



U.S. Consumer Product
Safety Commission
www.cpsc.gov



U.S. Food and Drug Administration
www.fda.gov

June 13, 2013

We are writing to request your assistance with much-needed efforts to reduce injuries and deaths associated with the use of adult portable bed rails. Incident reports received by the U. S. Consumer Product Safety Commission (CPSC) indicate that adult portable bed rails currently on the market are associated with a substantial number of injuries and deaths among users, particularly the elderly. Specifically, CPSC staff is aware of 160 tragic incidents between 2003 and 2012 alone that involved entrapments, entanglements, or strangulations in bed rails. Of these 160 reported incidents, 155 resulted in fatalities.¹ Additionally, seven death reports associated with portable bed rails were submitted to FDA's Manufacturer and User Facility Device Experience (MAUDE) database from 2005 through 2012.

Considering the number of deaths and injuries, we strongly believe all reasonable and timely efforts should be undertaken to address this hazard and protect the safety of the public. Currently, there are no mandatory or voluntary product safety standards for adult portable bed rails.² This must change.

At the request of CPSC and FDA, ASTM International is forming a committee to develop a new voluntary standard for adult portable bed rails. If your company or organization has not already committed to join this process and participate in the development of a consensus-based, voluntary industry standard to address the hazards associated with the use of adult portable bed rails, we request that you do so.

It is our understanding that ASTM has set a meeting on this topic. This meeting is scheduled for **Wednesday, June 19, 2013, at 2:00 pm (EST)** and will be held via the web through Webex, an

¹ For additional information about adult bed rail related incidents, please see a CPSC staff report at: <http://www.cpsc.gov/PageFiles/133466/adultbedrail.pdf>.

² The ASTM International (ASTM) voluntary standard for portable bed rails, ASTM F 2085, *Standard Consumer Safety Specification for Portable Bed Rails* defines a "portable bed rail" as a device intended to be installed on an adult bed to prevent children from falling out of bed. These bed rails are intended for children who can get in and out of an adult bed unassisted, typically ranging in age from two to five years old. However, this standard is not intended to address the risks associated with the use of adult portable bed rails.

online interactive conferencing tool.³ The meeting is open to anyone, and ASTM membership is not required to participate. Please feel free to forward this information to other interested parties. Please **RSVP to Jamie Huffnagle (jhuffnag@astm.org) to receive the access information for the Webex meeting.**

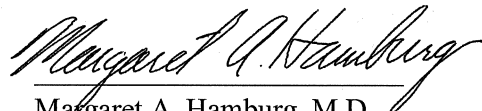
Our staffs will be participating in the ASTM effort and can provide technical assistance for this process. If you have any questions, please contact either the CPSC coordinator of its Mechanical Hazards Team, Richard McCallion, by phone at 301.987.2222 or by email at rmccallion@cpsc.gov or contact the FDA Bed Rails Standards Workgroup Coordinator, Joan Ferlo Todd, Nurse Consultant, by phone at 301.796.6079, or by email at joan.todd@fda.hhs.gov.

Thank you for your assistance. We look forward to your involvement in the ASTM committee meeting.

Very truly yours,



Inez. M. Tenenbaum
Chairman
U.S. Consumer Product Safety Commission



Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration

cc: Colin Church, Voluntary Standards Coordinator, U.S. Consumer Product Safety Commission
Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health

³ For more information about the meeting, please contact Len Morrissey, Director, ASTM, by phone at 610.832.9719 or by email at lmorris@astm.org.