of 21 – FREE SHIPPING AND 2X REWARDS POINTS WITH SHOP YOUR WAY MAX. Search results "*portable side rails for adult beds*" ...

[Bed Rails - Vitality Medical](#)

www.vitalitymedical.com/bed-rails.html

Items 1 - 28 of 42 – Bed Railing DISCOUNT *Bed Rail*, Safety *Bed Rails*, Bed Guard Rails, Bed Side Rails, *Adult Bed Rail*, Kids *Bed Rails*, *Bed Rails* for Elderly & More. WHOLESALE Bed ... Regalo *Portable Kids Bed Rails*. \$22.81. Regalo ...

[Bed Rails & Handles | 1800Wheelchair.com](#)

www.1800wheelchair.com/asp/view-category-products.asp?...id...

Bed rails and assist handles for children and *adults*. Shop from 24 different models. ... Stander Children's *Portable Bed Rail* and Sports Pouch ...

[Tall and High Bed Rails for Adults - Bed Time Elder Care Safety](#)

[www.parentgiving.com](#) › [Bedding](#) › [Bed Rails](#)

Tall (high) *adult bed rails* provide extra security against roll accidents or unsafe climbing. Safety and assist rails reach the extra mile of bed safety!

[Standers Portable Bed Rail with Pocket Organizer - Walmart.com](#)

[www.walmart.com/ip/Standers-Portable-Bed-Rail-with.../6372783](#)

\$49.88 - In stock

Find the Standers *Portable Bed Rail* with Pocket Organizer at Every Day Low Prices.

Save money, live better. *Walmart*.

[Item Description](#) - [Product Warranty and Service ...](#) - [Specifications](#) - [Gifting Plans](#)

[Regalo Easy Hide-Away Bed Rail - Walmart.com](#)

[www.walmart.com/ip/Regalo-Easy-Hide-Away-Bed-Rail/4433184](#)

\$28.00 - In stock

Get the Regalo Easy Hide-Away *Bed Rail* from *Walmart.com*. ... provides security and will accommodate pillow-top mattresses; Easy-to-assemble and *portable* ...

APPENDIX D

*CMS (Centers for Medicare and Medicaid Services) State Operations Manual
Appendix PP - Guidance to Surveyors for Long Term Care Facilities
Excerpts from CMS §483.13(a) Restraints*

Physical Restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

'Physical restraints' include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily. Also included as restraints are facility practices that meet the definition of a restraint, such as:

- Using side rails that keep a resident from voluntarily getting out of bed. . .

The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed.

As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom. The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another.

.

Devices Associated with Entrapment Risks - Devices can be therapeutic and beneficial; however, devices are not necessarily risk free so it is important to weigh the relative risks and benefits of using certain devices. For example, while physical restraints may be used to treat a resident's medical symptom, the devices may create a risk for entrapment.

Physical restraints are defined in the SOM at F221 as any manual method, physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body. In 1992, the Food and Drug Administration (FDA) issued a Safety Alert entitled 'Potential Hazards with Restraint Devices'.

Serious injuries, as well as death, have been reported as a result of using physical restraints. Some physical restraints carry a risk of severe injury, strangulation, and asphyxiation. Restrained residents may be injured or die when they try to remove restraints, to ambulate while restrained, or due to an improperly fitted or used device.

Regardless of the purpose for use, bed rails (also referred to as “side rails,” “bed side rails,” and “safety rails”) and other bed accessories (e.g., transfer bar, bed enclosures), while assisting with transfer and positioning, can increase resident safety risk. Bed rails include rails of various sizes (e.g., full length rails, half rails, quarter rails) that may be positioned in various locations on the bed.

In 1995, the FDA issued a Safety Alert entitled “Entrapment Hazards with Hospital Bed Side Rails.” Residents most at risk for entrapment are those who are frail or elderly or those who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, acute urinary retention, etc. that may cause them to move about the bed or try to exit from the bed. The timeliness of toileting, appropriateness of positioning, and other care-related activities can contribute to the risk of entrapment.

Entrapment may occur when a resident is caught between the mattress and bed rail or in the bed rail itself. Technical issues, such as the proper sizing of mattresses, fit and integrity of bed rails or other design elements (e.g., wide spaces between bars in the bed rails) can also affect the risk of resident entrapment. . . .”

APPENDIX E

Gathering of Signatures on a Petition Created by The National Consumer Voice for Quality Long-Term Care to be submitted to the CPSC and FDA jointly.

In December 2012, The National Consumer Voice for Quality Long-Term Care (referred to here as Consumer Voice) began seeking signatures on a national petition http://wfc2.wiredforchange.com/o/8641/p/dia/action/public/?action_KEY=8970 which they presently are planning to send to both the FDA and the CPSC, asking the two agencies to:

Please protect vulnerable elderly consumers by establishing minimum safety standards for all adult bed rails and prohibiting the use of dangerous bed rails currently in use.

Consumer Voice goes on to say, “The statistics are appalling.”

While the delivery of the signatures for the Consumer Voice document has not yet taken place, the following details emerge from an analysis of the current signatories: of the more than 500 signatories who have signed the petition and submitted comments to date (April 23, 2013), roughly an astounding 77 come forward and acknowledge that they have first-hand knowledge of injuries or deaths—and in several instances multiple deaths—among people using bed rails. Many of those approximately 77 signatories are health care providers who work with the elderly, some are family members whose loved one died in a bed rail, some are witnesses to the results, and one was a clergy person. Every geographic part of the United States is represented among those signing the petition. One person signing anonymously writes, “I don’t understand why anyone would not care about this issue.” Given that it is a fact that, on average, with each passing month a minimum of one to two people die in a bed rail-related incident, it does seem to beg the question: why do we seem to not care about this issue? Is it because most of the victims are elderly? Let us be reminded, there are children being documented as dying in these adult bed rails as well.

Additional comments on the petition include the following:

“This is a scandalous practice of restraining the elderly that might kill them. Every single individual deserves the opportunity to be safe.”

“As an Ombudsman and RN, there must be safer ways to protect older adults than with the use of bed rails. It is clear that this has been an on-going issue for many years.”

“Our senior citizens deserve the same focus and protections as our youngest citizens.”

With the inclusion of reference to the Consumer Voice gathering of signatures, no assumption is made that signatories on that particular document would support or not support this present Petition made to CPSC. The document is included in this Appendix E only because of the relevance to the issue of bed rails and safety.

APPENDIX F

Joint Letter from Public Citizen and Consumer Voice to the Federal Trade Commission

September 6, 2012

Jon Leibowitz, Chairman
J. Thomas Rosch, Edith Ramirez, Julie Brill, and Maureen Ohlhausen
Commissioners
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Dear Commissioners,

Public Citizen, a consumer advocacy group representing more than 300,000 members and supporters nationwide, and the National Consumer Voice for Quality Long-Term Care hereby request that the Federal Trade Commission (FTC), pursuant to the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52-55, order Bed Handles, Inc., to stop its deceptive advertising of Bedside Assistant bed handles. In particular, the website for Bed Handles promotes Bedside Assistant bed handles as “[making] any bed a safer bed,”ⁱ whereas this consumer product, in fact, poses an unreasonable risk of injury and has resulted in the deaths of at least four adults.

I. BACKGROUND

A. Manufacturer of Bedside Assistant bed handles

Bedside Assistant bed handles are manufactured by Bed Handles, Inc., located at 2905 SW 19th Street, Blue Springs, MO 64015.ⁱⁱ

B. Advertisement for the Bedside Assistant bed handles

Bedside Assistant bed handles are devices intended to assist patients in getting in and out of bed, sitting up in bed, and rolling over in bed. They are used by patients in private homes, assisted living facilities, and nursing homes. Bedside Assistant bed handles typically are sold by home-health-care medical supply stores, which do not require a doctor’s prescription.

The manufacturer’s website provides the following description of the Bedside Assistant bed handles:ⁱⁱⁱ

Makes any bed a safer bed [emphasis in original] ... Especially for anyone who is mobility impaired and simply needs something to hold on to as they get in and out of bed.

Designed by an engineer for his wife who had [multiple sclerosis], the Bedside Assistant has been used by many that need a little extra help to be more independent.

The Bedside Assistant is stable in all directions and can be firmly pulled, pushed, lifted and leaned on.

The Bedside Assistant is easy to install on any bed you use: at home, visiting friends and family, even at hotels.

Continue to use an existing bed with the added help of a stable pair of handles to hold while standing, sitting, rising and rolling over.

The device is installed by sliding the long horizontal bar of the bed handle between the mattress and box spring of a bed and securing it with a strap.^{iv}

C. Public Citizen's petition to the Food and Drug Administration (FDA)

On May 4, 2011, Public Citizen petitioned the FDA, pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360f and 360h, and 21 C.F.R. §§ 10.30, 810, and 895, to immediately:

(1) ban the marketing of Bedside Assistant bed handles, model numbers BA10W and BA10W-6, manufactured by Bed Handles, Inc., because these devices have directly caused the deaths of at least four adult patients through entrapment and subsequent strangulation or positional asphyxia and therefore present “an unreasonable and substantial risk of illness or injury” ...

(2) order Bed Handles, Inc. to recall all Bedside Assistant bed handles, model number BA10W and BA10W-6, that have been sold or distributed; and

(3) investigate thoroughly the association between (a) the design and use of all similar bed handle or bed rail devices manufactured by Bed Handles, Inc. or any other manufacturer and (b) the risk of life-threatening injury or death due to entrapment and subsequent strangulation or positional asphyxia, and as appropriate, based on the result of this investigation, take action to ban the marketing of, and to recall, those devices that pose similar risks of death and injury as seen with Bedside Assistant bed handles.

Public Citizen has not received a decision from the FDA on its petition (enclosed).

II. EVIDENCE THAT BEDSIDE ASSISTANT BED HANDLES POSE LIFE-THREATENING RISKS

Contrary to the manufacturer's claim that its bed handles improve the safety of any bed, data provided to the FDA demonstrate that these devices can turn a bed into a death trap for individuals who are physically weak and have physical or mental impairments — the type of individuals for whom this device is intended. Our review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database reveals that since 1999, the FDA has received reports of four deaths secondary to entrapment by Bedside Assistant bed handles.^{v,vi,vii,viii} In three of these cases, the description clearly is consistent with death being caused by asphyxiation or strangulation. A fifth report describes another life-threatening incident in which this device entrapped a hospital patient.^{ix}

The deaths and injuries caused by Bedside Assistant bed handles that have been reported to the FDA's MAUDE database likely represent a minority of actual cases. Major reasons for such underreporting include the following:

- Many — perhaps most — healthcare providers and consumers are unaware that Bedside Assistant bed handles are classified as medical devices and, as a result, would not even think about reporting adverse events related to these devices to the FDA.
- These devices are commonly used in the home setting without any involvement of a healthcare provider, and family members of people injured or killed by these devices likely are not aware of the procedures for reporting adverse events to the FDA.

The mechanism by which the Bedside Assistant bed handles and similar devices can cause death is straightforward and well-known.^x Given their design and installation, the bed handles can slip out of place, creating a gap between the edge of the mattress and the vertical bars. A person in the bed can then slip into this gap, becoming entrapped. Even a small gap, particularly resulting from use of these devices with soft or worn mattresses, can lead to entrapment. Death may ensue either through compression of the trachea against the horizontal support bars and subsequent strangulation, or through positional asphyxia.^{xi} Enclosed with Public Citizen's petition to the FDA are pictures in which a caregiver, who found the body of a deceased person entrapped by a Bedside Assistant bed handle, demonstrates the position of the patient at the time of death (the death of this patient was reported to the FDA^{xii}).

The manufacturer's inclusion of a security strap with the Bedside Assistant bed handles does not sufficiently mitigate the risk of entrapment and death. Many people may not use the strap or may fail to install the strap properly.

Even with proper installation of the strap in accordance with the manufacturer's directions, entrapment and subsequent asphyxiation or strangulation still may occur, depending on a variety of factors, including the condition of the mattress and the size of the person using this product.

III. CONCLUSION

In conclusion, given the risk of serious injury and death by entrapment and subsequent strangulation or positional asphyxia that may occur when using Bedside Assistant bed handles, the manufacturer's advertising of this consumer product as making any bed a safer bed is deceptive. Therefore, the FTC should sanction Bed Handles, Inc., for deceptive advertising and require the company to pull its advertisement immediately and publish corrective advertising that discloses the risk of entrapment and death.

Thank you for your prompt attention to this important consumer protection issue.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

Sarah F. Wells
Executive Director
National Consumer Voice for Quality Long-Term Care

Robyn Grant
Director of Public Policy and Advocacy
National Consumer Voice for Quality Long-Term Care

cc: David Vladeck, Director, Bureau of Consumer Protection, FTC

Enclosure: Public Citizen's May 4, 2011, petition to the FDA to ban Bedside Assistant bed handles

ⁱ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.

ⁱⁱ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/>. Accessed August 22, 2012.

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- ⁱⁱⁱ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.
- ^{iv} Bed Handles, Inc., website. Available at <http://bedhandles.com/SecurityStrapInstallationPictorial.pdf>. Accessed August 22, 2012.
- ^v Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 27, 1999, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=218072. Accessed August 22.
- ^{vi} Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on February 4, 2002, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366564. Accessed August 22.
- ^{vii} Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on January 10, 2004, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI_ID=507241. Accessed August 22.
- ^{viii} Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007 associated with Bedside Assistant® bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.
- ^{ix} Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of an entrapment incident in 2006 associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=836669. Accessed August 22, 2012.
- ^x Food and Drug Administration. Guidance for industry and FDA staff: hospital bed system dimensional and assessment guidance to reduce entrapment. March 10, 2006. Available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf>. Accessed August 22, 2012. Available at
- ^{xi} Hyman WA. Bed-rail entrapments still a serious problem. McKnight's Long-Term Care News and Assisted Living. July 24, 2008. <http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/>. Accessed August 22, 2012.
- ^{xii} Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.

