Markey Calls for National Task Force to Help Protect Patients from Bed Rail Injury, Strengthen Safety

Lawmaker queries FDA on regulations related to the manufacture, sale, and oversight of patient beds and bed accessories

In the wake of a recent review conducted by The New York Times that revealed 550 people have died since 1995 as a result of entrapment in bed rails, including 27 people in 2011, Congressman Edward J. Markey (D-Mass.) today called on the Food and Drug Administration (FDA), Federal Trade Commission (FTC), and Consumer Product Safety Commission (CPSC) to form a national task force dedicated to better addressing the regulation and oversight of bed systems and bed rails. Despite efforts undertaken in recent years by federal agencies and device manufacturers to improve the design and use of new bed systems, including voluntary measures released by the FDA, Rep. Markey remains concerned about the injury that bed rails can cause to elderly patients, particularly when the injury stems from beds that are already in use. Bed rails, while commonly used in hospitals, nursing homes, and assisted living facilities and marketed as products that assist patients or prevent patients from falling out of bed, but can entrap elderly and frail patients, leading to suffocation and death.

“While bed rail design has improved in recent years, older models that pose a risk to the elderly are still used in some hospitals and nursing homes across the country,” said Rep. Markey, a senior member of the Energy and Commerce Committee, which has jurisdiction over the FDA, FTC and CPSC. “Comprehensive oversight of these products, which sometimes blur the line between medical devices and consumer products, requires coordination among federal agencies. We need a national task force dedicated to addressing any regulatory gaps in order to protect these vulnerable patients from preventable bed rail injuries.”

A copy of Rep. Markey’s letter to the FDA can be found HERE [1].

Rep. Markey asks the FDA to respond to question that include:

- What are 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?
- Does FDA believe permanently affixed labels could improve awareness among health care workers, patients, and families and help reduce entrapment?
- Does FDA believe that claims of universal compatibility or statements that a bed rail increases the safety of “any bed” by preventing patient injury are appropriate or supported by available evidence?

- Does FDA verify claims made by manufacturers in the advertising for their bed rail devices?
- Does FDA verify whether a manufacturer's design is meeting recommended safety standards for bed rails?

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Links:
[1] http://markey.house.gov/document/2012/letter-fda-bed-rails