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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 § 890.5050²) 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 FDA¹²).

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.

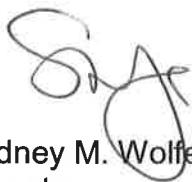
V. CERTIFICATION

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

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

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- 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/prhtml/10/10225.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.

BEDSIDE ASSISTANT®



FOR HELP GETTING IN AND OUT OF BED, MORE CONVENIENT THAN A BED RAIL -
A BED HANDLE™ MAKES ANY HOME BED A SAFER BED!

- Helps sitting, standing, rising, rolling over
- Secured between box spring and mattress,
no need to lift mattress,
nothing to harm sheets



Bonus: CONVENIENT BEDSIDE POCKETS USING A STANDARD PILLOWCASE

- 1 Pull pillowcase down over the handle, tuck in the corner points
- 2 Fold the pillowcase back over itself, pulling the hem up to the handle
- 3 Fold the pillowcase hem down again, exposing the right side of the fabric

Easy to install :

- *When you are in the bed one bar should be next to your ribcage and the other bar next to your calves.*
- ***Position** bars on the same side of the bed leaving a comfortable sitting space in between.*
- ***Slide** the long ends of the bars all the way under the mattress.*
- ***Push** the handle end snugly against the side of the mattress.*
- *Bars may be pulled out a few inches to make the bed or change the sheets but must be pushed all the way in before using.*



ONE SET: MODEL BA10W

Caution: This equipment is designed to give you a place to put your hands for assisting while sitting, standing, rising and rolling over. Do not sit on the bed handle. Do not allow children to play with. Read other side before using. **MAY NOT BE SUITABLE FOR USE WITH SOME LIGHTWEIGHT TWIN MATTRESS BEDS. NOT FOR USE WITH HOSPITAL BEDS. TEST CAREFULLY.**

Dear Valued Customer,

Thank you for purchasing the **BEDSIDE ASSISTANT**[®]. We hope that this product meets your needs and makes your life a little easier. This product has been designed to assist while sitting, standing, rising and rolling over in bed. Bed Handles are like grab bars and are not bed rails. Our hope is to offer a helpful product at a reasonable price; we are not responsible for losses, damages, injuries or death caused by use or misuse thereof.

Please use the **BEDSIDE ASSISTANT**[®] with care and caution but use it at your own risk. Do not rely on the bed handle to support your entire weight, do not allow children to use, do not allow the handle to be obscured by bedding. If bar becomes dented or crimped discontinue use. This product may not be suitable for use with some lightweight (usually foam) twin mattress beds. Not intended for hospital beds.

IMPORTANT - READ CAREFULLY BEFORE USING PRODUCT

INTENDED USE - This model BA10W **BEDSIDE ASSISTANT**[®] is designed to be used only for assisting while sitting, standing, rising and rolling over. However, *each* handle of the model BA10W **BEDSIDE ASSISTANT**[®] is designed to support no more than 175 pounds of weight when used. Remember, the **BEDSIDE ASSISTANT**[®] must only be used when each unit is completely inserted between conventional box springs and mattress with each handle portion fully inserted up to the mattress. Failure to do this will compromise the ability of the **BEDSIDE ASSISTANT**[®] to sustain the designed maximum weight capacity. *Avoid using this product where the bed frame may dent the **BEDSIDE ASSISTANT**[®].*