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1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

May 9, 2013

Inez Moore Tenenbaum
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Dear Commissioners:

Public Citizen hereby petitions the Consumer Product Safety Commission (CPSC), pursuant to the Administrative Procedures Act, 5 U.S.C. section 553 (e) and regulations of the CPSC, 16 C.F.R. Part 1051, to determine, under section 8 of the Consumer Product Safety Act (CPSA), 15 U.S.C. section 2057, that all currently marketed adult portable bed rails pose an unreasonable risk of injury, that no feasible consumer product safety standard under the CPSA would adequately protect the public from the unreasonable risk of injury associated with adult bed rails, that the Commission shall, in accordance with section 9 of the CPSA, 15 U.S.C. section 2058, promulgate a rule declaring all currently marketed adult bed rails to be a banned hazardous product. Public Citizen also petitions the CPSC to exercise its authority under section 15 of the CPSA, 15 U.S.C. section 2064, to require adult bed rail manufacturers to issue a public recall notice and offer a refund for all adult portable bed rails.

I. Interest of Petitioner

This petition is brought by Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide.

II. The Product

For the purpose of this petition, adult portable bed rails are defined as those that are sold and marketed directly to the public and are intended to be used with a home, rather than a hospital,

bed. Such bed rails are made of rigid materials, have horizontal and vertical components joined together at a right angle, and are installed by sliding the horizontal component of the bed handle between the mattress and box spring of a bed, with or without a supporting strap. These products would include those portable bed rails marketed on the Internet, in department stores and other retail outlets, and directly by manufacturers. The scope of this definition also includes bed rails sold in medical supply stores, since no special requirement or prescription is currently needed for the sale or purchase there,¹ even though such a store may advertise that it specializes in medical supplies.

Excluded from the scope of this petition are all bed rails that are intended to be installed as part of, or an accessory to, hospital beds. The exclusion of hospital bed rails from our definition of adult portable bed rails does not mean that such rails are necessarily safe. They are being excluded here for jurisdictional reasons, as discussed in the next section.

The term “bed rails,” as referenced in this petition, includes but is not limited to side rails, split rails, half rails, bed handles, full length rails, and bed canes. If a manufacturer develops another term to define their company’s bed rails, such new terminology should not create an exemption from oversight and regulation as proposed in this petition.

III. CPSC Has Authority to Regulate Portable Bed Rails

The CPSC has the authority to regulate portable bed rails that were not intended to be a part of, or an accessory to, a hospital bed. The CPSA provides the CPSC with authority to regulate consumer products sold to consumers or intended for use by consumers, but excludes medical devices regulated under the Federal Food, Drug, and Cosmetic Act (FDCA).²

Certain adult portable bed rails intended as components of hospital beds may be considered “medical devices” under the FDCA, and are therefore subject to regulation by the Food and Drug Administration (FDA) rather than the CPSC. The FDA has several regulations pertaining to hospital beds, including sections 880.5100, 880.5110, 880.5120, which cover various adjustable hospital beds. However, many portable bed rails are sold directly to patients and are not intended as attachments to hospital beds. These portable bed rails are used as attachments to ordinary beds in private residences, nursing homes, and other long-term care facilities and are not currently covered under FDA regulations governing hospital beds. As such, they can be regulated as consumer products by the CPSC.

IV. Overwhelming Evidence of Hazards Presented by Adult Portable Bed Rails

In the summer of 2012, the CPSC conducted a study to examine the issue of bed rail injuries and deaths for adults. The resulting findings were reported in the CPSC’s October 11, 2012, memo, “Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: January 2003 to September 2012.” People age 13 years and older were included in the analysis.

¹ We note that requirements for prescriptions from doctors to purchase bed rails will not address the fundamental problem of flawed designs in bed rails. Many deaths are documented in which doctors recommended purchase of a bed rail, in the misguided belief the bed rail would make the individual “safer,” only to find a person dies instead — allegedly from use of the bed rail.

² See 15 U.S.C. § 2052.

The reported CPSC study results were stunning. The agency uncovered 155 fatalities in that approximately nine-year period. Of these 155 fatalities, 129 were in adults age 60 years and over. The CPSC found that 94 of these fatalities (61%) took place at home, 25 (16%) in nursing homes, 15 (10%) in assisted living facilities, and 3 (2%) in hospice care settings.³

In this same study, the CPSC also estimated that 36,900 adults and children older than 13 years were treated for bed rail-related injuries in U.S. hospital emergency departments nationwide between January 2003 and December 2011. These estimates were based on data gathered through the National Electronic Injury Surveillance System, an injury-tracking system that gathers injury data from a representative sample of emergency departments nationwide.⁴ The injuries were fairly evenly distributed among age groups and did not increase or decrease significantly from one year to the next. The most commonly injured body parts were the head (14%), lower leg (12%), and foot (12%). Most injuries involved laceration (30%), contusions/abrasions (30%), and fracture (14%). There were no reported deaths among these patients, all of whom were treated in hospital emergency rooms.

A. Rail Entrapment

Adult portable bed rails currently on the market are responsible for a large number of deaths and injuries among users, particularly the elderly and frail. Many of these deaths result from asphyxiation caused by entrapment within openings of the rail or between the rail and the mattress or bed frame.

For example, on Christmas morning in 2004, a 75-year-old man was found with his neck entrapped between the mattress or bed frame and a bed rail.⁵ *The New York Times* blog in which this story was identified includes an important common, but flawed, perception of these products:

Like a lot of people, I supposed that bed rails were a safety device, analogous to a seat belt in a car, meant to keep, sick, drugged, confused or restless people from falling or climbing out of beds in hospitals and nursing homes.

This story is unfortunately not an isolated occurrence. In its 2012 study, the CPSC found that out of the 155 fatalities related to bed rail use in teenagers and adults between June 2003 and September 2012, 145 incidents were related to rail entrapment. This category included incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, or between the headboard and rail. Based on the narrative, the most frequently injured body parts were the neck and head. Most of these incidents (143 out of 145) resulted in fatalities.⁶

³ Memorandum to Richard McCallion, Adult Portable Bed Rails Project Manager: Adult portable bed rail-related deaths, injuries, and potential injuries: January 2003 to September 2012. October 11, 2012.

⁴ These estimates excluded injuries related to hospital beds.

⁵ In March 10, 2010, in *The New Old Age* blog, reporter Paula Span described a Christmas morning death.

⁶ *Ibid.*

Enclosure #1 to this petition includes pictures of a caregiver who found the body of a deceased patient entrapped by a Bedside Assistant® bed handle demonstrating the position of the patient at the time of death.

Enclosure #2 includes images of other portable bed rail products currently marketed to adults. These products are secured to the bed by slipping between the mattress and box spring, and they can easily slip out again, creating a gap between the mattress and rail where a person can slide in and become trapped. While one of the pictured products employs a “safety strap” intended to prevent such slipping, the product can easily be used without properly securing and tightening the strap, failing to eliminate entrapment risks. Even if properly secured with the safety strap, entrapment injuries can still occur, particularly if the mattress is very soft or old and deteriorated.

B. Increased Risk From Serious Falls

In addition to posing an entrapment risk, individuals attempting to climb over bed rails placed on their beds can also become victims of injury. Bed rails raise the height from which patients can fall, potentially increasing the risk of serious injury. These risks are exacerbated among patients with limited cognitive function, who may fail to recognize the challenge of climbing over the rail or call for appropriate assistance. Bilateral full-length side rails can also be used as a form of restraint by impeding an individual’s ability to voluntarily get out of bed, creating a risk that patients will injure themselves attempting to navigate over the rail.⁷

Use of side bed rails and other restraints on patient movement in nursing homes is not associated with decreased risk of falls.^{8,9} In fact, one study of 322 nursing home residents found that confused ambulatory residents whose movement was restricted by bed rails or other restraints were significantly more likely to experience falls (odds ratio: 1.65, 95% CI: 0.69, 3.98) and recurrent falls (odds ratio: 2.46, 95% CI: 1.03, 5.88) than unrestrained residents.¹⁰

Observational studies conducted in institutional settings have indicated that risk of serious falls can be reduced by programs to remove bed side rails and other restraints while addressing fall risk through other measures. For example, a study published in 1999 reported that introducing a fall-reduction program aimed at reducing the use of bed rails and occurrence of fall-related injuries lowered the number of beds with bedrails attached and successfully reduced the risk of serious injuries, including head injuries.¹¹

Two other studies published in 2003 and 2007 also assessed outcomes at long-term care facilities that had enacted quality improvement programs to reduce fall rates. The 2003 study found that a

⁷ Capezuti E, Minimizing the use of restrictive devices in dementia patients at risk for falling. *Nurs Clin N Am* 2004;39:625-647.

⁸ Capezuti E, Maislin G, Strumpf N, Evans LK. Side rail use and bed-related fall outcomes among nursing home residents. *J Am Geriatr Soc* 2002;50(1):90–6.

⁹ Gallinagh R, Nevin R, Mc Ilroy D, Mitchell F, Campbell L, Ludwick R, McKenna H. The use of physical restraints as a safety measure in the care of older people in four rehabilitation wards: findings from an exploratory study. *Int J Nurs Stud*. 2002 Feb;39(2):147-56.

¹⁰ Capezuti E, Evans L, Strumpf N, Maislin G. Physical restraint use and falls in nursing home residents. *J Am Geriatr Soc*. 1996 Jun;44(6):627-33.

¹¹ Hanger HC, Ball MC, Wood LA. An analysis of falls in the hospital: can we do without bedrails? *J Am Geriatr Soc*. 1999 May;47(5):529-31.

decrease in bed rail usage was accompanied by an 11% reduction in bed-related falls and a slight decrease in the frequency of injuries related to those falls.¹² The 2007 study found that the largest reduction in fall rate following program implementation was among patients whose bed rails had been removed.¹³

This evidence demonstrates that consumers who purchase bedrails hoping to reduce the risk of falls are being tragically misled: bed rails do nothing to prevent falls, and may actually increase fall risk in some cases. These dangerous products should be banned from the market to prevent consumers from relying upon them falsely as “safety” devices.

V. Risks Are Increased by Misleading Advertising of Bed Rails and Inadequate Hazard Warning Labeling

Portable bed rails are purchased as consumer products by well-meaning family members and are used in the home or sometimes in various long-term care facilities (nursing homes and other institutions) in which loved ones are living. These concerned consumers and their loved ones too often fall victim to misleading advertising claiming that the use of bed rails makes a bed safer, when evidence suggests otherwise.

In September 2012, Public Citizen and the National Consumer Voice for Quality Long-Term Care sent a letter to the Federal Trade Commission (FTC) identifying advertising by a manufacturer claiming that its bed rails “Ma[de] any home bed a safer bed.”¹⁴ Public Citizen identified these claims as misleading, stating:

Contrary to the manufacturer’s claim that its bed handles improve the safety of any bed, data provided to the FDA demonstrate that these devices can turn a bed into a death trap for individuals who are physically weak and have physical or mental impairments — the type of individuals for whom this device is intended. Our review of the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database reveals that since 1999, the FDA has received reports of four deaths secondary to entrapment by Bedside Assistant bed handles. In three of these cases, the description clearly is consistent with death being caused by asphyxiation or strangulation. A fifth report describes another life-threatening incident in which this device entrapped a hospital patient.¹⁵

To date, the FTC has not responded substantively to Public Citizen’s complaint.

Existing warnings are grossly inadequate to advise consumers of the deadly risks. For example, the website “parentgiving Store: the ultimate senior care resource” advertises “Adjustable Width

¹² Hoffman S, Powell-Cope G, Rathvon L, Bero K. BedSAFE: Evaluating a program for bed safety alternatives for frail elders. *Journal of Gerontological Nursing*. 2003;29(11), 34-42.

¹³ Capezuti E, Wagner LM, Brush LB, et al. Consequences of an intervention to reduce restrictive side rail use in nursing homes. *J Am Geriatr Soc* 55:334–341, 2007.

¹⁴ Public Citizen and National Consumer Voice for Quality Long-Term Care. Letter asking the Federal Trade Commission to order Bed Handles, Inc. to stop its deceptive advertising. September 6, 2012. <http://www.citizen.org/hrg2069>. Accessed April 23, 2012.

¹⁵ *Ibid.*

Full Bed Rails” (see Enclosure # 3 for an image of this product).¹⁶ The full-length bedrails pictured are made of steel rails with large gaps between the top, middle, and bottom rail. The rail arms “slip between the box spring and mattress” and can be raised or lowered to allow the user access to the bed. The website includes a set of “Editor’s Notes” in light blue text at the bottom of the product description informing potential buyers that “[w]hen purchasing a bed rail for use in a care facility, it is suggested you confirm with the facility to ensure the rail is not considered a restraint and prohibited from being used.”¹⁷ The entry offers no warning of entrapment or fall risks.

Product reviews indicate that purchasers are completely unaware of the safety risks from using this type of device to restrict the movement of an elderly person with impaired cognition. One happy buyer, “MT” wrote:

★★★★★
By MT
Buying for myself
Los Angeles, CA
Oct. 22, 2012

Worked out perfect.
My mother has Alzheimer and kept getting out of bed at night and sometimes falling. As soon as we put these on she stays put all night. Wonderful sense of security.

Pros: Easy to install.
Bottom Line: Yes, I would recommend this product.

Clearly, buyer MT is not in a position to accurately assess the deadly risks of using this device to help his or her mother “stay put all night.”

VI. Voluntary or Mandatory Standards Are Inadequate to Address the Risks Caused by Adult Portable Bed Rails

The CPSC must take immediate action to ban adult portable bedrails, as no feasible consumer product safety standard could adequately protect the public from the unreasonable risk of injury posed by these products.

A. The Existing Voluntary Standard for Child Portable Bed Rails Does Not Address the Risks Posed by Adult Portable Bed Rails

The American Society for Testing and Materials (ASTM), has developed a standard for child portable bed rails, *Standard Consumer Safety Specification for Portable Bed Rails* (ASTMF2085). This standard defines a “portable bed rail” as a product intended to be installed on an adult bed to prevent children from falling out of bed.¹⁸

Given the limited scope of the voluntary standard, which addresses bed rails intended for children only, it is clear that the voluntary standard fails to address the hazards posed by adult portable bed rails. Furthermore, given that injuries related to adult portable bed rails continue to occur, including at least 155 deaths in a nine-year span, it is clear that the existing voluntary standard does not adequately address the serious risks posed by these products.

¹⁶ Parentgiving Store. <http://www.parentgiving.com/shop/adjustable-width-full-bed-rails-chrome-1566/p/>. Accessed April 24, 2013.

¹⁷ Parentgiving Store. Adjustable Width Full Bed Rails. <http://www.parentgiving.com/shop/adjustable-width-full-bed-rails-chrome-1566/p/>. Accessed April 24, 2013.

