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September 6, 2012

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

Dear Commissioners,

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

I. BACKGROUND

A. Manufacturer of Bedside Assistant bed handles

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

B. Advertisement for the Bedside Assistant bed handles

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. CONCLUSION

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

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

Sincerely,

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Sarah F. Wells
Executive Director
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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

¹ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.

² Bed Handles, Inc., website. Available at <http://www.bedhandles.com/>. Accessed August 22, 2012.

³ Bed Handles, Inc., website. Available at <http://www.bedhandles.com/page4.htm#page4.htm>. Accessed August 22, 2012.

⁴ Bed Handles, Inc., website. Available at <http://bedhandles.com/SecurityStrapInstallationPictorial.pdf>. Accessed August 22, 2012.

⁵ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 27, 1999, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=218072. Accessed August 22.

⁶ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on February 4, 2002, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366564. Accessed August 22.

⁷ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on January 10, 2004, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI_ID=507241. Accessed August 22.

⁸ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007 associated with Bedside Assistant[®] bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.

⁹ Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of an entrapment incident in 2006 associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=836669. Accessed August 22, 2012.

¹⁰ Food and Drug Administration. Guidance for industry and FDA staff: hospital bed system dimensional and assessment guidance to reduce entrapment. March 10, 2006. Available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf>. Accessed August 22, 2012. Available at

¹¹ Hyman WA. Bed-rail entrapments still a serious problem. McKnight's Long-Term Care News and Assisted Living. July 24, 2008. <http://www.mcknights.com/bed-rail-entrapments-still-a-serious-problem/article/112809/>. Accessed August 22, 2012.

¹² Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007, associated with Bedside Assistant bed handles. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563. Accessed August 22, 2012.