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December 13, 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.  
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Food and Drug Administration  
Department of Health and Human Services  
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Silver Spring, MD 20993-0002

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5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**RE: Citizen Petition – Docket Number FDA-2011-P-0438**

Dear Drs. Hamburg and Shuren,

Public Citizen, a consumer advocacy group representing more than 225,000 members and supporters nationwide, wishes to supplement its May 4, 2011 petition to the Food and Drug Administration (FDA) (docket number FDA-2011-P-0438).<sup>1</sup>

**I. Summary and Status of Original Petition**

In our petition, we requested that 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, 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 U.S.C. § 360f and 21 C.F.R. § 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 numbers 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.

In our petition, we cited reports of four patient deaths secondary to entrapment by Bedside Assistant bed handles that had been submitted to the FDA’s Manufacturer and User Facility Device Experience (MAUDE) database.<sup>2,3,4,5</sup> In three of these cases, the description clearly was consistent with death caused by asphyxiation or strangulation. We also noted a fifth report in the MAUDE database describing another life-threatening incident in which this device entrapped a hospital patient.<sup>6</sup>

With respect to our requested action (3) above, we noted that there were a number of bed handles similar to the Bedside Assistant bed handles, model numbers BA10W and BA10W-6, that are manufactured by Bed Handles, Inc., and 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 included, but were not limited to, the following:

- Adjustable Bedside Assistant Model 1, manufactured by Bed Handles, Inc.;<sup>7</sup>
- Travel Handles, manufactured by Bed Handles, Inc.;<sup>8</sup>
- Freedom Grip Bed Rail, manufactured by ActiveForever;<sup>9</sup> and
- Home Bed Assist Handle, manufactured by Drive Medical Design and Manufacturing (Drive).<sup>10</sup>

We have not yet received a decision from the agency on our petition.

## II. Supplemental Information

Our recent review of the MAUDE database revealed a September 13, 2011 report of a patient who died from strangulation and suffocation on February 5, 2011, after becoming entrapped by a Home Bed Assist Rail, model number 15064, manufactured by Drive (Port Washington, NY)<sup>11</sup> (copy of report enclosed).

Like the Bedside Assistant bed handles, the Drive Home Bed Assist Rail<sup>12</sup> carries the FDA regulation description of “daily activity assist devices” (see 21 C.F.R. § 890.5050<sup>13</sup>) and the FDA product code IKX, is a class I device, and is 510(k) exempt.<sup>14</sup> The manufacturer’s product summary indicates that the device is used to assist patients in getting in and out of bed. The design and function of the Drive Home Bed Assist Rail are nearly identical to those of the Bedside Assistant bed handles.

The mechanism by which the Drive Home Bed Assist Rail resulted in the reported patient death is identical to that seen in the deaths caused by the Bedside Assistant bed handles.<sup>15</sup> Given its design and installation, the Drive Home Bed Assist Rail 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.<sup>16</sup> The presence of a safety strap that wraps around the mattress or box spring does not eliminate the risk of death from this type of medical device.

It is imperative that the FDA promptly grant our petition to immediately:

- (1) ban the marketing of (a) Bedside Assistant bed handles, model numbers BA10W and BA10W-6, manufactured by Bed Handles, Inc.; (b) the Home Bed Assist Rail, model number 15064, manufactured by Drive Medical Design and Manufacturing; and (c) any similarly designed bed handle or bed rail devices manufactured by Bed Handles, Inc., Drive Medical Design and Manufacturing, or any other manufacturer.
- (2) order the manufactures of these devices to recall all such devices that have been sold or distributed.

Further delay by the FDA will result in additional preventable deaths of vulnerable elderly patients due to these dangerous devices.

### III. Environmental Impact Statement

Nothing requested in this supplement to our original petition will have an impact on the environment.

### IV. Certification

We certify that, to the best of our knowledge and belief, this petition supplement includes all information and views on which this petition supplement 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's Health Research Group

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

Enclosures: (1) MAUDE report of patient death caused by the Drive Medical Design and Manufacturing Home Bed Assist Rail  
(2) Product Summary of the Drive Home Bed Assist Rail

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<sup>1</sup> Carome MA, Wolfe SM. Petition to the FDA to ban the marketing of Bedside Assistant<sup>®</sup> bed handles. May 4, 2011. Available at <http://www.citizen.org/documents/1947.pdf>. Accessed December 9, 2011.

<sup>2</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 27, 1999 associated with Bedside Assistant<sup>®</sup> bed handles. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=218072](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=218072). Accessed March 21, 2011.

<sup>3</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on February 4, 2002 associated with Bedside Assistant<sup>®</sup> bed handles. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=1366564](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366564). Accessed March 21, 2011.

<sup>4</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on January 10, 2004 associated with Bedside Assistant<sup>®</sup> bed handles. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI\\_ID=507241](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.cfm?MDRFOI_ID=507241). Accessed March 21, 2011.

<sup>5</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on March 9, 2007 associated with Bedside Assistant<sup>®</sup> bed handles.

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=1366563](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=1366563).

Accessed March 21, 2011.

<sup>6</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of an entrapment incident in 2006 associated with Bedside Assistant<sup>®</sup> bed handles.

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI\\_ID=836669](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI_ID=836669).

Accessed March 21, 2011.

<sup>7</sup> Bed Handles, Inc., website. <http://www.bedhandles.com/AJ1Page.htm>. Accessed March 22, 2011.

<sup>8</sup> Bed Handles, Inc., website. <http://www.bedhandles.com/TravelHandlesPage.htm>. Accessed March 22, 2011.

<sup>9</sup> ActiveForever website. <http://www.activeforever.com/p-2117-freedom-grip-bed-rail.aspx>. Accessed March 22, 2011.

<sup>10</sup> Drive Medical Design and Manufacturing website.

[http://drivemedical.com/catalog/product\\_info.php?products\\_id=733#](http://drivemedical.com/catalog/product_info.php?products_id=733#). Accessed March 22, 2011.

<sup>11</sup> Food and Drug Administration. Manufacturer and User Facility Device Experience database: report of patient death on February 5, 2011 associated with Drive Medical Design and Manufacturing Bed Assist Rail. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI\\_ID=2281458](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI_ID=2281458).

Accessed December 9, 2011.

<sup>12</sup> Drive Medical Design and Manufacturing. Product summary for Home Bed Assist Rail, model number 15064. Available at [https://www.drivemedical.com/catalog/product\\_info.php?products\\_id=2109#](https://www.drivemedical.com/catalog/product_info.php?products_id=2109#).

Accessed December 9, 2011.

<sup>13</sup> Title 21 Code of Federal Regulations, Part 890, Subpart F, section 890.5050.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?fr=890.5050>. Accessed December 9, 2011.

<sup>14</sup> Food and Drug Administration. Product Classification Database.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=4429>. Accessed

December 9, 2011.

<sup>15</sup> 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 December 9, 2011.

<sup>16</sup> 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 December 9, 2011.