¹⁸ <http://www.cpsc.gov/PageFiles/133466/adultbedrail.pdf> at 1.

B. No Feasible Mandatory Standard Would Adequately Address Risks

The mandatory standards developed for durable products for infants and toddlers demonstrate that an approach for adult portable bedrails based on mandatory standards would be inadequate to address the risks of these products. In 2011, as a result of the passage of the Consumer Product Safety Improvement Act in 2008, which required CPSC to promulgate mandatory standards for infant and toddler durable products, including bed rails, CPSC proposed a rule on children's portable bed rails.¹⁹ That rule was finalized in 2012.²⁰

To address strangulation risks, the CPSC rule on children's portable bed rails requires that the rails meet certain requirements, some of which are incorporated by reference to the standards developed by the ASTM. These requirements include:

- Testing requirements designed to ensure that the bed rail is not displaced (pushed away from) the mattress when a probe is wedged between the standardized testing mattress and the rail and forced downwards.²¹
- Testing requirements designed to ensure that a person's head cannot be caught in enclosed openings in the bedrail.²²
- Requirements designed to ensure that any components used to prevent displacement (such as anchor plates and straps) be "fully assembled, inseparable, and permanently attached to a component requiring consumer assembly."²³
- Requirements designed to ensure that when the bed that is not assembled with the appropriate parts or configuration of parts, it will show "sufficient visual cues" (such as sagging fabric or failure to remain upright) for a consumer to identify that a mistake had occurred.²⁴
- A warning label describing the suffocation, strangulation, and entrapment hazard.²⁵

Even if similar mandatory standards were developed for adult beds, such standards would not be sufficient to adequately protect against strangulation and fall hazards presented by portable bedrails. First, displacement testing is generally performed using a standardized mattress and does not take into account the additional displacement that can result when the product is used with an old or sagging mattress.

Second, mandatory standards cannot ensure that consumers will adequately secure the product to the bed. Many of the "safety" features of portable bed rail products involve a strap or latch intended to prevent movement by attaching firmly to the mattress or box spring. (See Enclosure #3 for an image of "Home Bed Assist Rail.") Yet consumers can easily use these products without securing the strap or without tightening firmly to a fixed part of the bed. Mandatory standards can only ensure that safety features will remain attached to the product. They cannot ensure that safety features will be appropriately attached and securely tightened to

¹⁹ CPSC Docket No. CPSC-2011-0019; Safety Standard for Portable Bed Rails.

²⁰ 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

²¹ 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

²² 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

²³ 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

²⁴ 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

²⁵ 77 FR 12182, February 29, 2012. Safety Standard for Portable Bed Rails: Final Rule.

the consumer's bed. Indeed, it is difficult to imagine any portable bed rail that could adequately account for this form of user error.

Third, mandatory standards developed and tested under standardized conditions also cannot take into account the uncertainties inherent in widespread, long-term use under a variety of conditions. For example, an ergonomic study was published in 2007 by researchers in the United Kingdom to determine the force exertions of participants performing seven tasks (including activities of both bed occupants and care providers), which were considered representative of the forces to which bed rails could be exposed during normal use.²⁶ Maximum static forces exerted by participants for most actions were found to range between 250 Newtons (N), a measurement of force, and 350 N, which were within the 500 N force tolerance requirements set by non-mandatory European standards. However, when adult participants "roll[ed] aggressively" against the bed rail, the impact resulted in highest peak force of 722 N, well above the 500 N requirement. Given the likelihood that at least some caregivers will obtain bedrails to restrict the movement of elderly persons suffering from dementia who may become confused upon encountering the restraint, the risk is high that at least some users will "roll aggressively" against the rails. Safety standards developed and applied under ordinary conditions are unlikely to account for repeated exposure to such extreme force.

Finally, existing examples of mandatory standards do not address the fall hazards posed by adult patients attempting to navigate around bars that have been used as restraints. This is a particular concern for adult bedrail users who have limited cognitive function and may be unable to ask for appropriate assistance.

Therefore, development of mandatory safety standards would not be an appropriate response to mitigate the life-threatening danger posed by adult portable bed rails. The only reasonable regulatory action is for CPSC to ban adult portable bed rails, which fail to serve a practical purpose in preventing falls and pose deadly risks to unsuspecting consumers who falsely rely on these products for safety.

C. Warnings Would Not be a Solution

Warnings alone are also not the solution to the dangers posed by these consumer products. William Hyman, Professor Emeritus of the Department of Biomedical Engineering at Texas A & M University, author of the article "Bed Rail Entrapments Still a Serious Problem," (*McKnights*, July 24, 2008), stated:

Warnings are not an appropriate way to "fix" dangerous designs, unless perhaps the warning says "Do Not Use This Product." Furthermore, effective warnings must not only identify a hazard but instruct on how to avoid it, and in a way that users will be able to understand and implement. The proper use of warnings is for residual risk; i.e., risk that cannot be reasonably eliminated by design, or replacement. Since most entrapment hazards can be eliminated by design (or by not using bed rails at all), there is no acceptable residual risk.

²⁶ Boocock MG, Weyman AK, McIlroy, R. Bedside safety rails: assessment of strength requirements and the appropriateness of current designs. *Ergonomics* 2006;49(7):631-650.

VII. Recall Action Is Necessary

The CPSC has recalled children's bed rails due to suffocation and strangulation hazards. For example, on December 6, 2012,²⁷ the CPSC conducted a recall of Dream On Me Children's Bed Rails. The hazards identified in this press release are that "the bed rail can separate from the mattress, allowing a child's body to become entrapped if it slips between the rail and the mattress. This poses suffocation and strangulation hazards to children." This is the identical hazard faced by adults who use portable adult bed rails. The CPSC should similarly recall bed rails when the bed rail poses the risk of strangulation to adults, *especially when reports indicate that there have been multiple deaths for the same model bed rail*. In the recall of the Dream On Me Children's Bed Rails, no incidents or injuries were reported, yet the recall was nonetheless conducted.

VIII. Action Requested

For the reasons enumerated above, Public Citizen requests that the Consumer Product Safety Commission (CPSC) ban adult bed rails pursuant to the Administrative Procedures Act, 5 U.S.C. section 553 (e) and regulations of the CPSC, 16 C.F.R. Part 1051, under section 8 of the Consumer Product Safety Act (CPSA), 15 U.S.C. section 2057, and exercise its authority under section 15 of the CPSA, 15 U.S.C. section 2064, to require adult bed rail manufacturers to issue a public recall notice and offer a refund for all adult portable bed rails that contain a product defect that creates a substantial risk of strangulation injury to the public.

Specifically, the petitioners request that CPSC initiate a rulemaking for a rule that states:

Under the authority of section 8 of the Consumer Product Safety Act, the Commission has determined that adult portable bed rails present an unreasonable risk of injury and no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with these products. Therefore, such products are banned hazardous products under section 8 of the Act.

This petition also requests that the CPSC:

Exercise recall authority and require notices and refunds to consumers for portable bed rails presently on the market that present risk of entrapment, asphyxiation, or other failure that can lead to injury.

²⁷ <http://www.cpsc.gov/cpsc/pub/prerel/prhtml13/13060.html>.

Thank you for your consideration of this petition addressing an important public health threat to older Americans.

Sincerely,



Sarah Sorscher, J.D., M.P.H.
Attorney
Public Citizen's Health Research Group



Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Enclosures:

- #1 Photographs of caregiver demonstrating the position of injury victim
- #2 Images of existing portable bed rails and descriptions of installation features
- #3 Public Citizen Letter Asking the Federal Trade Commission to Order Bed Handles, Inc., to Stop Its Deceptive Advertising, September 6, 2012

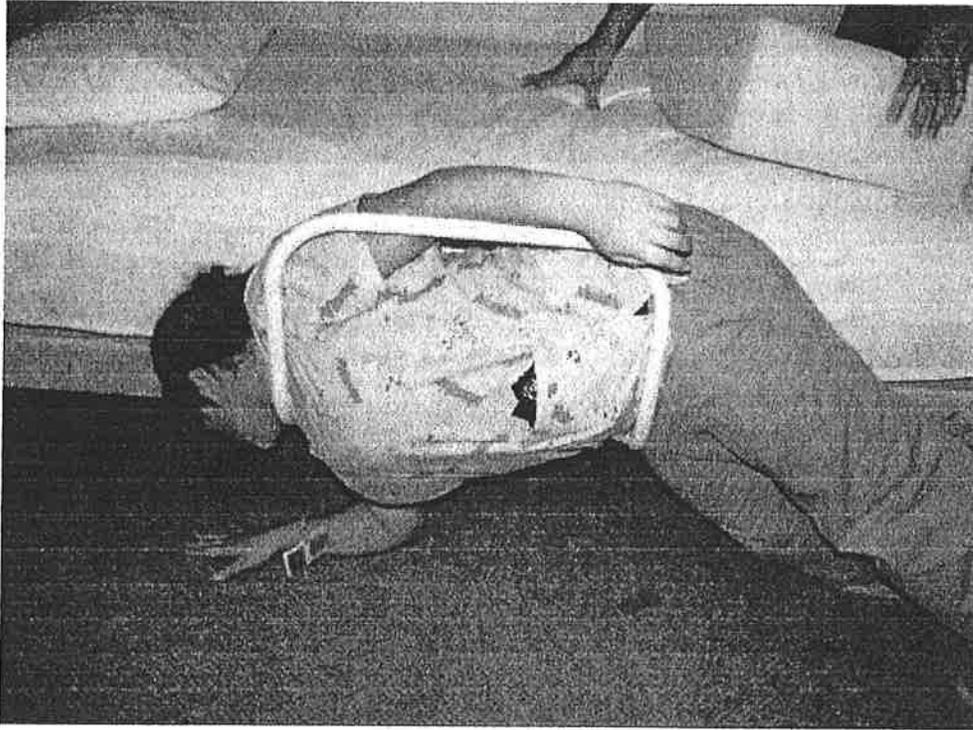


Photo # 9: View of the Caregiver demonstrating the position of the victim.

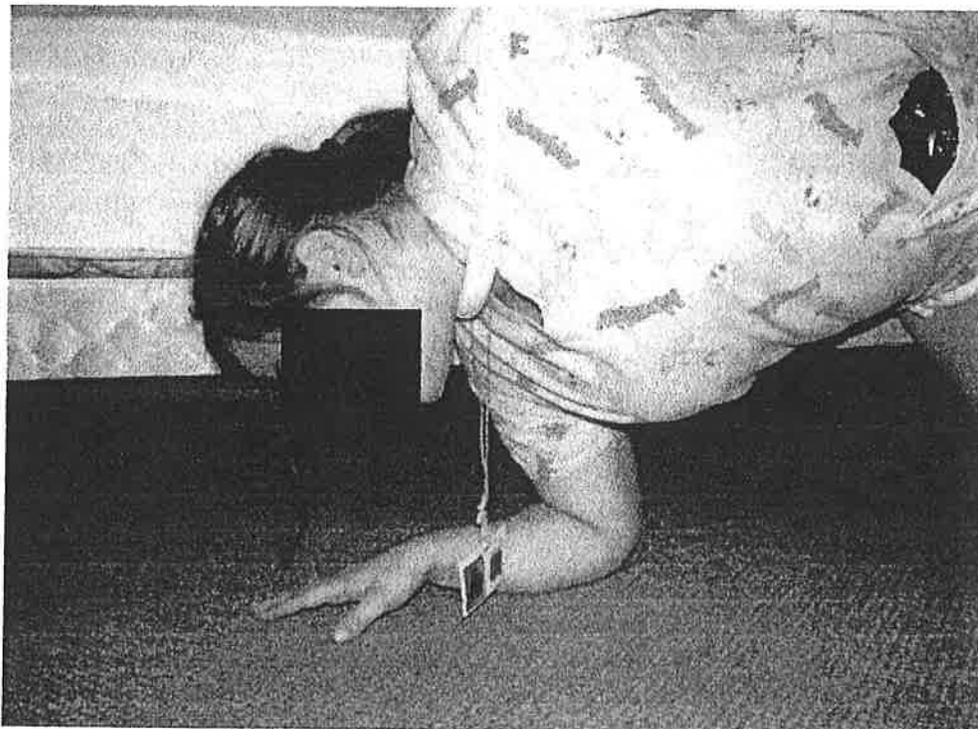


Photo # 10: Close-up view of the demonstration.

Enclosure #2: Images of existing portable bed rails and descriptions of installation features

Copyrighted Material

View original at:

<http://www.parentgiving.com/shop/product-gallery/1241/1384/>

Freedom Grip Adjustable Travel Bed Rail

“ . . . Put it together and then just slide the 29” long base of the travel handle between the mattress and box spring. You can secure it to the bed frame with the included nylon strapping.”¹

Copyrighted Material

View original at:

<http://www.parentgiving.com/shop/product-gallery/1566/1859/>

Adjustable Width Full Bed Rails - Chrome²

“ . . . Rail arms slip between the box spring and mattress.”

¹ <http://www.parentgiving.com/shop/freedom-grip-adjustable-travel-bed-rail-1241/p/>. Accessed April 24, 2013.

² <http://www.parentgiving.com/shop/adjustable-width-full-bed-rails-chrome-1566/p/>. Accessed April 24, 2013.

Enclosure #2: Images of existing portable bed rails and descriptions of installation features

Copyrighted Material

View original at:

<http://www.parentgiving.com/shop/product-gallery/3770/5204/>

Bed Rail Assist by Drive

“ . . . It simply slides underneath the mattress and includes an added feature on the base bar: no-slip foam that helps hold the bar in place. . . .”³

Copyrighted Material

View original at:

<http://www.parentgiving.com/shop/product-gallery/3768/5202/>

Home Bed Assist Rail

“ . . . The home bed-assist rail by Drive Medical provides patients with assistance getting into and out of the bed. This model features a safety strap you wrap around the mattress or box spring to ensure a safe and secure fit. The removable power-coated steel handle includes a mid bar, which creates a reliable grip at any height and can be detached when not in use. . . .”⁴

³ <http://www.parentgiving.com/shop/bed-rail-assist-by-drive-3770/p/>. Accessed April 24, 2013.

⁴ <http://www.parentgiving.com/shop/home-bed-assist-rail-3768/p/>. Accessed April 24, 2013.



