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November 30, 2012

The Honorable Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Hamburg:

Bed rails commonly used in hospitals, nursing homes, assisted living facilities, and patients' homes are often marketed as products that prevent individuals from falling out of bed or that help them get up. However, elderly and frail patients, especially those who are sedated or suffer from diseases such as Alzheimer's, can become trapped and injured in the space between or within the rails. Others may slip into the narrow gap between the bed rails and the mattress and suffocate when their head or torso is compressed in that space. Though manufacturers have made significant strides in bed rail design since 2006, recent injuries and deaths underscore the need for additional steps to improve the safety of these devices, particularly those that are already in use.

In 2006, the Food and Drug Administration (FDA) issued guidance to reduce the risk of fatal entrapments associated with hospital bed systems, including side bed rails. The guidance, which focused primarily on beds used in the hospital setting, recommended the dimensional limits of gaps that should occur in hospital bed systems in order to reduce the risk of entrapment. Though these recommendations have led to improvements in the design of new hospital beds and their use in clinical settings, elderly patients continue to suffer injury and death as a result of entrapment in the bed rails. According to a review conducted by *The New York Times*, 550 people have died since 1995, including 27 people last year alone.¹ The real number is almost certainly higher, since bed rails may not be listed as a cause of death and health care facilities, unclear on how to report the incident or worried about liability, may not accurately report the accident.

¹ Nixon, Ron. "After Dozens of Deaths, Inquiry Into Bed Rails." *The New York Times* [New York] 25 Nov. 2012

Providing health care workers with information about the maximum gaps in hospital beds is an important step toward protecting patient safety. However, other factors are also important when it comes to ensuring the safety of bed systems. For example, the firmness of the mattress or the size of the mounting brackets used to support the bed rails could increase the risk of the patient slipping in between the mattress and bed rail. Furthermore, because many hospital bed components have varying life expectancies, they will need to be replaced at different times. The Hospital Bed Safety Work Group (HBSWG), a partnership between FDA, patient groups, the medical bed industry, and other federal agencies, found that improving the compatibility of the different components of hospital beds could significantly reduce the risk of bed rail injuries.

FDA recognized this problem in its 2006 guidance, which encouraged bed system manufacturers to “identify compatible mattresses, rails, and accessories” and encouraged healthcare facilities to “contact their equipment suppliers for entrapment mitigating solutions that may already be available.”² However, this guidance is voluntary and lack of a standardized system for identifying compatible components can be confusing for users. According to Elizabeth Capezuti, a geriatric nurse researcher at New York University, the problem of mismatched components is especially relevant with legacy beds (i.e., beds that are already in use). Because the bed components, including bed rails and mattresses, exceed their life expectancy at different times, they are often replaced with versions that are incompatible – and dangerous – when assembled with the rest of the bed system.

- 1) Does FDA believe that standardizing the system used to identify compatible hospital bed components, as well as requiring manufacturers of hospital beds and hospital bed accessories (i.e. bed rails, mattresses, head and foot boards) to list the other components that are compatible with their product, could reduce entrapment? Please explain why or why not.

Most large bed manufacturers currently include entrapment warning material along with the bed instructions, but this information can quickly become separated from the beds and lost. This is especially true of older beds that are resold to nursing homes or assisted living facilities. A more effective approach could be requiring that warning labels be permanently affixed to the rails, communicate the risk of entrapment, and provide risk mitigation strategies.

- 2) Does FDA believe permanently affixed labels could improve awareness among health care workers, patients, and families and help reduce entrapment? Please explain why or why not.

Some manufacturers make claims indicating that their bed rails are universally compatible by stating, for example, that the rail “makes any bed a safer bed”. Such a statement seems to contradict the findings of the HBSWG and FDA’s own guidance,

² U.S. Food and Drug Administration. Center for Devices and Radiological Health. *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*. N.p., 10 Mar. 2010.

which describe the many factors that could change the way a bed system fits together and thus pose a risk to patients. In addition, some medical experts and consumer advocate groups believe that certain patients, such as those who are confused and disoriented, face added risks of injury when bed rails are in use, whether through entrapment or a fall.³

- 3) Does FDA believe that claims of universal compatibility or blanket statements that a bed rail increases the safety of "any bed" by preventing patient injury are appropriate or supported by available evidence? Please explain why or why not.
- 4) Does FDA verify claims made by manufacturers in the advertising for their bed rail devices? If yes, how? If not, why not?
- 5) Does FDA coordinate with the Federal Trade Commission (FTC) in evaluating these claims?
- 6) Does FDA verify whether a manufacturer's design is meeting recommended safety standards for bed rails? If yes, how? If not, why not?

An additional factor complicating efforts to reduce entrapment is the issue of which federal agency has oversight responsibility of patient beds and accessories. While beds and accessories used in hospitals, nursing homes, and assisted living facilities – the focus of the 2006 guidance – are under FDA's purview, there is more gray area when it comes to beds purchased for use in a patient's home. According to the articles in *The New York Times*, new coordination efforts between FDA and the Consumer Product Safety Commission (CPSC) are underway to "find a way to close the regulatory gap" on this issue.⁴

- 7) Please describe FDA's effort to address any regulatory gap that exists between the agency and CPSC or FTC when it comes to regulating the manufacture, sale, and oversight of patient beds and bed accessories?

I commend efforts undertaken in recent years by federal agencies and device manufacturers to improve the design and use of new bed systems but remain concerned about the injury that bed rails can cause to elderly patients, particularly when the injury involves legacy beds. I therefore ask that the FDA join CPSC and FTC in forming a task force dedicated to better addressing the regulation and oversight of these products. The task force should address ways to improve the oversight of devices that blur the line between "medical devices" and "consumer products", strengthen provider education about entrapment risks, and advance the use of compatible bed and bed rail systems among healthcare providers. Because responsibility for the safety of this class of products is ultimately shared between these agencies, the FDA, FTC, and CPSC should increase their coordination in order to achieve more oversight.

³ See Parker, Kara, BA, and Steven H. Miles, M.D. "Deaths Caused by Bedrails." *Journal of American Geriatric Society* 45.7 (1997): 797-802; Adekanmbi, Omoniyi. "The Myth of Benign Bedrails." *The National Consumer Voice for Quality Long-Term Care*, 2011.

⁴ Nixon, Ron. "After Dozens of Deaths, Inquiry Into Bed Rails." *The New York Times* [New York] 25 Nov. 2012.

I appreciate your attention to this issue and request a response no later than February 28, 2013. If you have any questions, please contact Sara Schaumburg in my office at 202-225-2835 or sara.schaumburg@mail.house.gov.

Sincerely,

Edward J. Markey

cc: Jon Leibowitz, Chairman, Federal Trade Commission
Inez Tenenbaum, Commissioner, Consumer Product Safety Commission