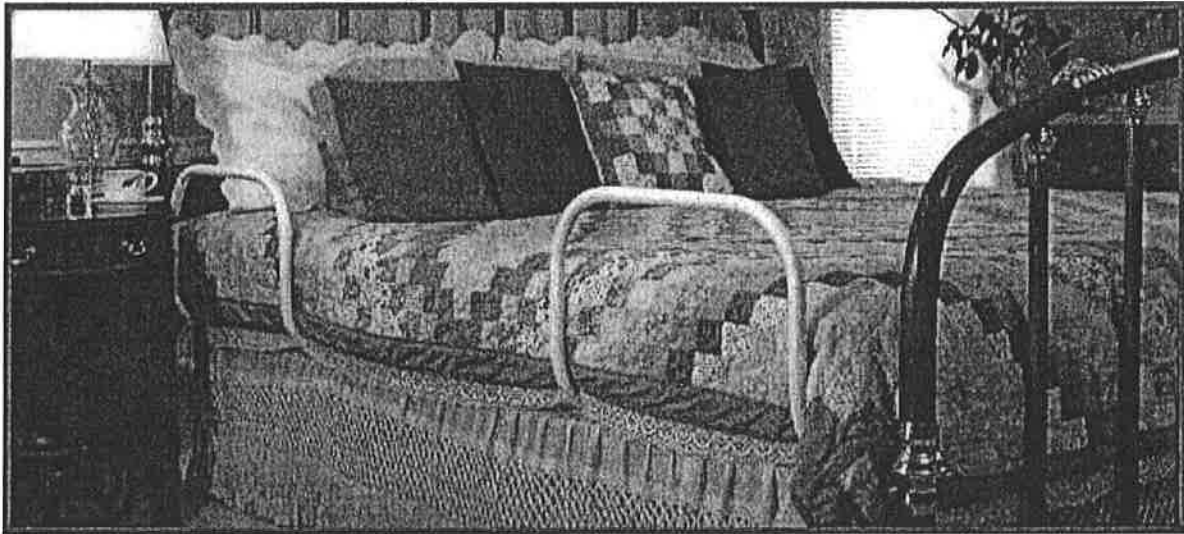
THE **BEDSIDE ASSISTANT[®] OBTAINS ITS STRENGTH FROM STEEL TUBING. AS WITH ANY PRODUCT MADE FROM TUBING, ITS USE SHOULD BE DISCONTINUED IF THE TUBING SHOULD BECOME DENTED. SUCH DAMAGE MAY LEAD TO PRODUCT FAILURE AND MAY CAUSE PERSONAL INJURY. IF DENTED THE PRODUCT MUST NOT BE USED.**

LIMITED WARRANTY Bed Handles, Inc. warrants this product under normal use against defects in material and workmanship to the original purchaser for one (1) year from the original date of purchase. Any implied warranties, including the warranties of merchantability and fitness for a particular purpose, are limited to the duration of the express warranty described above. Some states do not allow limitations on the duration of an implied warranty, so the above limitation may not apply to you. This warranty is void if, in the sole discretion of Bed Handles, Inc., the product has been damaged by accident, neglect, misuse, abuse or other causes not arising out of defects in material or workmanship.

DISCLAIMER OF WARRANTY - The foregoing warranties are in lieu of all other warranties, express or implied, including but not limited to the implied warranties of merchantability and fitness for a particular purpose.

EXCLUSIVE REMEDY - During the warranty period Bed Handles, Inc. will repair or replace the defective unit free of charge when the unit is returned to Bed Handles, Inc. or to the dealer from which the product was purchased.

Bedside Assistant[®] on a bed



-
- **Convenient** - For help getting in and out of bed
 - **Strong** - Each handle features one piece steel construction
 - **Attractive** - White, textured, cushioned vinyl grip surface
 - **Unique** - A handle for each hand, no twisting to one side
 - **Economical** - Keep your own bed
 - **Adaptive** - Adjustable room to sit
 - **Safer** - Leaves floor space clear
 - **Easy** - Super simple to install
 - **Works** - with ordinary mattress & box springs, platform or water bed

[Home Page](#)

[Previous Page](#)

[Next Page](#)

Bedside Assistant (R), Travel Handles (tm) and Bed Handle (tm) and ByteSwitch (tm) are registered trademarks of Bed Handles, Inc. and are protected by one or more United States patents.

