

APPENDIX ONE

*Office of the***Maine Attorney General****Consumer Alerts***Tired of telemarketers? Sign up for the **DO NOT CALL** list.*

CONSUMER SAFETY ALERT

Fall 2006

THE USE OF AIR MATTRESSES AND BEDRAILS CAN CAUSE DEATHS
OR SERIOUS INJURY TO
ELDERLY AND VULNERABLE MAINE CITIZENS

The Maine Elder Death Analysis Review Team ("MEDART") and the Maine Office of the Attorney General issue this Consumer Safety Alert to warn Maine citizens about the potential danger to elderly or vulnerable individuals from combining the use of air mattresses and bedrails. Individuals susceptible to decubitus ulcers or pressure sores are frequently placed on an air mattress on top of a regular mattress. Unfortunately during the last two annual reporting periods, MEDART has reviewed cases involving deaths attributed to asphyxia caused by compression of the neck after an individual slipped off an air mattress and became entrapped in a bed rail.

According to the U.S. Food and Drug Administration, there are about 2.5 million hospital and nursing home beds in use in the United States in facilities and homes. Between 1985 and 2005, 691 incidents of patients caught, trapped, entangled, or strangled in beds with rails were reported. Of these reports, 413 people died, 120 had a nonfatal injury, and 158 were not injured because staff intervened. Most patients were frail, elderly or confused.

What you need to know:

1. You should have a heightened level of concern when using an air mattress in conjunction with any bedrail, including quarter length rails.

2. You should continually check and monitor the bed rails, mattress height / fit and bed choice to ensure patient safety. You should be watchful of any product failure or malfunction (such as loss of air or compressibility due to weight) and report any concerns or problems to the facility where your family member resides or to the manufacturer if you are using the product at home.

3. Your family member should receive a proper individual patient safety assessment and ongoing patient monitoring to determine the benefits and/or risks of using bed rails and other safety restraints from either facility or home care professionals.

For additional information check out the following website and reports.

A. On August 21, 1995, the Food and Drug Administration (FDA) sent an "Alert" to hospitals and long-term care facilities which warned them of the dangers that bed rails pose.

See <http://www.fda.gov/cdrh/beds/index.html>

B. On July 13, 2001, the Veterans Administration issued a Safety Alert concerning patient entrapment because of bedrails and air mattresses.

See <http://www.va.gov/NCPS/alerts/BedEntrap.doc>

C. On March 9, 2006, the Food and Drug Administration (FDA) issued FDA Issued Guidance on Hospital Bed Design to Reduce Patient Entrapment.

See <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01331.html>

D. A Bed Safety Entrapment Kit is available for purchase at:

NST Sales & Customer Service Office:
5154 Enterprise Blvd.
Toledo, Ohio 43612
(800) 678-7072