U.S. SENATOR MICHAEL BENNET

/Member: Agriculture, HELP, Banking and Aging Committees/

FOR IMMEDIATE RELEASE* *CONTACT:* *Adam Bozzi – 202-228-5905

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*Bennet Statement on FDA Response to Bennet Letter following Triad Recall *

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Washington, DC – Colorado US Senator Michael Bennet today released the following statement on the FDA's response to a letter Bennet and Senator Lamar Alexander (R-TN) sent following the recent recall of millions of Triad Group medical products due to contamination and sterilization problems in the manufacturing process. _The FDA letter is attached. Text of the Bennet-Alexander letter is below._

"The incidents relating to Triad wipes, as well as the recent recalls of children's medicine and deaths associated with Heprin, remind us all too clearly that the supply chain for drugs and medical devices needs to be fixed. The last thing families in Colorado and across the country should have to worry about is that the treatments they use may do them harm, or potentially worse.

"It appears that in this case the FDA has provided an honest assessment in recognizing that stronger actions should have been taken earlier to prevent this incident from occurring. It is imperative that the FDA take appropriate action in the future to avoid a repeat of this unfortunate incident.

"FDA is charged with enormously important, though often overlooked, tasks. It is challenged by limited resources, antiquated technology and outdate laws. As FDA reauthorization approaches in Congress, I will continue to fight for stronger oversight for industry, robust quality standards for manufacturers, and greater accountability from the FDA."

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/Bennet-Alexander March 31 letter to FDA below. *FDA Letter attached.*/

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/Dear Dr. Hamburg:/

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/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. /

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/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./

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/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. /

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/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. /

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

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