1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

September 6, 2012

Jon Leibowitz, Chairman
J. Thomas Rosch, Edith Ramirez, Julie Brill, and Maureen Ohlhausen
Commissioners
Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Dear Commissioners,

Public Citizen, a consumer advocacy group representing more than 300,000 members and supporters nationwide, and the National Consumer Voice for Quality Long-Term Care hereby request that the Federal Trade Commission (FTC), pursuant to the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52-55, order Bed Handles, Inc., to stop its deceptive advertising of Bedside Assistant bed handles. In particular, the website for Bed Handles promotes Bedside Assistant bed handles as “[making] any bed a safer bed,”¹ whereas this consumer product, in fact, poses an unreasonable risk of injury and has resulted in the deaths of at least four adults.

I. BACKGROUND

A. Manufacturer of Bedside Assistant bed handles

Bedside Assistant bed handles are manufactured by Bed Handles, Inc., located at 2905 SW 19th Street, Blue Springs, MO 64015.²

B. Advertisement for the Bedside Assistant bed handles

Bedside Assistant bed handles are devices intended to assist patients in getting in and out of bed, sitting up in bed, and rolling over in bed. They are used by patients in private homes, assisted living facilities, and nursing homes. Bedside Assistant bed handles typically are sold by home-health-care medical supply stores, which do not require a doctor’s prescription.

The manufacturer’s website provides the following description of the Bedside Assistant bed handles:³

Makes any bed a safer bed [emphasis in original] ... Especially for anyone who is mobility impaired and simply needs something to hold on to as they get in and out of bed.

Designed by an engineer for his wife who had [multiple sclerosis], the Bedside Assistant has been used by many that need a little extra help to be more independent.

The Bedside Assistant is stable in all directions and can be firmly pulled, pushed, lifted and leaned on.

The Bedside Assistant is easy to install on any bed you use: at home, visiting friends and family, even at hotels.

Continue to use an existing bed with the added help of a stable pair of handles to hold while standing, sitting, rising and rolling over.

The device is installed by sliding the long horizontal bar of the bed handle between the mattress and box spring of a bed and securing it with a strap.⁴

C. Public Citizen's petition to the Food and Drug Administration (FDA)

On May 4, 2011, Public Citizen petitioned the FDA, pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 360f and 360h, and 21 C.F.R. §§ 10.30, 810, and 895, to immediately:

- (1) ban the marketing of Bedside Assistant bed handles, model numbers BA10W and BA10W-6, manufactured by Bed Handles, Inc., because these devices have directly caused the deaths of at least four adult patients through entrapment and subsequent strangulation or positional asphyxia and therefore present “an unreasonable and substantial risk of illness or injury” ...
- (2) order Bed Handles, Inc. to recall all Bedside Assistant bed handles, model number BA10W and BA10W-6, that have been sold or distributed; and
- (3) investigate thoroughly the association between (a) the design and use of all similar bed handle or bed rail devices manufactured by Bed Handles, Inc. or any other manufacturer and (b) the risk of life-threatening injury or death due to entrapment and subsequent strangulation or positional asphyxia, and as appropriate, based on the result of this investigation, take action to ban the marketing of, and to recall, those devices that pose similar risks of death and injury as seen with Bedside Assistant bed handles.

Public Citizen has not received a decision from the FDA on its petition (enclosed).

II. EVIDENCE THAT BEDSIDE ASSISTANT BED HANDLES POSE LIFE-THREATENING RISKS

Contrary to the manufacturer's claim that its bed handles improve the safety of any bed, data provided to the FDA demonstrate that these devices can turn a bed into a death trap for individuals who are physically weak and have physical or mental impairments — the type of individuals for whom this device is intended. Our review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database reveals that since 1999, the FDA has received reports of four deaths secondary to entrapment by Bedside Assistant bed handles.^{5,6,7,8} In three of these cases, the description clearly is consistent with death being caused by asphyxiation or strangulation. A fifth report describes another life-threatening incident in which this device entrapped a hospital patient.⁹

The deaths and injuries caused by Bedside Assistant bed handles that have been reported to the FDA's MAUDE database likely represent a minority of actual cases. Major reasons for such underreporting include the following:

- Many — perhaps most — healthcare providers and consumers are unaware that Bedside Assistant bed handles are classified as medical devices and, as a result, would not even think about reporting adverse events related to these devices to the FDA.
- These devices are commonly used in the home setting without any involvement of a healthcare provider, and family members of people injured or killed by these devices likely are not aware of the procedures for reporting adverse events to the FDA.

The mechanism by which the Bedside Assistant bed handles and similar devices can cause death is straightforward and well-known.¹⁰ Given their design and installation, the bed handles can slip out of place, creating a gap between the edge of the mattress and the vertical bars. A person in the bed can then slip into this gap, becoming entrapped. Even a small gap, particularly resulting from use of these devices with soft or worn mattresses, can lead to entrapment. Death may ensue either through compression of the trachea against the horizontal support bars and subsequent strangulation, or through positional asphyxia.¹¹ Enclosed with Public Citizen's petition to the FDA are pictures in which a caregiver, who found the body of a deceased person entrapped by a Bedside Assistant bed handle, demonstrates the position of the patient at the time of death (the death of this patient was reported to the FDA¹²).

The manufacturer's inclusion of a security strap with the Bedside Assistant bed handles does not sufficiently mitigate the risk of entrapment and death. Many people may not use the strap or may fail to install the strap properly. Even with proper installation of the strap in accordance with the manufacturer's directions, entrapment and subsequent asphyxiation or strangulation still may occur, depending on a variety of factors, including the condition of the mattress and the size of the person using this product.

III. CONCLUSION

In conclusion, given the risk of serious injury and death by entrapment and subsequent strangulation or positional asphyxia that may occur when using Bedside Assistant bed handles, the manufacturer's advertising of this consumer product as making any bed a safer bed is deceptive. Therefore, the FTC should sanction Bed Handles, Inc., for deceptive advertising and require the company to pull its advertisement immediately and publish corrective advertising that discloses the risk of entrapment and death.

Thank you for your prompt attention to this important consumer protection issue.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

Sarah F. Wells
Executive Director
National Consumer Voice for Quality Long-Term Care

Robyn Grant
Director of Public Policy and Advocacy
National Consumer Voice for Quality Long-Term Care

cc: David Vladeck, Director, Bureau of Consumer Protection, FTC

Enclosure: Public Citizen's May 4, 2011, petition to the FDA to ban Bedside Assistant bed handles

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- ¹ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.
- ² Bed Handles, Inc., website. Available at <http://www.bedhandles.com/>. Accessed August 22, 2012.
- ³ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.
- ⁴ Bed Handles, Inc., website. Available at <http://bedhandles.com/SecurityStrapInstallationPictorial.pdf>. Accessed August 22, 2012.
- ⁵ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 27, 1999, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=218072. Accessed August 22.
- ⁶ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on February 4, 2002, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366564. Accessed August 22.
- ⁷ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on January 10, 2004, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI_ID=507241. Accessed August 22.
- ⁸ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007 associated with Bedside Assistant[®] bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.
- ⁹ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of an entrapment incident in 2006 associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=836669. Accessed August 22, 2012.
- ¹⁰ Food and Drug Administration. Guidance for industry and FDA staff: hospital bed system dimensional and assessment guidance to reduce entrapment. March 10, 2006. Available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf>. Accessed August 22, 2012. Available at
- ¹¹ Hyman WA. Bed-rail entrapments still a serious problem. McKnight's Long-Term Care News and Assisted Living. July 24, 2008. <http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/>. Accessed August 22, 2012.
- ¹² Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.

[Federal Register Volume 78, Number 107 (Tuesday, June 4, 2013)]
[Notices]
[Pages 33393-33394]
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[FR Doc No: 2013-13000]

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2013-0022]

Petition Requesting a Ban or Standard on Adult Portable Bed Rails

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission (CPSC or Commission) has received two requests, asking that the Commission initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. Because both requests ask for rulemaking concerning the same product, CPSC is considering the requests as a single petition (CP13-1). The Commission invites written comments concerning the petition.

DATES: The Office of the Secretary must receive comments on the petition by August 5, 2013.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2013-0022, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through www.regulations.gov. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions in the following way: Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or

comments received, go to: <http://www.regulations.gov>, and insert the docket number, CPSC-2013-0022, into the "Search" box, and follow the prompts. A copy of the petition is available at <http://www.regulations.gov> under Docket No. CPSC-2013-0022, Supporting and Related Materials.

FOR FURTHER INFORMATION CONTACT: Rockelle Hammond, Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-6833.

SUPPLEMENTARY INFORMATION: The Commission received two requests to initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. See 15 U.S.C. 2057 and 2058. Gloria Black, the Consumer Federation of America, and 60 other organizations (Consumer Group) made one request; Public Citizen made the other request (collectively referred to as petitioners). The CPSC has docketed the requests as a single petition.

Petitioners assert that adult portable bed rails currently on the market are responsible for many injuries and deaths among users, particularly the elderly and frail. Petitioners state that many of these deaths result from asphyxiation caused by entrapment within openings of the rail or between the rail and the mattress or bed frame. In addition, petitioners claim that individuals who attempt to climb over bed rails may be at greater risk of injury or death than they would be if no rail were used at all. In support of their request, petitioners cite a CPSC memorandum dated October 11, 2012, "Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: January 2003 to September 2012." According to petitioners, the CPSC's data showed that there were 155 fatalities, of which 129 involved victims ages 60 years and over; most of the fatalities related to rail entrapment. In addition, petitioners state that the CPSC found an estimated 36,900 adult portable bed rail-related injuries that were treated in U.S. hospital emergency departments from January 2003 to December 2011.

Petitioners request that the CPSC initiate proceedings under section 8 of the CPSA that would ban all adult portable bed rails because, they assert, the product presents an unreasonable risk of injury and no feasible consumer product safety standard would adequately protect the public from these products. Public Citizen contends that no mandatory standard or warnings could be developed that would adequately protect against the hazards presented by adult portable bed rails. The Consumer Group, however, states that if the CPSC does not pursue a ban, the Commission should initiate a rulemaking to promulgate mandatory standards under section 9 of the CPSA, to reduce the unreasonable risk of asphyxiation and the entrapment hazards posed by adult portable bed rails, and to include warning labels in the standards. The Consumer Group also requests action under section 27(e) of the CPSA to require manufacturers of adult portable bed rails to provide performance and technical data regarding the safety of their products.

In addition, petitioners request a public recall notice and refund for all adult portable bed rails under section 15 of the CPSA. However, the Commission may docket as petitions only requests for action that the Commission is authorized to take through the issuance, amendment, or revocation of rules. 16 CFR 1051.2(a). Accordingly, the recall and

refund requested by petitioners are outside the scope of a rulemaking proceeding and will be forwarded to the CPSC Office of Compliance and Field Operations for review.

[[Page 33394]]

By this notice, the Commission seeks comments concerning this petition. Interested parties may obtain a copy of the petition by writing or calling the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923. A copy of the petition also will be made available for viewing under ``Supporting and Related Materials'' in www.regulations.gov under this docket number. www.regulations.gov.

Dated: May 29, 2013
Todd A. Stevenson,
Secretary, U.S. Consumer Product Safety Commission.
[FR Doc. 2013-13000 Filed 6-3-13; 8:45 am]
BILLING CODE 6355-01-P

TAB B



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: January 30, 2014

TO : Richard McCallion
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Engineering Sciences

THROUGH: Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Angie Qin
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries:
January 2003 to December 2013⁶

I. Introduction

This memorandum provides the statistics on deaths and injuries and characterizes the types of hazard patterns related to adult portable bed rails (product code 4075) from January 2003 to December 2013. The counts are based on reports received by U.S. Consumer Product Safety Commission (CPSC) staff. The report also includes the estimated number of emergency department-treated injuries from January 2003 to December 2012.

⁶ This analysis was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission. Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff. If the date of incident or injury is not reported, date of entry is used.

ASTM International (ASTM) currently has a voluntary standard for children's portable bed rails: ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails*. According to the ASTM definition in that standard, a "portable bed rail" is a device intended to be installed on an adult bed to prevent children from falling out of bed. Bed rails covered by ASTM F2085 are intended for children who can get in and out of an adult bed unassisted, typically ranging in age from 2 to 5 years old. Adult portable bed rails, however, are generally designed for use by adults, particularly older adults. Some manufacturers of adult portable bed rails make medical claims regarding their product; and therefore, those bed rails would likely fall under the jurisdiction of the U.S. Food and Drug Administration. In this memorandum, CPSC staff limited the data to incidents reporting user age to be 13 years or older; incidents where the user's age is unknown or unreported are also included. The data did not include complete details of every incident; thus, it is possible that the memorandum may include some products outside of the CPSC's jurisdiction, although cases known to be outside the CPSC's jurisdiction were removed.

II. Incident Data⁷

CPSC staff received reports of 180 incidents, which included 174 fatalities and six noninjuries or "injury not reported" incidents, related to adult portable bed rails that occurred and were reported from January 2003 to December 2013. Death certificates were the source of incident reports for 111 of the 174 fatalities. These certificates contain limited information on the incident scenario. The remaining reports were reviewed by CPSC staff and obtained through various sources, such as consumer hotlines and Internet reports, medical examiner/coroner reports, newspaper clippings, and from retailers and manufacturers. The victims' ages (fatalities and noninjuries or "injury not reported" incidents) ranged from 13 to 103 years. There were six incidents (3%) with unknown or unreported age. The reporting is ongoing. The number of reported fatalities, injuries, and non-injury or "injury not reported" incidents may change in the future.

A. Fatalities

There were 174 fatal adult portable bed rail-related incidents that occurred and were reported from January 2003 to December 2013.

⁷ The CPSC databases searched were those of Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to adult portable bed rails.

All data coded under product code 4075 for patients ages 13 years or older were extracted. Upon careful joint review with Engineering and Health Sciences staff, some cases were considered out of scope for the purposes of this memorandum. Medical condition and injury location categories were reviewed jointly with Health Sciences staff. Cases specifying hospital bed and incidents occurring in hospitals were excluded. Cases involving bed rail injuries resulting from playing, running, and tripping are excluded. Examples of such excluded cases are incidental cases, falls or strains while pushing or carrying the bed rail, tripping over the bed rail, or tripping and hitting the bed rail. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside of the United States have been excluded. All incidents where a hazardous environment in and around the bed rail resulted in fatalities, injuries, or near-injuries were retained.

Table 1: Distribution of Reported Fatal Adult Portable Bed Rail-Related Incidents by Year (1/1/2003 to 12/31/2013)

Year of Incident*	Fatalities
2003	17
2004	25
2005	20
2006	26
2007	19
2008	19
2009	9
<i>2010</i>	<i>11</i>
<i>2011</i>	<i>11</i>
<i>2012</i>	<i>10</i>
<i>2013</i>	<i>7</i>
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS)

* If the date of incident or injury is not reported, the date reported is used.

Note: Data in italics indicates reporting is ongoing for 2010–2013.

Two new incidents that occurred in 2004 and 2009 were reported to CPSC in 2013.

Of the fatal incidents, 161 incidents (93%) were related to rail entrapment; 12 incidents (7%) were related to falls on the bed rail; and one was categorized as a miscellaneous incident (the victim hit his head on the rail). The fatality victims' ages ranged from 14 to 103 years old. One hundred and forty-five decedents (83%) were age 60 and over; 28 (16%) were under 60 years old; and one was of unknown age.

About half of the reports concerning a fatality indicated that the victim had some kind of medical condition. Reported conditions included Alzheimer's disease, dementia, or other mental limitations (13%), cardiovascular disease (13%), mobility limitations or paralysis (5%), seizure (3%), Parkinson's disease (3%), cerebral palsy (2%), drug medicated (2%), multiple conditions (2%), multiple sclerosis (2%), pulmonary disease (2%), or other conditions (4%). Most injuries (60%) occurred at home. The rest occurred at nursing homes (16%), assisted living facilities (10%), hospice facilities (2%), other (5%), or unspecified locations (7%).

Table 2: Distribution of Reported Fatal Adult Portable Bed Rail-Related Incidents by Age
(1/1/2003 to 12/31/2013)

Age	Fatalities
13 to 30 years	7
30 to 59 years	21
60 to 69 years	11
70 to 79 years	20
80 to 89 years	69
90 years and over	45
Not reported*	1
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

Table 3: Distribution of Reported Fatal Adult Portable Bed Rail-Related Incidents by Medical Conditions
(1/1/2003 to 12/31/2013)

Medical Conditions	Fatalities
Alzheimer/dementia/mental	23
Cardiovascular disease	22
Mobility/paralysis	8
Seizure	5
Parkinson	5
Cerebral palsy	4
Drug medicated	4
Multiple conditions	4
Multiple sclerosis	3
Pulmonary disease	3
Other*	7
No medical condition reported	86
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

* Other included tracheotomy and G-tube, severe burn, post hip surgery, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, cancer hospice, and muscular dystrophy.

Table 4: Distribution of Reported Fatal Adult Portable Bed Rail-Related Incidents by Injury Location
(1/1/2003 to 12/31/2013)

Injury Location	Fatalities
Home	104
Nursing home	28
Assistant living facility	18
Hospice	3
Other*	9
Unknown	12
Total	174

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

*Other included a care home, a foster home, a group home, a hotel, a retirement center, town/country manor, rehab center, and an adult family home.

B. Nonfatal Incidents

There were six nonfatal adult portable bed rail-related incidents that occurred and were reported from January 2003 to December 2013. Of the nonfatal incidents:

- Two incidents were related to rail entrapment;
 - one of these incident reports states that a person may have become entrapped due to the bed rail moving away from the bed; and
 - the second incident report states that the consumer’s arm got trapped between the mattress and the top of the rail while he was sleeping.
- Two incidents were related to side rail breakage;
 - one incident report states that the small boards on the side rails ripped through the screws, causing the boards underneath to fall; and
 - the second incident states that the bed rail broke about three-quarters of the way while the victim was sitting on the bed.
- The remaining two incidents were categorized as “miscellaneous incidents” (a misleading label and an inquiry about a replacement for a recalled product).
- No injury was reported for these six nonfatal incidents.

III. Hazard Patterns

CPSC staff reviewed all 180 incidents to identify hazard patterns associated with adult portable bed rails. Staff grouped the incidents into four categories of hazard patterns based on the components presenting the hazard. The category list is ordered from the highest frequency to the lowest.

- A. *Rail entrapment*: There were 163 incidents related to rail entrapment. This category included incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, or between the headboard or footboard and rail. Based on the narrative in the reports, the most frequently injured body parts were the neck and head. Most of these incidents (161 out of 163) were fatalities.
- B. *Falls*: There were 12 incidents related to falls. This category included incidents in which the victim fell off the bed rail, climbed over the bed rail, fell and hit the bed rail, or fell due to an un-raised bed rail. Each incident resulted in a fatality.
- C. *Miscellaneous*: There were three incidents with miscellaneous problems (the victim hit his head on the rail, a complaint about a misleading label, and a complaint inquiring about a replacement for a recalled bed rail). This category included one death and two noninjuries.
- D. *Structural integrity*: There were two incidents related to structural component problems. In one incident, the small boards on the side rails ripped through the screws, causing the boards underneath to fall. In the other incident, the bed rail broke about 3/4 of the way while the victim was sitting on the bed. No injury was reported.

Table 5: Distribution of Reported Adult Portable Bed Rail-Related Incidents by Hazard Type.
(1/1/2003 to 12/31/2013)

Hazards	Counts
Rail entrapment	163
Falls	12
Miscellaneous	3
Structural integrity	2
Total	180

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

IV. National Injury Estimates⁸

There were an estimated 39,600 adult portable bed rail-related injuries (sample size=952, coefficient of variation=0.08) treated in U.S. hospital emergency departments from January 2003 to December 2012. Estimates for 2013 will not be available until NEISS data for 2013 is finalized in spring 2014. There was no statistically significant trend observed from January 2003 to December 2012 (p=0.11).

Table 6: Adult Portable Bed Rail-Related Injury Estimates by Year (1/1/2003 to 12/31/2012)

Year	Cases	Estimates
2003	104	4,600
2004	87	3,800
2005	97	3,900
2006	73	3,500
2007	102	4,500
2008	110	4,400
2009	105	3,900
2010	103	4,200
2011	100	4,100
2012	71	2,700

Source: National Electronic Injury Surveillance System (NEISS)

No deaths were reported through NEISS. The data included an age range from 13 to 101 years old. The injuries were fairly evenly distributed among age groups. Forty percent of victims were 60 years and older; 34 percent were between 30 and 59 years old; and 26 percent were younger than 30 years old. Most of the injuries (92%) were treated and released. The following injury characteristics occurred most frequently:

- Injured body part – head (15%), lower leg (12%), foot (11%)
- Injury type – contusions/abrasions (30%), laceration (30%), fracture (14%).

⁸ The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

All data coded under product code 4075 for patients ages 13 years or older was extracted. Upon careful joint review with ES and HS staff, some cases were considered out of scope for the purposes of this memorandum. Cases specifying hospital bed were excluded. Cases involving bed rail injuries resulting from playing, running, and tripping are excluded. Examples of such excluded cases are incidental cases, falls or strains while pushing or carrying the bed rail, tripping over bed rail, or tripping and hitting the bed rail. These records were excluded prior to deriving the statistical injury estimates.

TAB C



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: February 27, 2014

TO : Richard McCallion
Adult Portable Bed Rails Project Manager
Office of Hazard Identification and Reduction

THROUGH : Gregory B. Rodgers, Ph.D., Associate Executive Director,
Directorate for Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator,
Directorate for Economic Analysis

FROM : Robert Squibb, Directorate for Economic Analysis

SUBJECT : Market Analysis for Adult Portable Bed Rails

Background

The Commission received two requests to initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails (APBR) pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. Gloria Black, The National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (the Consumer Group) made one request; Public Citizen made the other request (collectively referred to as petitioners). The CPSC has docketed the requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails.

The petitioners claim that APBR currently on the market are responsible for many injuries and deaths among users, particularly the elderly and frail. The petitioners state that many of these deaths are the result of asphyxiation caused by entrapment within the openings of the APBR or between the APBR and the mattress or bed frame. The petitioners also claim that individuals who attempt to climb over these products may be at greater risk of injury or death than they would be had there been no APBR in place. Public Citizen contends that no mandatory standard or warnings could be developed that would adequately address the hazards presented by APBR. However, the Consumer Group has stated that if the CPSC does not pursue a ban, the Commission should initiate rulemaking to promulgate mandatory standards, including warning labels, to reduce the risk of death and injury presented by these products. This memorandum provides a description of the relevant product, an explanation of CPSC's jurisdiction, an examination of the current market for APBR, and preliminary estimates of the societal costs of injuries associated with the product.

The Product

APBR are products designed for adult use. The user installs these products on or along the side of a bed. The bed rails are attachable to and removable from a standard bed and are not part of the bed design (unlike hospital beds, which generally involve an integrated system of rails, mattress, and bed). APBR are installed to prevent the occupant from falling out of bed; to prevent falls by aiding the occupant when getting in and out of the bed; or to aid the user in adjusting their position while in bed.

APBR are typically constructed from rigid metal or plastic material and are attached to the bed or floor or anchored under the mattress. Models can be adjustable, angled for ergonomic assistance in getting in and out of bed, and can range in size from handles, to quarter bed-length, to full-bed length. Models are also rated for different weights; some are designed for use with bariatric beds and obese patients.

Products defined in this memorandum as APBR align with the list of products under consideration by the ASTM subcommittee currently developing a voluntary standard for APBR. The products to be covered will likely include two groups of products: those products marketed as bed rails, adult portable bed rails, or side rails, as well as those marketed as bed handles, bed assists, assist rails, or grab bars. These two product groups share many design similarities; bed handles are typically of a simpler construction and smaller, but bed handles largely consist of the same perpendicular pole and rail mechanism for attachment and use as bed rails. Typically, products listed as rails are marketed as a system for keeping the occupant from falling out of bed; in contrast, products listed as handles or assists are marketed to assist users in getting in and out of bed and with moving around within a bed.

Some APBR are sold with accessories intended to increase safety, such as a cushion or piece of fabric covering a portion of the product or the entire product to prevent entrapment between the rails. This still leaves the possibility for entrapment between the rail and the mattress or the rail and the headboard. One manufacturer also markets an “Add-On Entrapment Guard” designed to eliminate the gap between the mattress and the rail, as a precaution against entrapment.⁹

Jurisdiction

The FDA has jurisdiction over some APBR. This complicates the analysis of both the market and societal costs presented below. The FDA regulates adjustable hospital beds used for medical purposes. Bed rails that are an accessory to regulated hospital beds, which are typically integrated into the bed itself and are not portable between beds, are considered by the FDA to have a medical purpose and to be “devices” subject to FDA jurisdiction, whether the bed is located in a hospital or elsewhere. Therefore, FDA-regulated bed rails are excluded from the

⁹Amfab Product “Add-on Entrapment Guard.” Amfab. Accessed 1/16/2013.
http://www.amfab.com/store/item_view.php?id=30&item=Add-On+Entrapment+Guard+5120.

definition of “consumer products.” In addition, FDA also considers APBR that have a medical purpose to be a medical device, and therefore, they are also excluded from CPSC jurisdiction.

APBR intended for use with a non-FDA regulated bed and that are not considered by the FDA to be a medical device, would fall under the CPSC's jurisdiction. APBR that are not appurtenant to hospital beds and that the FDA does not consider medical devices fall within the CPSC's jurisdiction, irrespective of where the bed is used (long-term care facility or residence), if the APBR is not regulated by the FDA. Other than hospital beds (where the rail typically is integrated into the design of the bed), it is not necessarily apparent from direct observation which regulatory authority applies. Without specific information on the manufacturer and whether the APBR has a medical purpose, it cannot be determined whether the product falls under FDA or CPSC jurisdiction.

Market for Adult Portable Bed Rails

Currently, CPSC staff is aware of 16 suppliers of APBR marketing their products in the United States. Collectively, these entities supply approximately 74 models of APBR. This estimate attempts to exclude products listed as medical devices, as available information allowed. Of these suppliers, 15 are domestic manufacturers, and one is a foreign manufacturer who exports directly to the United States via Internet sales. Of those for whom publicly accessible data were available, three firms appear to be small manufacturers based on the U.S. Small Business Administration guidelines (500 or fewer employees for a domestic manufacturer in this industry sector); nine are large manufacturers; and the size of the remaining four are unknown.

Sales data, either as units or monetary value, are not available. Staff is not aware of any trade associations tracking APBR sales, and manufacturers did not respond to staff requests for such information. Additionally, estimates of the number of APBR in use are not available.

Typically, APBR are available directly from the manufacturers; through retailers such as Walgreens, CVS, and Wal-Mart; through trade shows; and from home medical device retailers. These products range in price from approximately \$30 for some assists and handles, to more than \$200 for larger, more complex rails, with prices typically around \$125 for most products marketed as bed rails.

The consumer market for APBR consists primarily of elderly and/or disabled users. APBR are different from children's bed rails in their intended use. Children's portable bed rails are designed for use by children ages 2–5 years old, to prevent children from falling out of bed in their sleep. Most APBR are designed to aid mobility and prevent falls both while the occupant is in bed or while getting into or out of bed. Most adult users either struggle with mobility or have mental or physical needs that make them more likely to fall out of bed.

Preliminary Estimate of Societal Costs

The preliminary estimates of societal costs of nonfatal injuries are based on estimates from the CPSC's Injury Cost Model (ICM) (Miller et al., 2000). The ICM is fully integrated with NEISS

and provides estimates of the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between injuries treated in hospital emergency departments and injuries medically treated in other settings, the ICM also estimates the number and societal costs of injuries medically treated in other settings (such as doctors' offices, emergency clinics, etc). Based on the ICM, there was an average of about 11,000 medically attended injuries involving APBR annually, from 2003 through 2012 (including about 3,960 treated in hospital EDs and another 7,040 treated in other settings). According to the ICM, the societal costs of these injuries amounted to about \$250 million annually. Medical costs and work losses accounted for about 26 percent of total costs. The remainder of estimated societal costs consisted of the intangible costs associated with pain and suffering (72 percent) and product liability costs (2 percent).

In addition to the nonfatal injuries, there were 174 reported deaths involving APBR between 2003 and 2013, or about 16 annually. The Commission does not ascribe a value to life. If, however, we assign a cost of \$5 million for each death, which is generally consistent with willingness-to-pay estimates of the value of a statistical life (VSL),¹⁰ the societal costs associated with these deaths would amount to about \$80 million. When combined with the estimated societal costs resulting from nonfatal injuries, aggregate societal costs amount to about \$330 million annually.

