Stevenson, Todd

From: Rachel Weintraub <rweintraub@consumerfed.org>
Sent: Thursday, April 25, 2013 9:32 AM
To: Stevenson, Todd
Subject: Adult Bed Rail Petition from CFA, Consumer Voice, Gloria Black and 60 other organizations
Attachments: Bed Rail petion April 25 final.pdf

Todd,

Attached please find a petition that Consumer Federation of America, the National Consumer Voice for Quality Long-Term Care (Consumer Voice), bed rail activist Gloria Black, and 60 other organizations are submitting to CPSC to ban adult portable bed rails and to take other actions to protect consumers.

If you need any further information, please do not hesitate to contact me.

Sincerely,
-Rachel Weintraub

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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

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[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]

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[3] http://www.canhr.org/about/index.html

[4] http://www.ossmc.org/html/ossmchome.htm

[5] http://dhss.delaware.gov/dhss/main/ltcop.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-

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[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]

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[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]

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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 welfare[25]

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]

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[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

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[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

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[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-

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[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

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[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]

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[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:

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[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 father 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)

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[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

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[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

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[67] http://www.cpsc.gov/cpscpub/prerel/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/hrg2069 , 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.

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

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[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.

[iii] Bed Handles, Inc., website. Available at http://www.bedhandles.com/page4.htm#page4.htm. Accessed August 22, 2012.
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[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.
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[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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"Bed-rail entrapments still a serious problem," W.A. Hyman, (2008) McKnight's, http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/

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"Safe Portable Bed Rails – There's No Such Thing," Lisa Marshall, *Biomedical Safety & Standards*, Feature article, November 15, 2012.

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"When Bed Rails Kill Confused Patients, Facilities Do Not Tell the Family!" David Zeman and Patricia Montemurri, Hospice Patients Alliance, http://www.hospicepatients.org/bedraildangers.html.

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.

Respectfully submitted,
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Dated: April 25, 2013

Appendices

The following pages contain:

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. W*hile 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 strangulated 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 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.**bedrails**forseniors.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%20**rails**%20for%20**adult**%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. . . ."

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

May 9, 2013

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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]

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[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" (Enclosure #3).[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

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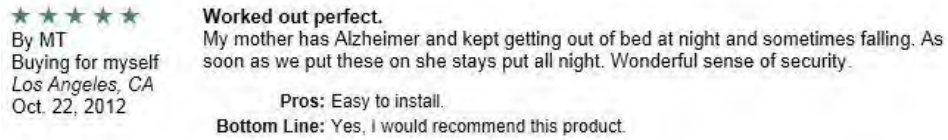
[12] Hoffman S, Powell-Cope G, Rathvon L, Bero K. BedSAFE: Evaluating a program for bed safety alternatives for frail elders. *Journal of Gerontological Nursing*. 2003;29(11), 34-42.
[13] Capezuti E, Wagner LM, Brush LB, et al. Consequences of an intervention to reduce restrictive side rail use in nursing 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 # 2 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.

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[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 #2 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/cpscpub/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

