

## U.S. SENATOR MICHAEL BENNET

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

FOR IMMEDIATE RELEASE

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### **Following Record Drug Recalls and Shortages, Bennet Helps Pass FDA Reform in Senate**

*Bill Includes Bennet's Drug Innovation, Drug Safety, Medical Device Provisions to get Safe and Effective Treatments to Colorado Patients*

*Work Continues on Track and Trace; Mobile Apps*

**Washington, DC** – Colorado U.S. Senator Michael Bennet today help push through passage of a bill in the Senate to modernize the Food and Drug Administration.

The bill contains a number of policy provisions aimed at improving the safety of pharmaceutical drugs and medical devices and the speed in which they are available for patients and families in Colorado and across the country. The *FDA Safety and Innovation Act* passed the Senate with broad bipartisan support by a vote of 96-1.

The United States is currently facing critical drug shortages and drug recalls that can hurt patients who need treatment the most. In Colorado Springs, drug shortages have forced doctors at Penrose-St. Francis Hospital to delay therapy for some leukemia patients and to substitute less effective antibiotic medications for those that are in short supply. In 2010, Colorado Children's Hospital flagged a problem with tainted sterile alcohol wipes that were tied to several cases of people becoming suddenly ill, including a 10-year-old Glenwood Springs boy and the death of a 2-year-old Houston boy.

“Parents in Colorado and across the country want to know that the drugs in their medicine cabinet will help, not harm their kids,” **Bennet said.** “This bill changes a number of antiquated regulations to improve the safety and quality of the drugs and therapies Coloradans use every day. It also will

help get new life-saving treatments to patients faster and support innovation in our health IT and bioscience sectors, which are growing in Colorado. Chairman Harkin and Ranking Member Enzi showed incredible leadership in guiding this bill through the Senate, and I am confident that we will be able to get a bill to the president's desk for his signature.”

Bennet's work on the bill was born out of numerous discussions with doctors, patients, families, and other stakeholders who detailed their stories about why FDA regulations need updating. During the markup of the bill in the Senate Committee on Health, Education, Labor and Pensions (HELP), Bennet successfully secured provisions to improve drug safety, bring breakthrough treatments to patients more quickly, advance medical device innovations and prevent critical drug shortages.

Additionally, Bennet is continuing to work on two additional provisions as the bill moves toward a conference committee. He continues to work with FDA to reach consensus on regulations for medical mobile apps that foster innovation and protect patient safety. He also worked with Harkin, Enzi and Senator Richard Burr of North Carolina to include placeholder language in the bill to establish a uniform, national traceability framework. The language allows for continued discussions on this policy as Congress works toward a final FDA user fee bill.

### *Drug Safety*

The [drug safety component](#) of the bill enhances the ability of the FDA and increases oversight of the pharmaceutical industry to ensure U.S. prescription and over-the-counter drugs are both safe and effective – regardless of where they are made.

“We applaud Senator Bennet for taking these proactive steps to ensure meaningful changes in drug monitoring to increase patient safety,” **stated Dr. Daniel Hyman DO, Chief Quality Officer at Children's Hospital Colorado in Aurora.** “Risks associated with medications, including manufacturing safety, are especially problematic for children, and efforts to mitigate these risks are positive. Expanded testing for medication safety and effectiveness in children remains a priority for our country. We cannot solve our existing drug shortage challenges by allowing unsafe drugs into the market.”

### *Drug Innovation & Breakthrough Products*

The drug approval and patient access component of the bill includes a [bipartisan bill led by Bennet](#), along with Senators Orrin Hatch (R-UT) and Richard Burr (R-NC), to expedite U.S. Food and Drug Administration (FDA) approval and provide more flexibility for breakthrough drugs or treatments that show dramatic responses early in development, while still ensuring drug safety and efficacy.

“We are entering a golden age of biology where our understanding of life threatening diseases like cancer our allowing us to develop specific, targeted therapies that may bring meaningful benefit to focused patient populations,” **stated Patrick J. Mahaffy, president & CEO of Clovis Oncology in Boulder.** “Senator Bennet has been instrumental in helping to create an up to date regulatory process that that supports this innovation.”

### Medical Device Innovation

The medical device component of the bill includes [Bennet’s bill](#) to reduce regulatory burdens that unnecessarily delay new medical devices from reaching the market, such as delays in the 510(k) process, as well as language from [Bennet’s bill](#) to give the Food and Drug Administration the tools it needs to improve oversight and tracking of medical devices after they are approved.

“The medical technology industry is an American success story,” **stated David B. Perez, president & CEO of Terumo BCT in Lakewood.** “Let me thank Senator Bennet for his leadership and focus on driving continuous efficiency and effectiveness of FDA regulations. Recently introduced policy proposals represent Senator Bennet’s commitment to this important issue.”

“I’ve heard it been said that the least effective drug or device is the one the patient truly needs, but can’t get access to,” **stated Rick Jory, president & CEO of Sandhill Scientific, Inc. in Highlands Ranch.** “We view the FDA as being in partnership with us. We share a mutual goal of wanting to assure that we provide and promote safe and effective products. The work Senator Bennet and his staff are doing to clarify the process and make it timelier truly benefits everyone.”

“Everyday lives are disrupted and families are broken when the device used to sustain a patient’s airway is accidentally removed,” **stated Arthur Kanowitz, MD FACEP, medical director & CEO of Securiysn Medical in Highlands Ranch.** “I am certain that the Medical Device Regulatory Improvement Act co-sponsored by Senator Bennet will enable startup companies, like ours, to partner with the FDA in quickly and efficiently commercializing innovative products without compromising patient safety. It will also reduce the unnecessary regulatory hurdles which pose a significant threat to the entrepreneurial companies driving innovation and economic development.”

Additional Bennet-backed provisions include:

- Bennet was part of the bipartisan working group that drafted the [drug shortage component](#) of the bill. This piece would enhance the ability of the FDA to address and avoid drug shortages. The plan calls for enhanced notification of potential drug shortages or disruptions and gives FDA authority to expedite reviews of drugs in short supply to mitigate the effects of a shortage.

- The new antibiotic development component of the bill includes the GAIN Act, a bipartisan bill cosponsored by Bennet to spur development of new drugs to treat increasing cases of bacterial infections resistant to conventional antibiotics, which are particularly prevalent among military personnel returning from overseas. This provision provides incentives to increase the commercial value of innovative antibiotic drugs and streamlines the regulatory process so that pioneering infectious disease products can reach patients.
- Bennet was also part of the bipartisan working group that drafted the pediatric component of the bill, which would help ensure drugs and medical devices are specifically tested, labeled, and proven to be safe and effective for children. It also ensures children are prioritized in the drug development process and that drug labels provide clear, detailed information about the proper use and dosage of medications for children.

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