In developing injury and deaths estimates, the Directorate for Epidemiology attempted to eliminate cases known to involve bedrails under FDA jurisdiction (by excluding cases involving hospital beds and incidents occurring in hospitals). However, it is possible that some cases involving FDA-regulated APBR remain. Consequently, the total of \$330 million in societal costs may be an overestimate of the societal costs associated with the adult bed rails of interest.

Additionally, adult bed rails under CPSC jurisdiction are used as safety items to protect consumers. This analysis of societal costs does not attempt to evaluate the reduction in societal costs (*i.e.*, benefits) that result because of the use of adult bed rails because available data and information are insufficient to support such an evaluation.

Voluntary Standard

Currently, there is no voluntary standard governing APBR. At this time, APBR are under evaluation by an ASTM subcommittee working to develop a voluntary standard for the product, with the goal of reducing the hazards currently associated with APBR.

¹⁰ According to OMB's 2013 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act, willingness-to-pay estimates of the value of a statistical life (VSL) generally vary from about \$1.2 to \$12.2 million in 2010 dollars. Available at: http://www.whitehouse.gov/sites/default/files/omb/inforg/2013_cb/draft_2013_cost_benefit_report.pdf. Accessed on February 5, 2014.

TAB D



Memorandum

Date: February 6, 2014

TO : Richard McCallion, Project Manager, Adult Portable Bed Rails Petition,
 Office of Hazard Identification & Reduction

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director
 Directorate for Health Sciences

Jacqueline Ferrante, Ph.D., Director
 Division of Pharmacology and Physiology Assessment

FROM : Suad Wanna-Nakamura, Ph.D. Physiologist
 Division of Pharmacology and Physiology Assessment

SUBJECT : Health Sciences Assessment for Petition CP 13-1, Requesting a Ban and/ or to
 Promulgate a Standard for Adult Portable Bed Rails

Introduction: The Commission received two requests to initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails (APBR) pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. Gloria Black, The National Consumer Voice for Quality Long-Term Care, the Consumer Federation of America, and 60 other organizations (the Consumer Group) made one request; Public Citizen made the other request (collectively referred to as petitioners). The CPSC has docketed the requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. This memorandum provides information on hazard patterns and serious injury entrapment hazards of APBR.

Background and Product Description: The petitioners identified APBR as side rails, full-length rails, split rails, bed handles, and other similar products sold for home use. Adult portable bedrails are designed to fit on the side of a standard adult bed. The products are advertised on the market as side rails intended to prevent occupants from falling out of bed (Figure 1) and bed handles and grab bars (Figure 2) intended to help users get in/out of bed and sit up in bed.

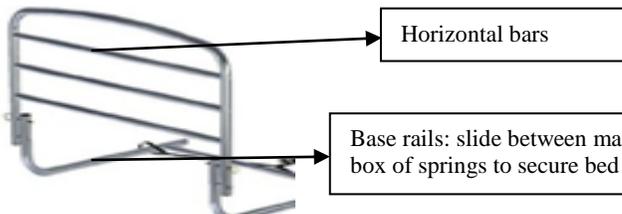


Figure 1: Bedside rail

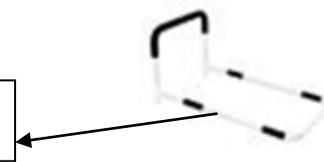


Figure 2: Grab bar

Some products can serve both functions. Side rails and grab bars are similar in design and overall shape and are secured to the side of the bed by a set of two bent base rails that slide between the mattress and box springs. Because of the similarity in design and mechanism of attachment to the side of the bed, both products pose the same potential entrapment hazards. HS staff has identified three sites where entrapments have occurred:

- gaps between the mattress and side rail.
- openings within the horizontal bars of the side rail space between the headboard /footboard and vertical end bar of the side rail.
- upper body entrapment between the mattress and rail can lead to positional asphyxia by chest or neck compression.

Incident Data: The Division of Hazard Analysis staff conducted searches of CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS) from January 2003 to December 2013, searching for all data under product code 4075 for patients age ≥ 13 years old (Qin, 2014). CPSC staff received 174 incident reports covering this 10-year period. Of these, 167 were fatalities (only two were associated with grab bars) and six noninjuries or “injury not reported.” More than half of the reported deaths were identified from death certificates (111 of 174), while the remaining reports were submitted to CPSC from several sources, including consumer hotlines and Internet reports, medical examiners, coroner reports, manufacturers, and newspaper clippings. The age of the victims ranged from 13 to 103 years old (Table 1). The vast majority of the fatalities 145 (83%) were adults 60 years and older (114 of 145 were 80 years and over).

Age	Fatalities
13 to 30 years	7
30 to 59 years	21
60 to 69 years	11
70 to 79 years	20
80 to 89 years	69
90 years and over	45
Not reported*	1
Total	174

Table 1: Age Distribution of adult bedrail fatalities (Source: Table 2: Distribution of Reported Fatal Adult Portable Bed Rail-Related Incidents by Age (1/1/2003 to 12/31/2013) Tab B (Qin, 2014 Adult Portable Bed Rail Staff Briefing Package)

Of the fatal incidents, 161 incidents (93%) were related to rail entrapment, and 12 incidents (7%) were related to falls on the bed rail (Qin, 2013). In about half of the reported fatalities, the victim had a preexisting chronic medical condition, such as cardiovascular disease, Alzheimer’s disease/dementia/other mental limitations, seizures, mobility limitations or paralysis, Parkinson’s disease, cerebral palsy, multiple sclerosis, and pulmonary disease. Moreover, many victims had multiple disorders or were heavily sedated. Patient entrapments happened in private homes and in patient care settings (e.g., hospice, assisted living, or long-term care facilities).

Entrapment between the side rail and mattress was the most common hazard pattern and accounted for 161 fatalities (93 percent). These incidents also included cases in which the victim was entrapped between the bed rail bars. Further analysis of the data by HS staff revealed that the head or neck was the part of the body most frequently entrapped, with positional asphyxia as the most common cause of death. Sustained external pressure on the neck can lead to “asphyxia,” defined in the literature as the failure of cells to thrive in the absence of oxygen. Neck compression, with or without airway blockage, can result in death, even when the body remains partially supported. This deprivation can be partial (hypoxia), when there is an inadequate oxygen supply to the lungs, or total (anoxia), when there is total impairment of oxygen transport to tissues, often accompanied by carbon dioxide retention. A reduction of oxygen delivery (per unit time) to the tissue can result in tissue injury and permanent irreversible damage (Feldman, 1980). The brain is particularly sensitive to oxygen deprivation and is the most affected organ (DiMaio VJ, DiMaio D. 2001, Spitz, 2006; Oehmichen et al., 2005; Saukko P, Knight, 2004, Gordon I, Shapiro, 1982; McNie, 1980; Adams et al., 2006, Saukko P, Knight, 2004). Blood vessels, taking blood to and from the brain, and the carotid sinuses are located in soft tissues of the neck and are relatively unprotected. Compression of either the jugular veins or the carotid arteries can lead to death (Hoff, 1978, Iserson, 1984, and Polson, 1973). The amount of force required to cause mechanical vascular occlusion and blockage of blood flow is small because compression of the jugular veins in the neck requires as little as 2 kg (4.4 pounds) of force (Brouardel, 1897, Iserson, 1984), leading to unconsciousness and even death. Of the 174 fatalities, 146 (84 percent) involved victims age 60 years and older, and about half of the reports, indicated that the victim had some kind of medical condition.

Conclusions: HS staff evaluated the possible role that bed rails may have played in entrapment deaths. Unfortunately for most of the deaths, there is limited information available describing how the victims became entrapped, and most of the incidents appear to have been unwitnessed. The death certificates provided little detail. Accordingly, HS staff is unable to make any firm conclusions regarding the role that the bed rails may have played in the deaths of the victims. However, there are a number of factors to be considered in such an evaluation. The vast majority, 146 (84%) of victims in the incidents involving APBR entrapment, were 60 years and older, and 114 (66%) were 80 years and older. This is a potentially vulnerable population associated with an overall progressive decline in muscle strength, balance, and cognitive abilities and who are also increasingly susceptible to a variety of ailments prevalent among the elderly. In addition to these age-related issues, more than half of the entrapment victims had a diagnosed condition commonly known to cause cognitive impairment, as well as other physical and/or neurological conditions that would have increased their vulnerability and risk of entrapment and falls. A review of the cases suggests that in some instances, the bedrails may have been used in a way intended by the product manufacturer, such as to restrain such individuals in the bed, which increased their risk of injury or death.

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TAB E



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

DATE: February 7, 2014

TO: Richard McCallion, Project Manager, Adult Portable Bed Rail Petition,
Office of Hazard Identification & Reduction

THROUGH: Bonnie B. Novak, Director,
Division of Human Factors, Directorate for Engineering Sciences

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

SUBJECT: Human Factors Assessment for Petition CP 13-1, Petition Requesting a Ban or
Standard on Adult Portable Bed Rails

BACKGROUND

The Commission received two requests to initiate proceedings under section 8 of the Consumer Product Safety Act (CPSA) to determine that adult portable bed rails (APBR) pose an unreasonable risk of injury and initiate related rulemaking under section 9 of the CPSA. Gloria Black, The National Consumer Voice for Quality Long-Term Care, Consumer Federation of America, and 60 other organizations (collectively referred to as “the Consumer Group”) made one request; Public Citizen made the other request (collectively referred to as petitioners). CPSC has docketed the requests as a single petition: Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails.

The petitioners claim that APBR currently on the market are responsible for many injuries and deaths among users, particularly the elderly and frail. The petitioners state that many of these deaths are the result of asphyxiation caused by entrapment within the openings of the APBR or between the APBR and the mattress or bed frame. The petitioners also claim that individuals who try to climb over these products may be at greater risk of injury or death than they would be had there been no APBR in place. Public Citizen contends that no mandatory standard or warnings could be developed that would adequately address the hazards presented by APBR. However, the Consumer Group states that if CPSC does not pursue a ban, the Commission should initiate rulemaking to promulgate mandatory standards, including warning labels, to reduce the risk of death and injury that these products present. This memorandum, prepared by staff of CPSC’s Directorate for Engineering Sciences, Division of Human Factors (ESHF), discusses human factors issues relevant to the petition.

DISCUSSION

THE PRODUCTS

The petitioners identified the APBR of concern: side rails, split rails, half rails, bed handles, full-length rails, bed canes, and similar products sold and marketed directly to the public and

intended to be used with a home bed, rather than a hospital bed. Public Citizen specifically characterized these products as being made of rigid materials, having horizontal and vertical components joined at right angles, and being installed by sliding the horizontal component of the product between the bed's mattress and box spring. These products generally are advertised and marketed as: (1) rails intended to prevent consumers from falling out of bed, or (2) assistive devices intended to aid weak or unsteady consumers in getting in and out of bed or repositioning within the bed. In some cases, the product claims to serve both functions.

The Commission regulates portable bed rails under the CPSA, and the regulation is codified at 16 C.F.R. part 1224. This regulation incorporates by reference the ASTM voluntary standard on portable bed rails, ASTM F2085 – 12, *Standard Consumer Safety Specification for Portable Bed Rails*. However, section 3.1.15 of ASTM F2085 defines a “portable bed rail” as a portable railing installed on the side of an adult bed or mattress surface “to keep a child from falling out of bed.” The standard additionally states that the bed rails encompassed by the standard are those intended “for children who can get in and out of an adult bed unassisted (typically from 2 to 5 years of age)” (section 1.3), and are intended “to minimize hazards to children” (section 1.2). Thus, the current regulation and voluntary standard on portable bed rails are not intended to address APBR or the hazards that portable bed rails might pose to adults.

INCIDENT DATA REVIEW

INCIDENT AND INJURY DATA

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), identified 180 incidents—174 fatalities and six incidents without injury—associated with portable bed rails that occurred and were reported to CPSC from January 2003 through December 2013, and which involved a victim age 13 years or older (Qin, 2014). The most common hazard pattern was rail entrapment, which accounted for 163 incidents (91 percent). These incidents included cases in which the victim was caught, stuck, wedged, or trapped between the bed rail and the mattress or bed, between bed rail bars, or similar entrapment scenarios. Most incidents appear to have been unwitnessed; therefore, the incidents lack details about how the victim became entrapped. The next most common hazard pattern, falls, accounted for 12 incidents (7 %). Of the 174 fatalities, 145 (83%) were to an individual 60 years old or older, and about half of the reports indicated that the victim had some kind of medical condition.

RELEVANT ADULT AGING ISSUES

As shown in the available incident data, most incidents involving adults and portable bed rails involve consumers 60 years or older. In addition, ESHF staff notes that most fatalities involving these older consumers involved consumers in their 80s and beyond. Older adults are a potentially vulnerable population, and adult aging is associated with declines in many perceptual, cognitive,

and physical abilities (Smith, 2005). Some of these deficits likely contribute to entrapment incidents with APBR. For example:¹¹

- *Muscle strength*: Muscle strength tends to decline after one's 20s or 30s, and strength losses seem to accelerate with age, particularly after the age of 70. Declines in muscular strength may limit the extent to which a consumer can escape an entrapment scenario.
- *Muscular power*: Age-related declines in muscular power, which involves the rapid generation of force, such as that required to correct for an unexpected loss of balance, are even greater than declines in strength.
- *Motor control and coordination*: Research indicates that movement variability increases with age and that motor coordination consequently deteriorates.
- *Balance*: The ability to maintain balance depends on the sensory, cognitive, and motor control systems. Age-related declines in some or all of these systems are likely to be responsible for observed age-related deficits in balance.

Although most capabilities deteriorate at least somewhat with age, and some of these observed differences are substantial, the degree of decline can be highly variable among individuals. Furthermore, some differences between the young and the elderly can be attributed to disuse and inactivity, rather than the aging process per se. The principle causes of age-related losses in muscular strength and power, for example, are believed to be reduced physical activity levels and disuse of the muscles, with consequent losses in muscle mass (Ketcham & Stelmach, 2001; Spirduso, Francis, & MacRae, 2005). Thus, infrequently used muscles tend to show greater declines. The elderly often use APBR to assist in getting in or out of the bed. Therefore, consumers who use these products are likely to require such assistance and would be more likely than others to suffer from deficits in strength or coordination. One would expect these consumers to be less capable of removing themselves from an entrapment scenario. Deficits in muscular strength and coordination are likely to discourage the use of weakened muscles and may promote inactivity,¹² thereby creating a sort of feedback loop that results in even greater deficits and an increased likelihood that affected consumers will be unable to extricate themselves from an unsafe situation.

