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May 9, 2013

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U.S. Consumer Product Safety Commission
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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.

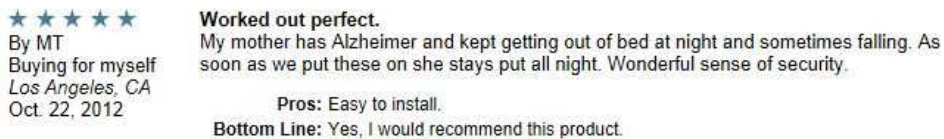
¹³ Capezuti E, Wagner LM, Brush LB, et al. Consequences of an intervention to reduce restrictive side rail use in nursing homes. *J Am Geriatr Soc* 55:334–341, 2007.

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:



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

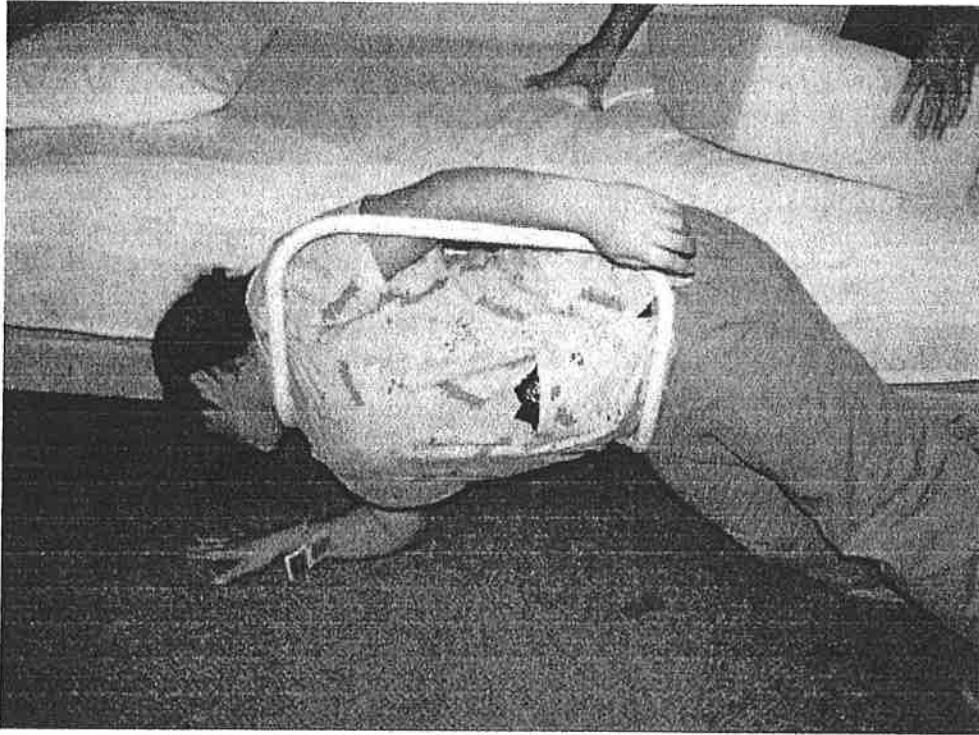


Photo # 9: View of the Caregiver demonstrating the position of the victim.

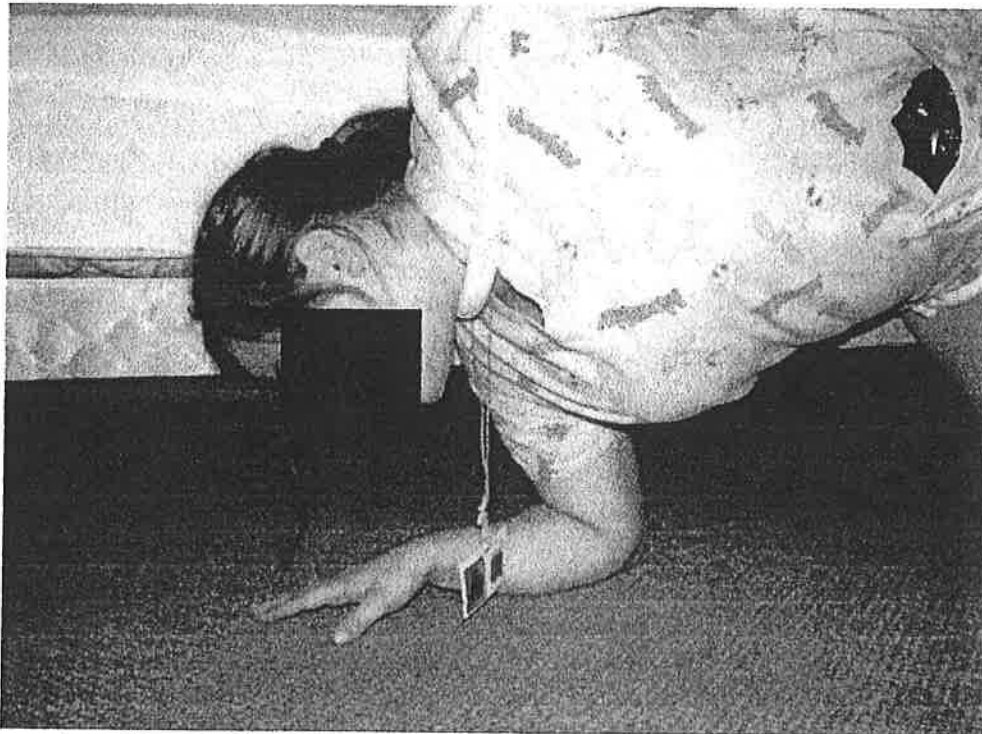


Photo # 10: Close-up view of the demonstration.

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.



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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,

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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

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.