UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

Memorandum

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SUBJECT : Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: January 2003 to September 2012[1]

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 September 2012. 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 2011.

The ASTM International (ASTM) voluntary standard for portable bed rails is ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails*. According to the ASTM definition, a "portable bed rail" is a device intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted, typically ranging in age from 2 to 5 years old. Adult bed rails are generally designed for use by adults, particularly

[1] 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.

older adults. Some manufacturers of adult 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. This review is not intended to address jurisdictional questions. 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.

II. Incident Data[2]

CPSC staff received 160 incidents, which included 155 fatalities and 5 non-injuries or "injury not reported" incidents, related to adult portable bed rails that occurred and were reported from January 2003 to September 2012. There were 98 death certificates that contained limited information on the incident scenario. The remaining reports were submitted to CPSC staff through various sources, such as consumer hotline and Internet reports, medical examiner/coroner reports, newspaper clippings, and from retailers and manufacturers. The victims' ages (fatalities and non-injuries or "injury not reported" incidents) ranged from 13 to 103 years. There were 6 incidents (4%) 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 155 fatal adult portable bed rail-related incidents that occurred and were reported from January 2003 to September 2012.

Table 1: Distribution of Reported Fatal Bed Rail-Related Incidents by Year

Year of Incident*	Fatalities
2003	17
2004	25
2005	20
2006	26
2007	19
2008	19
2009	*8*
2010	*7*
2011	*11*
2012	*3*
Total	155

Source: CPSC epidemiological databases IPII, INDP and DTHS.

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

Note: Data in italics indicates reporting is ongoing for 2009−2012.

[2] The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, and the Death Certificate (DTHS) file. 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 bed rails.

All data coded under product code 4075 (Bed Rails), where the patients' ages was 13 years or older, were extracted. Upon careful joint review with ES and HS staff, some cases were considered out of scope for the purposes of this memo. 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 Sates have been excluded. All incidents where a hazardous environment in and around the bed rail resulted in fatalities, injuries, or near-injuries were retained.

Of the fatal incidents, 143 incidents (93%) were related to rail entrapment; 11 incidents (7%) were related to falls on the bed rail; and 1 was categorized as a miscellaneous incident (the victim hit his head on the rail). The ages of the fatality victims ranged from 14 to 103 years old. One hundred and twenty nine decedents (83%) were 60 and over; 19 (12%) were between 30 and 60 years old; 6 (4%) were under 30 years old, and 1 was of an unknown age. About half of the reports concerning the fatality victims indicated that the victim had some kind of medical condition. Reported conditions included cardiovascular disease (15%), Alzheimer's disease, dementia, or other mental limitations (12%), seizure (4%), mobility limitations or paralysis (3%), Parkinson's disease (3%), cerebral palsy (3%), multiple sclerosis (2%), the victim taking medication (2%), multiple conditions (1%), pulmonary disease (1%), or other conditions (4%). Most injuries (61%) occurred at home. The rest occurred at nursing homes (16%), assisted living facilities (10%), hospice facilities (2%), other (3%), or unspecified locations (8%).

Table 2: Distribution of Reported Fatal Bed Rail-Related Incidents by Age

Age	Fatalities
13 to 30 years	6
30 to 60 years	19
60 years and over	129
Not reported	1
Total	155

Source: CPSC epidemiological databases IPII, INDP and DTHS.

Table 3: Distribution of Reported Fatal Bed Rail-Related Incidents by Medical Conditions

Medical Conditions	Fatalities
Cardiovascular disease	23
Alzheimer's disease/dementia/mental limitation	18
Seizure	6
Mobility/paralysis	5
Parkinson's disease	4
Cerebral palsy	4
Multiple sclerosis	3
Drug medicated	3
Multiple conditions	2
Pulmonary disease	2
Other*	6
No medical condition reported	79
Total	155

Source: CPSC epidemiological databases IPII, INDP and DTHS.
*Other included tracheotomy and G-tube, severe burn, post hip surgery, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, cancer hospice.

Table 4: Distribution of Reported Fatal Bed Rail-Related Incidents by Injury Location

Injury Location	Fatalities
Home	94
Nursing home	25
Assisted living facility	15
Hospice	3
Other*	5
Unknown	13
Total	155

Source: CPSC epidemiological databases IPII, INDP and DTHS.
*Other included a care home, a foster home, a group home, a hotel, and an adult family home.

B. Non-fatal Incidents

There were 5 non-fatal adult portable bed rail-related incidents that occurred and were reported from January 2003 to September 2012. Of the non-fatal incidents, 2 incidents were related to rail entrapment; 1 incident report states that people may become entrapped due to the bed rail moving away from the bed, and the second incident states that the victim's arm got trapped between the mattress and the top of the rail while he was sleeping. One incident was related to a broken side rail (the small boards on the side rails ripped through the screws, causing the boards underneath to fall); and the remaining 2 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 5 non-fatal incidents.

III. Hazard Patterns

CPSC staff reviewed all 160 incidents to identify hazard patterns associated with adult portable bed rails. The hazard patterns can be grouped into four categories based on the components presenting the hazard. The category list is ordered from the highest frequency to the lowest.

A. Rail entrapment: 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.

B. Falls: There were 11 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 unraised bed rail. All incidents resulted in a fatality.

C. Miscellaneous: There were 3 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 1 death and 2 non-injuries.

D. Structural integrity: There was 1 incident related to a structural component problem. In the incident, the small boards on the side rails ripped through the screws, causing the boards underneath to fall. No injury was reported.

Table 5: Distribution of Reported Bed Rail-Related Incidents by Components Presenting the Hazard (1/1/2003 to 9/30/2012) (Victims age 13 years or older)

Hazards	Counts
Rail entrapment	145
Falls	11
Miscellaneous	3
Structural integrity	1
Total	160

Source: CPSC epidemiological databases IPII, INDP and DTHS.

IV. National Injury Estimates[3]

There were an estimated 36,900 adult portable bed rail-related injuries (sample size=881, coefficient of variation=0.08) that were treated in U.S. hospital emergency departments from January 2003 to December 2011. Partial estimates for 2012 will not be available until NEISS data for 2012 is finalized in spring 2013. The injury estimates for individual years are not reportable because they fail to meet publication criteria.[4] There was no statistically significant increase or decrease observed in the estimated injuries from one complete year to the next ($p>0.1$), nor was there any statistically significant trend observed from January 2003 to December 2011 ($p=0.40$).

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. 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 most frequently:

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

[3] 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 the 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 memo. 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.

[4] According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller.