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BS&S FEATURE

Safe, Portable Bed Rails: There's No Such Thing

Request to Stop False Advertising Goes to Federal Trade Commission

Consumer groups have opened another front in the long battle to prevent injury of patients from use of devices commonly thought to promote safety—bed rails—by involving the Federal Trade Commission (FTC).

These devices have been recommended by both families and physicians who may have little reason to suspect that the very products intended to make patients safer, and advertised as such, instead, make the bed far more dangerous.

In September, watchdog groups Public Citizen and the National Consumer Voice for Quality Long-Term Care sent the FTC a formal request¹ to order Bed Handles Inc to stop making false claims of safety for its Bedside Assistant portable bed rails. In May 2011, Public Citizen had submitted a petition² to the FDA (FDA-2011-P-0438) to ban the marketing of Bedside Assistant bed handles, models BA10W and BA10W-6; direct Bed Handles Inc to recall them; and investigate the design and use of similar bed handle or bed rail devices and the risk of

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RECALLS & FIELD CORRECTIONS—CLASS I

Custom Medical Specialties Procedure Kits

Custom Medical Specialties Inc (Pine Level, North Carolina) recalled a series of kits that contain previously recalled povidone-iodine prep solutions and pads. The firm notified customers on August 23, 2012, of the following class I recalls:

- 1) CMS-4501-R1 Custom HSG Tray containing 2 oz PVP Prep Bottle—5 cases (Recall # Z-2349-2012);
- 2) CMS-8457 Hysteroscopic Sterilization Pack containing 4 oz bottle PVP Prep—3 cases (Recall # Z-2350-2012);
- 3) CMS-4316 Custom Vein Tray containing 4 oz bottle PVP Prep Solution—6 cases (Recall # Z-2351-2012);
- 4) CMS-8450-R1 Custom Vein Tray containing 4 oz bottle PVP Prep Solution—3 cases (Recall # Z-2352-2012);
- 5) CMS-2586 Custom Amnio Tray containing 2 oz bottle PVP Prep Solution—7 cases (Recall # Z-2353-2012);

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life-threatening injury or death from entrapment, strangulation, or positional asphyxia and ban those devices as appropriate.

The FDA has reports of more than 525 deaths associated with the use of bed rails. The Consumer Product Safety Commission (CPSC) has reports of more than 155 deaths as well. Most often, these deaths are a result of entrapment (Figure 1), which, particularly where a portable bed rail is concerned, can occur when the device slides outward as the child or adult leans into the handle or rail. Altogether, 7 entrapment zones have been identified with use of bed rails.

Manufacturers such as Bed Handles Inc have been allowed to make advertising claims that include “makes any bed a safer bed,” and “stable in all directions and can be firmly pulled, pushed, lifted, and leaned on,”¹ unfettered by requirements to prove such claims.

The CPSC was required by Congress in the Consumer Product Safety Improvement Act of 2008 to set mandatory safety standards for durable infant nursery products, including portable children’s bed rails. Use of these rails had resulted in well-documented injuries and deaths in children up to 6 years of age. After implementation of the standards, childhood crib and bed-related injuries declined quickly and dramatically. In 2012, the CPSC passed its rulemaking CPSC-2011-0019 on Safety Standard for Portable Bed Rails,



Figure 1. Rail and mattress entrapment resulting in asphyxiation. Hospital bed side rails and portable rails such as Bed Handles pose similar dangers. (From *Am J Nurs.* 2001;101(7):43-48.²)

but this addressed portable bed rails for children and toddlers only, not adults.

It’s important to know that although elderly patients fall at a much higher rate than the general population, and a fall at an advanced age can be catastrophic, research demonstrates the following:

- The presence of bed rails does not deter adults or children from trying to get out of bed;

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- There is no evidence that side rails prevent falls;
- There are already evidence-based methods to reduce the incidence of bed-related falls, including lowering bed height and placing anti-slip matting at the bedside;
- Bed rails themselves can be more dangerous to patients than falls;
- A fall with a bed rail in place is more dangerous than a fall without a rail, because of the change in trajectory of the fall; and
- Patients can be injured or killed through use of these devices.¹⁻⁴

The FDA is fully aware that incidents of injury or death associated with bedrail use are vastly under-reported. When an incident has taken place, home users and even medical staff in a care facility or hospital might not be aware that adverse events should be reported to the FDA and/or CPSC. Some facilities may seek to conceal a person's cause of death for fear of liability or suggest that the patient bore some responsibility for the event.

During an investigation of a 2007 death involving the Bedside Assistant device, the owner of Bed Handles Inc stated that he does not think patients with dementia should use his products. Two of the FDA Manufacturing and User Facility Device Experience (MAUDE) database reports of death allegedly involving Bed Handles devices state that the company has not complied with mandatory reporting requirements when a death has occurred. In legal proceedings, Bed Handles Inc claimed ignorance of any documented safety concerns related to its product, and no warnings of asphyxiation appeared on the devices or labeling. A further problem is that these are class I devices and as such are exempt from the 510(k) approval process.

CPSC commissioner Robert Adler points out that older Americans comprise 13% of the population yet suffer 60% of the deaths associated with consumer products. Injury-related emergency department visits at age 75 and up occur at double the rate for persons age 65 to 74.⁵ In addition to the human toll, the overall cost is at least \$100 billion per year.

Given portable bed rails are sold directly to consumers and in medical supply stores, consumer groups think the CPSC and the FDA, both of which have been petitioned for rulemaking repeatedly in these matters, should be taking action to regulate, force recalls, and effectively oversee marketing and sales of the devices. Commissioner Adler says, "The time is now for the creation of a national action plan for the prevention of deaths and injuries to older Americans."⁶ The addition

of the FTC to this full court press recognizes that resolving this problem will be a multi-agency effort. ♦

References

1. Public Citizen. Letter to Federal Trade Commission. September 2, 2012. <http://www.citizen.org/hrg2069>.
2. Public Citizen. Petition to ban Bedside Assistant Bed Handles, model numbers BA10W and BW10W-6, manufactured by Bed Handles, Inc. Mary 4, 2011. <http://www.citizen.org/hrg1947>.
3. Talerico KA, Capezuti E. Myths and facts about side rails. *Am J Nurs.* 2001;101(7):43-48.
4. Span P. Safe in bed? *New York Times.* March 10, 2010. <http://newoldage.blogs.nytimes.com/2010/03/10/safe-in-bed/>.
5. US Consumer Product Safety Commission. Statement of Robert S. Adler Commissioner before the House Committee on Energy and Commerce Subcommittee on Commerce, Manufacturing, and Trade. August 2, 2012.
6. Adler R. Adler: We need a plan to protect older Americans. *Roll Call.* June 14, 2012. http://www.rollcall.com/issues/57_151/We_Need_Plan_to_Protect_Older_Americans-215351-1.html.

RECALLS & FIELD CORRECTIONS—CLASS I

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- 6) CMS-8162-R1 Fox Chase Specials Pack containing 2 oz bottle PVP Prep Solution—75 cases (Recall # Z-2354-2012);
- 7) CMS-8325-R2 Abington Radiology Drainage Pack and CMS-8325-R3 Abington Radiology Drainage Pack containing 4 oz bottle PVP Prep Solution—195 cases (Recall # Z-2355-2012);
- 8) CMS-8495-R5 Custom Vein Tray containing 4 oz bottle PVP Prep Solution—15 cases (Recall # Z-2356-2012);
- 9) CMS-4873 Custom CT Biopsy Tray, CMS-4873-R1 Custom CT Biopsy Tray containing 4 oz bottle PVP Prep Solution—538 cases (Recall # Z-2357-2012);
- 10) CMS-4975 HSG Tray containing 4 oz bottle PVP Prep Solution—4 cases (Recall # Z-2358-2012);
- 11) CMS-5284 Custom Myelogram Tray containing 2 oz bottle PVP Prep Solution—8 cases (Recall # Z-2359-2012); and
- 12) BR980-9600 Hysteroscopy Sterile Procedure Kit containing 2 oz bottle PVP Prep Solution—75 cases and 60 bottles (Recall # Z-2360-2012).