As noted in the incident data, about half of the reports concerning fatality victims indicated that the victim had a medical condition (Qin, 2014). It seems reasonable to conclude that some of these conditions—for example, Alzheimer's disease and other forms of dementia, mobility limitations or paralysis, Parkinson's disease, cerebral palsy, and multiple sclerosis—contributed to the incident. Neurodegenerative diseases, such as Alzheimer's disease, cause changes in one's memory, behavior, and ability to think clearly (Alzheimer's Association, 2013), which may lead

¹¹ See Smith (2005) for a detailed discussion of these and other age-related differences in the adult consumer population.

¹² Research generally indicates that people become more cautious, or risk-averse, with increasing age (Botwinick, 1984, as cited in Sternberg & Lubart, 2001; Panek, 1997; Sanfey & Hastie, 2000; Shaie & Willis, 2002).

affected consumers to place themselves in unsafe situations, to become entrapped, or to have difficulty removing themselves from a dangerous situation. Alzheimer's disease is a common affliction of old age, affecting about one in nine (11 percent) people age 65 and older and about one-third (32 percent) of people age 85 and older (Alzheimer's Association, 2013).

ADULT PORTABLE BED RAIL WARNINGS

WARNING EFFECTIVENESS AND OLDER ADULTS

Safety and warnings literature consistently describe a classic hierarchy of approaches that one should follow to control hazards, based primarily on the effectiveness of each approach in eliminating or reducing exposure to the hazard. Warnings are viewed universally as less effective than designing a hazard out of the product or guarding the consumer from a hazard; therefore, the use of warnings is lower in the hazard control hierarchy than these other two approaches (Vredenburg & Zackowitz, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective primarily because they do not preclude consumer exposure to the hazard; and, instead, warnings depend on persuading consumers to alter their behavior in some way to avoid the hazard. Thus, one should view warnings as "last resort" measures that supplement, rather than replace, redesign or guarding, unless these higher level hazard-control efforts are not feasible.

Controlling hazards through design or guarding, rather than warnings, is especially important when older adults are at risk, because the elderly are a potentially vulnerable population. As discussed earlier, age-related declines in physical skills and abilities may limit the ability of older adults to avoid or remove themselves from hazardous situations. The elderly are more likely to suffer from Alzheimer's disease and other forms of dementia. Thus, some elderly consumers may not have the cognitive ability to appraise a hazard, appreciate the consequences of their own actions, or determine how to avoid hazards. In addition, older adults have decreased sensory-perceptual abilities relative to younger adults. For example, virtually everyone requires some form of vision correction by their late 50s (Shaie & Willis, 2002); and, with increased age, there is an increased incidence of pathological diseases and conditions of the eye, such as cataracts, glaucoma, and macular degeneration, especially as one enters the late 60s (Haywood & Getchell, 2001; Schneider & Pichora-Fuller, 2000; Shaie & Willis, 2002). Deficits in visual acuity, in particular, are pronounced in very old age (*i.e.*, age 75 and older); and low lighting levels or similar poor viewing conditions tend to exacerbate these deficits (Fozard & Gordon-Salant, 2001; Shaie & Willis, 2002). As a result, older adults are less likely to be able to read and process a warning about hazards related to a product, especially for products like APBR, which often are used in the evening or in low-light conditions.

For the reasons stated above, warnings aimed at older adults are unlikely to be very effective and may be least effective for those most at risk. Design changes or performance requirements for APBR that prevent entrapment in the first place would be a far more effective solution. Nevertheless, warnings might offer some benefit as a supplemental safety measure, if the risk

cannot be eliminated through design.¹³ Some warnings pertaining to APBR hazards might have to target a family member or caregiver, rather than the person the product is intended to assist. However, even caregivers of the elderly may be older adults, and the caregiver may suffer from similar age-related deficits.¹⁴ Therefore, the ultimate impact of improved APBR warnings on fatalities might be quite limited.

CURRENT WARNINGS

In response to the petition, CPSC staff collected several sample APBR that were available on the market. ESHF staff examined these samples and found substantial variability among the warnings provided with the products. Some samples lacked warnings of any type on the product, and the packaging for these products also tended to lack warnings. Some APBR with warnings affixed to the product essentially used the warnings required for children's portable bed rails.¹⁵ As a result, the warning emphasized the dangers to children younger than 2 years old and said nothing about the dangers to older adults, despite this latter subpopulation being the target audience for APBR. Thus, even if consumers chose to read the warnings on these products, they would be unlikely to conclude that older adults are at risk. One product included a warning that instructed consumers to readjust the rail to be flush against the mattress if a gap forms, but the warning provided no details about the hazard this action was intended to address, or the consequences of exposure to the hazard. Another product warning instructed consumers to push the product under the bed and always use a safety strap; however, this warning also lacked information about the potential hazard and its consequences.

Besides lacking in content, the on-product warnings that were affixed to APBR were likely to be challenging for older adults to read. The warnings' type size was smaller than the size typically recommended for older adults.¹⁶ In some cases, the text was "warped" because the warning label was made of flexible material and was twisted on the product or bent to follow the tubular contours of the APBR.

VOLUNTARY STANDARDS ACTIVITIES

On June 19, 2013, ASTM held a preliminary meeting to discuss the development of a voluntary standard for APBR. Since then, ASTM has formed a subcommittee to develop a standard, using the children's portable bed rail standard as a framework. The ASTM subcommittee has formed three task groups to develop the scope, performance requirements, and marking and labeling requirements, respectively. CPSC staff has been participating in the meetings of all three of these

¹³ Vanderheiden and Jordan (2012) note that even if the elderly and disabled are factored into the design process, it is impossible to design all products so they are usable by all people.

¹⁴ Among those caring for someone 65 years old or older, the average caregiver age is 63 years, and one-third of these individuals reportedly are in fair to poor health (Administration on Aging, 2004 as cited in American Psychological Association, 2014).

¹⁵ See 16 C.F.R. part 1224 and ASTM F2085 – 12, *Standard Consumer Safety Specification for Portable Bed Rails*.

¹⁶ The literature generally recommends the use of at least 12- or 14-point type for information that older adults must read, and some resources recommend 18-point type for very old individuals (see, for example, Boot, Nichols, Rogers, & Fisk, 2012; Fisk, Rogers, Charness, Czaja, & Sharit, 2004; Fozard, 2003; Laux, 2001; Morrell, Dailey, & Rousseau, 2003; Morrell & Echt, 1997; Schieber, 2003).

task groups to assist in the development of requirements that might address the concerns of the petition.¹⁷ ESHF staff is the primary CPSC representative of the marking and labeling requirements task group and has been working with this group to strengthen and clarify the warnings about the hazards pertaining to adult bed portable rails.

CONCLUSIONS

Most incidents involving APBR involve entrapment and consumers age 60 or older. Older adults are a potentially vulnerable population, and adult aging is associated with declines in many perceptual, cognitive, and physical abilities. Some of these deficits likely contribute to entrapment incidents with APBR. Given that many of these products serve as support and assistive devices, consumers who use APBR are more likely than others to suffer from deficits that render them less capable of removing themselves from an entrapment scenario. Furthermore, about half of fatalities indicated that the victim had a medical condition, some of which are more prevalent among the elderly and may have contributed to the incident.

Warnings are recognized universally as being less effective than designing a hazard out of the product or guarding the consumer from a hazard. Controlling hazards through design or guarding, rather than warnings, is especially important when older adults are at risk. Age-related declines in physical skills and abilities may limit the ability of older adults to avoid or remove themselves from warned-about hazardous situations. Some elderly individuals may suffer from forms of dementia that prevent them from being able to appraise a hazard, appreciate the consequences of their own actions, or determine how to avoid hazards. Moreover, age-related deficits in vision are likely to limit the extent to which older consumers can read and process a warning. Even the caregivers of older adults may be older and suffer from similar age-related deficits. Thus, improved warnings on APBR are likely to have a limited positive effect on fatalities. Nevertheless, warnings might offer some benefit as a supplemental safety measure, if the risk cannot be eliminated through design.

Currently, the warnings provided with APBR vary greatly. Some APBR lack any on-product warnings, while others rely on the same warning mandated for children's portable bed rails, which emphasizes the dangers to children younger than 2 years old but says nothing about the dangers to older adults. Some warnings instruct consumers to keep the product against, or at least close to, a mattress, without describing the potential hazard and the consequences of the hazard. In addition, the warnings on these products do not seem to be formatted with older adults in mind. CPSC staff has been working with a newly formed ASTM subcommittee to develop requirements intended to address the concerns of the petition; ESHF staff, in particular, has been working with the marking and labeling task group to strengthen the warnings about the hazards associated with APBR. This work is ongoing.

¹⁷ For example, ASTM F2085 – 12, *Standard Consumer Safety Specification for Portable Bed Rails*, employs torso and wedge probes, which ESHF staff designed based on the anthropometric dimensions of those at risk (See Smith, 2001), to test children's portable bed rails for potential entrapment. Similarly, the Hospital Bed Safety Workgroup (HBSW) developed a cone and cylinder tool, based on anthropometric dimensions of those at risk, to identify gaps that could lead to patient entrapment in or around a bed rail on a hospital bed system (FDA, 2006). Requirements similar to these may be appropriate for an APBR voluntary standard.

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TAB F



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

Date: February 6, 2014

TO : Richard McCallion
Adult Portable Bed Rails Project Manager
Office of Hazard Identification and Reduction

THROUGH: Mark Kumagai
Director, Division of Mechanical Engineering
Directorate for Engineering Sciences

FROM : Vincent J. Amodeo
Mechanical Engineer
Directorate for Engineering Sciences

SUBJECT : Assessment of Existing Standards and Practices Related to Adult Portable Bed Rails

I. Introduction

This memorandum provides an assessment of existing standards and practices related to portable adult bed rails.

II. Background

The petition addresses products known as “portable adult bed rails” (APBR), sold and marketed directly to the public for use on home-style beds. As identified in the petition, the term “bed rails,” includes, but is not limited to, side rails, split rails, half rails, bed handles, full-length rails, and bed canes. CPSC staff used the following definitions in the evaluation of APBR:

- *Full Length* - Bedside product that is intended to extend the full length of the bed and generally constructed from tubular metal and rectangular in shape. It is one continuous piece commonly attached to the side of the bed between the mattress and box spring. A floor support or mattress top supported design is possible. Full length APBR may adjust to conform to varying bed sizes and mattress heights. This product is intended to keep consumers from falling from bed and reposition in the bed.



Full-Length Bed Rail

- *Half Length* - Bedside product that is intended to extend approximately half the length of the bed and generally constructed from tubular metal and rectangular in shape. It is commonly attached to the side of the bed between the mattress and box spring and may be used in conjunction with another APBR. A floor support or mattress top supported design is possible. Half-length APBR may adjust to conform to varying bed sizes and mattress heights. This product is intended to keep consumers from falling from bed and reposition in the bed. It may also be used to assist the consumer enter and exit the bed.



Half Rail

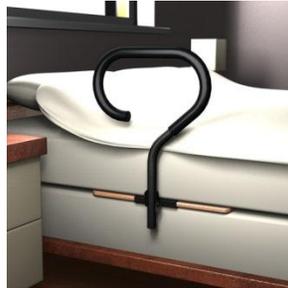
- *Bed Handle* - Bedside product that is generally constructed from tubular metal and available in various shapes and sizes. It is commonly attached to the side of the bed between the mattress and box spring or may be freestanding. Bed Handles may adjust to conform to varying bed sizes and mattress heights. This product is intended to assist consumers reposition in the bed. It may also be used to assist the consumer enter and exit the bed. A bed handle has the same basic purpose as a bed cane.



Bed Handle

- *Bed Cane* - Bedside product that is generally constructed from tubular metal and available in various shapes and sizes. It is commonly attached to the side of the bed between the mattress and box spring or may be freestanding. A bed cane may adjust to

conform to varying bed sizes and mattress heights. This product is intended to assist consumers with repositioning themselves in the bed. It may also be used to assist the consumer when entering and exiting the bed. A bed cane has the same basic purpose as a bed handle.



Bed Cane

The petitioners believe that the use of existing portable adult bed rails results in numerous injuries and deaths. The petitioners cite asphyxiation caused by entrapment within bed rail openings or between the rails and the mattress or bed frame. Additionally, the petitioners believe that bed rails contribute to numerous falls when individuals attempt to climb over the rail.

III. Existing Standards and Practices

- b. Currently, there are no CSPC regulations or voluntary standards pertaining to portable adult bed rails. ASTM International developed a voluntary standard for children's bed rails: ASTM F2085-12, *Standard Consumer Safety Specification for Portable Bed rails*. The scope of ASTM F2085-12 is limited to portable bed rails "intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted (typically from 2 to 5 years of age)."¹⁸ On August 29, 2012, CPSC issued a final rule, incorporating ASTM F2085-12 by reference.

ASTM F2085-12 contains the following performance requirements, which address known bedrail hazards for children:

- 1) Structural integrity – This requirement tests the bed rail's ability to resist movement when a specified force is applied.
- 2) Openings – This requirement tests for the existence of holes or slots that may present finger entrapment.
- 3) Enclosed openings – This requirement tests for the existence of openings in bed rail frame that would admit a torso probe.

¹⁸ ASTM 2085-12, *Standard Consumer Safety Specification for Portable Bed Rails*, Scope section 1.3; ASTM International, West Conshohocken, PA (January 1, 2012).

