U.S. SENATOR MICHAEL BENNET
Member: Agriculture, HELP, Banking and Aging Committees

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Bennet Pushes for Greater Safety Oversight of Medical Products to Protect Coloradans

Call Comes on the Heels of Recall of Millions of Triad Group Medical Products

Washington, DC – In light of the recent recall of millions of Triad Group medical products due to contamination and sterilization problems in the manufacturing process, U.S. Senators Michael Bennet (D-CO) and Lamar Alexander (R-TN) today called for better oversight by the Food and Drug Administration (FDA) of medical product manufacturing to protect Coloradans and all Americans from unnecessary health risks. In a letter to Dr. Margaret Hamburg, FDA commissioner, the Senators urged the FDA to carefully review its oversight of medical product manufacturing to avoid similar problems and recalls in the future.

"In light of this recall and the health consequences to patients being exposed to contaminated products, we urge the Food and Drug Administration (FDA) to carefully review its oversight of medical product manufacturing to ensure that manufacturers comply with the voluntary compliance measures suggested by FDA inspectors," wrote the Senators, who are both members of the Senate Committee on Health, Education, Labor and Pensions. "We are particularly concerned by media reports that suggest that the FDA was aware as early as July 2009 of manufacturing sterility and contamination problems at Triad Group, yet no public action was taken until physicians at the Children's Hospital in Denver, Colorado, alerted the FDA to a link between patient infections and Triad Group products in November 2010."

Alcohol prep products, including swabs, wipes and pads were found to be contaminated by the bacteria Bacillus cereus, and recalled by the Triad Group on January 3, 2011, in addition to an earlier December 2010 recall of lubricating jelly found to be unsterile. These products have become associated with at least one death and additional critical injuries nationwide including patients in Colorado, Tennessee, and Texas.

The full text of the letter is included below.

Dear Dr. Hamburg:

We are writing to inquire into the facts underlying the recent voluntary recall of millions of products manufactured by the Triad Group of Hartland, Wisconsin, due to contamination and sterilization problems in the manufacturing process. In light of this recall and the health consequences to patients being exposed to contaminated products, we urge the Food and Drug Administration (FDA) to

carefully review its oversight of medical product manufacturing to ensure that manufacturers comply with the voluntary compliance measures suggested by FDA inspectors.

In December 2010, Triad Group recalled lubricating jelly found to be unsterile. Alcohol prep products, including swabs, wipes and pads products were found to be contaminated by the bacteria Bacillus cereus, and recalled on January 3, 2011. These products were reportedly sold by Triad Group to hospitals, health providers, major pharmacies and other retail distributors, including Cardinal Health, PSS Select, VersaPro, Boca/Ultilet, Moore Medical, Walgreens, CVS, and Conzellin, and have become associated with at least one death and more than critical injuries nationwide including patients in Colorado, Tennessee, and Texas.

We are particularly concerned by media reports that suggest that the FDA was aware as early as July 2009 of manufacturing sterility and contamination problems at Triad Group, yet no public action was taken until physicians at the Children's Hospital in Denver, Colorado, alerted the FDA to a link between patient infections and Triad Group products in November 2010. FDA inspections in June 2009 and May 2010 found that, "procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed." Inspectors also found misidentified product, broken manufacturing equipment in use, and reported that shipments of product that failed quality tests were released for distribution.

We appreciate your time and attention to these issues, which we all recognize go to the heart of the public's confidence in the FDA and the health care system.

Please contact us or have your staff contact Rohini Ravindran or Mary-Sumpter Lapinski. We look forward to your response.

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