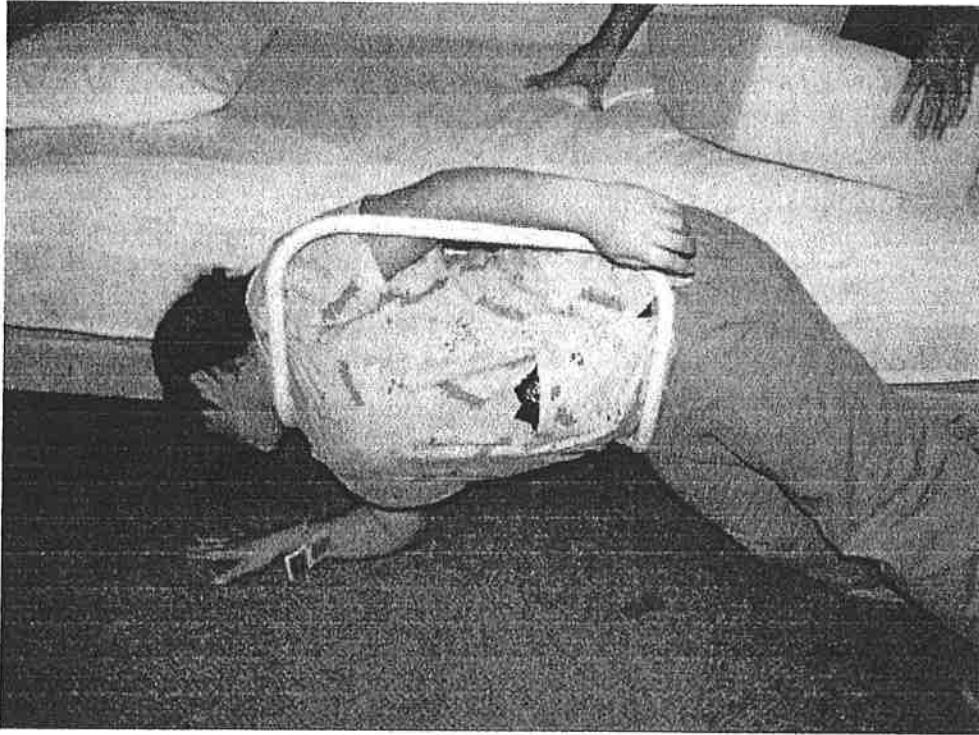


Photo # 9: View of the Caregiver demonstrating the position of the victim.

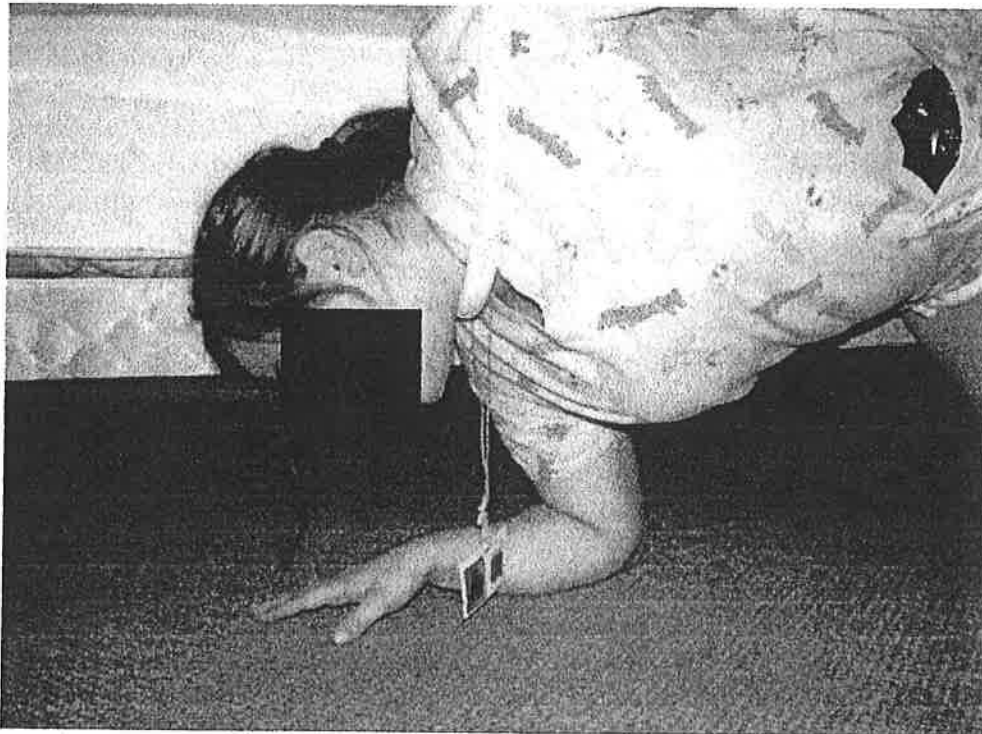


Photo # 10: Close-up view of the demonstration.