- 4) Displacement openings – This requirement tests for displacement that may be created between the bed rail and the mattress.
 - 5) Protrusions – This requirement tests for the existence of protrusions.
 - 6) Bedpost openings – This requirement tests for specific minimum dimensions between the bedposts and the left and right end of the portable bed rails.
 - 7) Misassembly – This requirement determines whether the bed rail can be installed in a manner that appears to be functional but presents hazards identified in the standard.
 - 8) General requirements – These requirements address sharp points and edges, small parts, component and hardware for assembly, and hazards associated with lead in paint and wood parts. The standard also contains marking, labeling, and instructional literature requirements.
- c. ASTM has assembled a subcommittee that is currently working on a safety specification for adult bed rails. The draft adult bed rail standard is in the early stages. Based on the existing F2085 children’s bed rail standard, the adult bed rail standard is expected to address similar hazards and any hazards specific to adult bed rails.
- d. The U.S. Food and Drug Administration (FDA) regulates adjustable hospital beds used for medical purposes. *See* 21 C.F.R. §§ 880.5100, 880.5110, 880.5120. Bed rails that are an accessory or appurtenant to regulated hospital beds are considered by the FDA to have a medical purpose and deemed to be “devices” subject to FDA jurisdiction. FDA regulations do not reference “bed rails” or “bed handles”; rather, FDA regulations refer to “movable and latchable side rails.” *See* 21 C.F.R. §§ 880.5100, 880.5110, 880.5120. FDA also regulates as “devices” bed rails that have a medical purpose. In contrast, bed rails intended for use with a non-FDA-regulated bed and that are not considered by the FDA to have a medical purpose or be considered a “medical device,” would fall under the CPSC’s jurisdiction (referred to in this memo as consumer bed rails). Accordingly, such bed rails fall within the CPSC’s jurisdiction, irrespective of where the bed is used (hospital, long-term care facility, residence), if they are not regulated by the FDA.

In March 2006, the FDA published a document to serve as guidance for industry and FDA staff titled; “Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment” (FDA Guidance). The FDA Guidance can be found at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf>. The scope of this voluntary guideline is limited to hospital beds.

To create this document, the FDA first reviewed hospital bed entrapment incident data and then categorized seven zones of potential entrapment. Six of the seven zones could be applied to consumer-grade bed rails: (1) entrapment within the rail; (2) entrapment under the rail; (3) entrapment between the rail and the mattress; (4) entrapment under the rail at the end of the rail; (5) entrapment between split rails; and (6) entrapment between the end of the rail and the side edge of the head or foot board. A testing methodology is included in Appendix F of the FDA Guidance so that the dimensional limits of these zones are not exceeded. Along with step-by-step instruction, a unique multifaceted probe

is described in the instructions. All recommended zone dimensions are based on anthropometric data and listed as Table 3 on page 21 of the FDA Guidance (shown in the table below).

Table 1. The dimensional limits for each zone described in the FDA guidance document

Zone	Dimensional Limit Recommendations
1 Within the rail	<120 mm (< 4 3/4 “)
2 Under the rail, between rail supports or next to a single rail support	< 120 mm (< 4 3/4 “)
3 Between rail and mattress	<120 mm (< 4 3/4 “)
4 Under the rail, at the ends of the rail	<60 mm (< 2 3/8 “) AND >60° angle

Finally, the most valuable resource available in the FDA Guidance might be the list of anthropometric data sources in Appendix D. Using these sources in conjunction with the established incident data on APBR, it may be possible to tailor a set of recommendations for consumer bed rails, which would be useful for the ASTM draft adult bed rail standard.

- e. Other resources that may provide valuable information for developing an adult bedrail standard:
- European standard, BS EN 60601-2-52:2010, *Medical Electrical Equipment – Particular Requirements for Basic Safety and Essential Performance of Medical Beds available for development of an adult bedrail standard*; and
 - *Safe Use of Bed Rails* bulletin, published in December 2013 by the United Kingdom’s Medicines and Healthcare products Regulatory Agency (MHRA), provides guidelines for the safe use of bed rails aimed at all users, caregivers, and staff with the responsibility for the provision, prescription, use, maintenance, and fitting of bed rails.

IV. Evaluation of Existing Adult Portable Bed Rails

In summer 2013, CPSC staff reviewed adult bed rail incidents and evaluated for hazards four adult bed rails on the market. Installation issues and entrapment hazards existed with the four bed rails. Staff concluded that an adult portable bed rail standard could address many of the hazards found in the incidents and with the evaluated products.

After the incident review, staff purchased four different types of APBR samples from various retailers. Staff selected the samples based on the identifiable products in the incident data and an Internet search by technical staff. A full-length rail, half rail, bed handle, and bed cane from different manufacturers were collected to evaluate the range of different types of APBR. Staff evaluated each sample using the requirements in the FDA hospital bed guidelines and ASTM F2085 standard for portable bed rails, which could be applied to the samples. The requirements included structural testing, measuring openings, and testing gaps between the mattress and rail. Staff performed additional testing to evaluate the rail attachment systems, such as straps and bed frame clamps.

During testing, staff successfully re-created scenarios similar to reported incidents regarding entrapment, strength and performance on each of the samples selected, except the bed cane. These tests were performed in an effort to evaluate the potential for the development of standardized tests that could be included in a product safety standard. Each sample was subjected to a uniform set of tests (entrapment, strength, etc.) and did not test specific samples to specific tests based on individual incidents for this review. Staff used the FDA entrapment hazard probe, in addition to the ASTM probes, in this evaluation to determine the failures. The FDA probe is designed based on adult anthropometrics. The tests for ASTM are designed for products used by children but the hazard patterns and incidents are similar for children and adults. Staff believes that the FDA probe may be used to test accurately for hazardous openings in APBR using the ASTM portable bed rail standard for children. Additionally, the FDA guidelines for hospital beds and ASTM F2085 provide other individual tests that could be used to evaluate rail strength, and product performance for APBR. Both the FDA guidelines and ASTM F2085 have been developed for other products and would need to be modified to apply to APBR.

V. Conclusion

Currently, there are no standards that apply to APBR, but there are similar product standards and guidelines. CPSC staff has evaluated a small sample of APBR, using requirements included in these standards and guidelines. This limited testing has shown that it is possible to develop performance standards and testing that can identify and reduce the hazards associated with the APBR and reduce the risk of injury to consumers. Staff has determined that development of effective performance requirements would require further testing and development. The analysis by staff was preliminary and requires additional evaluation before a final conclusion. Currently, ASTM, with CPSC participation, has undertaken this task. CPSC staff intends to use results from the ASTM subcommittee as a resource to develop an effective voluntary standard and a resource for CPSC staff if staff recommends future actions for APBR.

TAB G



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
ROCKVILLE, MD 20850

MEMORANDUM

DATE: February 12, 2014

TO : Adult Portable Bed Rail Petition File

THROUGH: George S. Borlase, Associate Executive Director,
Office of Hazard Identification and Reduction

FROM : Richard McCallion, Mechanical Engineer
Project Manager, Petition CP-13-1
Office of Hazard Identification and Reduction

SUBJECT: CPSC Staff Response to Public Comments CP-13-1

The Commission received a joint request from Gloria Black, The National Consumer Voice for Long-Term Care (the Consumer Voice), Consumer Federation of America and 60 other organizations to ban adult portable bed rails (APBR), and/or promulgate a standard to adequately address the asphyxiation and entrapment hazard caused by the use of adult bed rails, including a warning label. Public Citizen also submitted a separate request for a ban on adult bed rails, but states that no feasible mandatory standard or warning could be developed that would adequately protect against the hazards presented by adult portable bed rails. The requests were docketed as a single petition, CP13-1. On June 6, 2013, a notice of the petition requesting comments was published in the *Federal Register*. The comment period ended on August 5, 2013.

The Commission received a total of 99 comments; 92 support the ban and/or mandatory standard; seven oppose any action by the Commission. Commenters include family of victims, ombudsmen, health care professionals and facilities, safety advocacy groups, and other individuals.

1: Product Uniqueness

Comment: One commenter states that users of children's portable bed rails are distinguishable from users of adult bed rails because children are not typically victims of dementia or Alzheimer's. A number of commenters state that some adults require the rail for mobility and positioning.

Response: Staff agrees that there are considerable differences between consumers who use portable bed rails intended for use by children and consumers who use APBR. Children's portable bed rails are intended to prevent children from falling from an adult bed, but adult portable bed rails are intended to assist an adult in exiting, repositioning, or falling from the bed.

However, the types of incidents associated with both product categories are similar. Entrapments between rail and mattress and within the rail are the greatest hazard for both. Structural integrity is a concern for both but for different reasons. Children are more likely to climb over the rail, while adults are more likely to use a rail for support when standing or attempting to stand. Finally, when becoming entrapped, children may not have the strength or mental acuity to self-extricate, similar to older adults or adults with underlying medical conditions. Based on the similarities, staff believes the children's portable bed rail standard is useful in the development of any performance requirements for APBR.

2: Falls

Comment: Several commenters state that adult portable bed rails perform an important function, *i.e.*, to keep adults from falling out of bed, and therefore, bed rails should not be banned. Additionally, the commenters state that banning bed rails would require geriatric patients to depend more on others, increase pressure sores, falls, and cause greater risk of injury or death without such bed rails. One commenter also states that assuming the presence of a bed rail will stop a person from having falls is misguided; with bed rail use, the risk of falls remains, as well as an increased risk of strangulation. Another commenter provides literature for CPSC to review that discusses the effect of bed rails on falls and injuries after the bed rail is removed. The commenter states that a managed withdrawal of banned bed rail products, with replacement alternatives, may be required meaning any unsafe products are removed from the market while ensuring there continue to be safe products available to meet the needs of consumers.

Response: Staff agrees that APBR provide multiple functions and potentially increase safety to consumers, by reducing the risk of falling from bed and aiding those with physical limitations, but bed rails may not eliminate all fall incidents. Staff is not able to conclude from CPSC incident data that there is an increased rate of incidents from falls and/or entrapment when an APBR is used compared to a no-use scenario. Staff has reviewed all of the information provided or identified in the petition during the development of staff recommendations for the Commission. The literature provided on falls offers additional insight on how consumers are using APBR and how APBR are associated with falls. This information can be used to evaluate further the addressability of falls through performance requirements, labels, and warnings. If CPSC finds that the development of an APBR standard would reduce the hazards of APBR, the standard would be implemented in such a way to ensure that improved products are made available to consumers as existing products are retired from the market.

3. Adequate Warning Labels

Several commenters state that a mandatory safety standard for adult portable bed rails with adequate warning labels is necessary to keep a patient safe in his or her bed.

Response: Warnings are recognized universally as being less effective than designing a hazard out of the product or guarding the consumer from a hazard. Controlling hazards through design or guarding, rather than warnings, is especially important when older adults are at risk. However, warnings could offer some benefit as a supplemental safety measure, if the risk cannot be eliminated through design.

4. Design Issues

According to some commenters, entrapment deaths occur through continuous use when poorly designed portable adult bed rails move away from the bed, creating a gap. These commenters state that CPSC research conducted in 2012, covering a nine-year span, showed that there have been approximately 4,000 emergency department visits per year due to bed rail use. In addition, these commenters state that CPSC reported 155 bed rail-related deaths, and the FDA reports 550 bed rail-related deaths (although most of those are in hospitable bed rails), with the actual numbers likely to be higher. The commenters add that there were almost 37,000 injuries in hospital emergency departments from January 2003 to December 2011.

Response: Staff agrees that entrapment between bed and rail represents a serious safety hazard that has resulted in multiple injuries and deaths to consumers using an APBR. This is the primary hazard that staff believes should be addressed in the development of any standard.

5: Half-rails v. full rails

Comment: A few commenters note that many elder care facilities now use half rails for individuals who can assist themselves and that the use of full bed rails, on which entrapment risks may occur, are used mainly in the home.

Response: Staff is aware that different product designs are intended for different purposes, may be used differently, and could have different hazard patterns; however, CPSC incident data do not differentiate between half and full rails. Both half rails and full rails have been included under the definition of “APBR.” Staff has not fully evaluated all of the many different product APBR designs that are available in the market. Staff believes that different hazard patterns resulting from varying APBR designs may require different requirements. Review of such products is ongoing.

6. Other Standards

Comment: One commenter states that when used inappropriately, bed rails may pose a risk but that the Center for Medicare Services (CMS) regulations under F323-Accidents/Supervision address this risk. In addition, this commenter states that most states have regulations as well about safety and protective oversight. Another commenter states that the International Organization for Standardization and the International Electrotechnical Commission bed standards (IEC 60601-2-52; medical electrical equipment – Part 2-52; particular requirements for the basic safety and essential performance of medical beds) in place for hospital beds and rails should be used by the CPSC to develop safety standards for adult portable bed rails.

Response: Staff agrees that there are hazards associated with improperly using adult bed rails. A review of literature identified by the commenter was included as part of the preliminary product review performed by staff. The CMS regulations under the jurisdiction of the Center for Medicare and Medicaid Services and only applicable to healthcare providers. They provide

guidance for the use of APBR by healthcare providers and include information that may be useful in the development of labels and warnings. They are not applicable to APBR products. IEC 60601-2-52 is an International Electrotechnical Commission standard that provides technical requirements for the evaluation of hospital beds, which can be related to APBR. Additional standards, including state regulations that apply to APBR, will be considered by staff in completing the evaluation of APBR.

7. Bed rails as restraints

Comment: One commenter states that state and federal law protects citizens from unnecessary restraints. According to the commenter, bed rails are a form of restraint and can only be used in case of an emergency or severe physical debilitation, and prescribed by a physician.

Response: The commenter appears to refer to bed rails on hospital beds used for medical purposes. Bed rails that are an accessory or appurtenant to regulated hospital beds are considered by the FDA to have a medical purpose and to be “devices” subject to FDA jurisdiction. In contrast, bed rails intended for use with a non-FDA-regulated bed and that are not considered by the FDA to be a medical device would fall under the CPSC's jurisdiction. Staff considers non-FDA-regulated APBR to be an assist and safety device to help consumers in egressing, repositioning, or reducing the possibility of intentional falls from bed and do not restrict the motion of the consumer. Determination of each individual product application is the responsibility of the consumer or consumer's care giver.

8: Recall defective portable adult bed rails

Comment: Several commenters request that dangerous bed rails be removed from use and from sale. These commenters state that the Commission should exercise its authority to require adult bed rail manufacturers to issue a public recall notice and offer a refund for all adult portable bed rails.

Response: The Commission is currently reviewing the voluntary standards activities for implementing performance requirements and warning labels for portable adult bedrails in its consideration of whether a mandatory standard is necessary to address potential hazards associated with portable adult bed rails. The Commission has the authority to recall products with substantial product defects, including requiring remedial actions. However, those actions are outside the scope of a rulemaking proceeding and are addressed on a case-by-case basis by the CPSC's Office of Compliance and Field Operations.