Enclosure 1

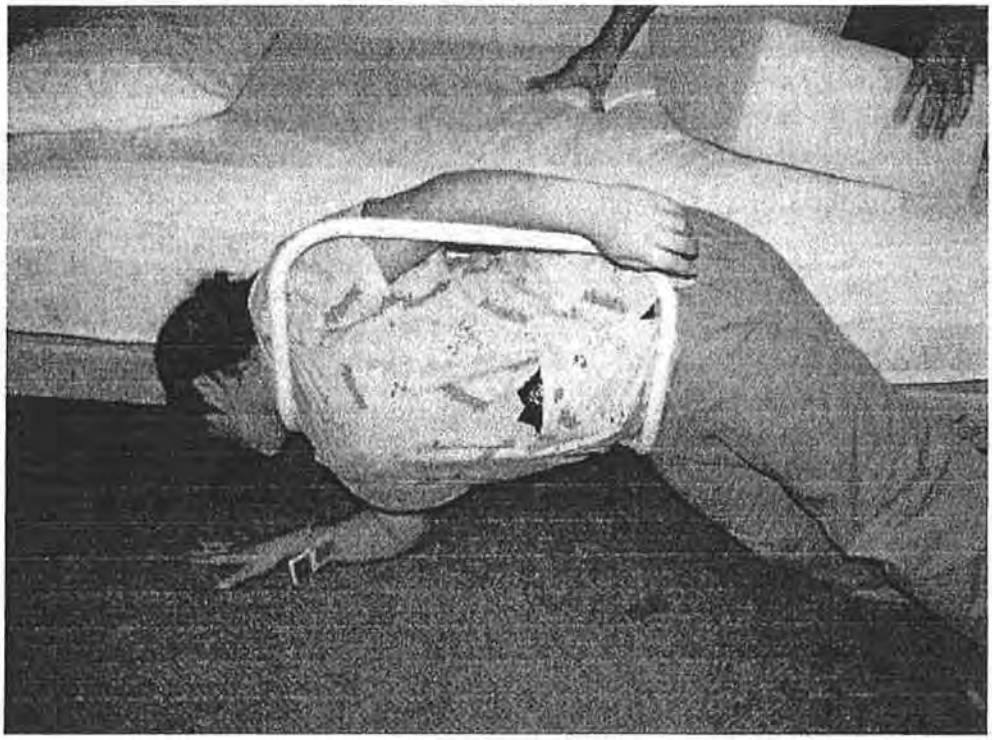

Photo # 9: View of the Caregiver demonstrating the position of the victim.

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

Enclosure 2

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 - Chrome[2]
". . . 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.

Enclosure 3

PUBLICCITIZEN

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

May 4, 2011

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.
Director, Center for Devices and Radiologic Health
Food and Drug Administration
Department of Health and Human Services
WO 66, Room 5442
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Drs. Hamburg and Shuren,

Public Citizen, a consumer advocacy group representing more than 225,000 members and supporters nationwide, hereby petitions the Food and Drug Administration (FDA), pursuant to the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, 21 USC §§ 360f and 360h, and 21 CFR §§ 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," the standard for the FDA to institute proceedings to ban a device under the device law, 21 USC § 360f and 21 CFR § 895.21(a) (these devices are intended for medical purposes to assist patients getting into 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);
>
> (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.

I. BACKGROUND

A. Regulatory status of Bedside Assistant® bed handles

Bedside Assistant® bed handles are manufactured by Bed Handles, Inc., located at 2905 Southwest 19th Street, Blue Springs, Missouri 64015.[1] These devices carry the FDA regulation description of "daily activity assist devices" (see 21 CFR § 890.5050[2]) and FDA product code IKX, are class I devices, and are 510(k) exempt.[3] A daily activity assist device is a modified adaptor or utensil (e.g., dressing, grooming, recreational activity, transfer, eating, or homemaking aid) that is intended for medical purposes to assist a patient to perform a specific function. These devices are exempt from the premarket notification procedures in Subpart E of 21 CFR Part 807.

B. Intended uses of Bedside Assistant® bed handles

Bedside Assistant® bed handles are intended for medical purposes to assist patients getting into 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, and typically are sold by home healthcare medical supply stores.

The manufacturer's website provides the following description of the Bedside Assistant® bed handles:

> Makes any bed a safer bed . . . Especially for anyone who uses a *cane* or *walker* or who feels dizzy or unsteady as they get in and out of bed.
>
> Designed by an engineer for his wife who has [multiple sclerosis], the Bedside Assistant was tested by people with weakness from Parkinson's (sic), injury, medication, hypertension, chemotherapy and stroke.[4]

The device is installed by sliding the long horizontal bars of the bed handles between the mattress and box spring of a bed (see the enclosed package insert for installation instructions for the Bedside Assistant® bed handles and the enclosed picture of Bedside Assistant® bed handles installed on a bed).

II. STATEMENT OF GROUNDS

Contrary to the manufacturer's claim that the Bedside Assistant® bed handles makes any bed a safer bed, data previously provided to the FDA demonstrates that these devices turn a bed into a death trap for patients who are physically weak and have physical or mental impairments. Our review of the FDA's Manufacturer and User Facility Device Experience (MAUDE) database reveals that since 1999 FDA has received reports of four patient 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, do 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 patients 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 cause death is straightforward and well-known to the FDA.[10] Given its design and installation, the bed handles can slip out of place, creating a gap between the edge of the patient's mattress and the vertical bars. The patient can then slip into this gap, becoming entrapped. Even a small gap, particularly when such devices are used with soft or worn mattresses, can lead to patient entrapment. Death may ensue either through compression of the trachea against the horizontal support bars and subsequent strangulation, or through positional asphyxia.[11] Enclosed are pictures in which a caregiver who found the body of a deceased patient 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[12]).

There are a number of similarly designed bed handles made by Bed Handles or other companies that have the same basic purpose and almost certainly pose the same risks of serious injury and death due to entrapment. Examples of such devices include, but are not limited to, the following:

- Adjustable Bedside Assistant Model 1™, manufactured by Bed Handles, Inc.;[13]
- Travel Handles™, manufactured by Bed Handles, Inc.;[14]

- Freedom Grip Bed Rail, manufactured by ActiveForever;[15] and
- Home Bed Assist Handle, manufactured by Drive Medical.[16]

III. SUMMARY OF REQUESTED ACTIONS

Given the risk of serious injury and death by entrapment and subsequent strangulation or positional asphyxia that is posed by Bedside Assistant® bed handles and similarly designed medical devices, as well as the limited benefits provided by these dangerous medical devices, we hereby petition the FDA to take the following actions immediately:

> (1) ban the marketing of Bedside Assistant® bed handles, model numbers BA10W and BA10W-6, by Bed Handles, Inc., because these devices present "an unreasonable and substantial risk of illness or injury," the standard for the FDA to institute proceedings to ban a device under the device law, 21 USC § 360f and 21 CFR § 895.21(a);
>
> (2) direct 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 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 a risk of death and injury similar to that seen with Bedside Assistant® bed handles.

In considering our petition, it is important for the FDA to take into account the Consumer Product Safety Commission's (CPSC's) multiple announcements in the past six years of 11 recalls involving more than 7 million drop-side baby cribs that posed a risk of death by strangulation or suffocation to infants and toddlers.[17] These recalls were in response to the deaths of 32 infants and toddlers due to strangulation or suffocation caused by or related to drop-side cribs made by various manufacturers that were reported to CPSC between January 2000 and May 2010.

The medical devices referenced in our petition pose a risk of death and serious injury primarily to older adults, who are on the opposite end of the age spectrum as the infants and toddlers exposed to dangerous drop-side cribs. It is important that Federal agencies responsible for protecting the public health act consistently by safeguarding the health and safety of both young and old individuals alike.

The number of Bedside Assistant® bed handles sold between 1994 and 2009 is in the "hundreds of thousands" according to the president of Bed Handles, Inc.[18], a number

which is between one and two orders of magnitude less than the more than 7 million drop-side cribs recalled by the CPSC over the past six years. Given the number of reported deaths caused by these two products, the ratio of patient deaths caused by the Bedside Assistant® bed handles to number of bed handles sold appears to at least equal, and more likely significantly exceeds, the ratio of infant and toddler deaths caused by drop-side cribs to the number of drop-side cribs that have been sold. Therefore, action by the FDA to ban the marketing of, and to recall, the Bedside Assistant® bed handles would be consistent with the actions taken by CPSC with respect to drop-side cribs.

IV. ENVIRONMENTAL IMPACT STATEMENT

Nothing requested in this petition will have an impact on the environment.

V. CERTIFICATION

We certify that, to the best of our knowledge and belief, this petition includes all information and views on which this petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

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

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

Enclosures: (1) Package insert for installation instructions for the Bedside Assistant® bed handles
(2) Picture of Bedside Assistant® bed handles installed on a bed
(3) Pictures demonstrating how one patient became entrapped by a Bedside Assistant® bed handle and died from strangulation

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[1] Bed Handles, Inc., website. http://www.bedhandles.com/index.htm. Accessed on March 21, 2011.

[2] Title 21 Code of Federal Regulations, Part 890, Subpart F, section 890.5050. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=890.5050. Accessed March 21, 2011.
[3] Food and Drug Administration. Product Classification Database. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=1366563. Accessed March 21, 2011.
[4] Bed Handles, Inc., website. http://www.bedhandles.com/page4.htm#page4.htm. Accessed March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=218072. Accessed March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1366564. Accessed March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI__ID=507241. Accessed March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1366563. Accessed March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=836669. Accessed March 21, 2011.
[10] Food and Drug Administration. Guidance for industry and FDA staff: hospital bed system dimensional and assessment guidance to reduce entrapment. March 10, 2006. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf. Accessed March 21, 2011.
[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 March 21, 2011.
[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. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1366563. Accessed March 21, 2011.
[13] Bed Handles, Inc., website. http://www.bedhandles.com/AJ1Page.htm. Accessed March 22, 2011.
[14] Bed Handles, Inc., website. http://www.bedhandles.com/TravelHandlesPage.htm. Accessed March 22, 2011.
[15] ActiveForever website. http://www.activeforever.com/p-2117-freedom-grip-bed-rail.aspx. Accessed March 22, 2011.
[16] Drive Medical website. https://drivemedical.com/catalog/product_info.php?products_id=733#. Accessed March 22, 2011.
[17] Consumer Product Safety Commission. CPSC issues warning on drop-side cribs: *32 fatalities in drop-side cribs in last 9 years*. May 7, 2010. http://www.cpsc.gov/cpscpub/prerel/prhtml10/10225.html. Accessed March 22, 2011.
[18] Deposition of Bon Shaw, President of Bed Handles, Inc., on February 12, 2009. Superior Court of Washington for Clark County, page 137.