U.S. SENATOR MICHAEL BENNET

Member: Agriculture, HELP, Banking and Aging Committees

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Bipartisan FDA Reauthorization Bill Passes Committee

Bill Includes Bennet Measures Aimed at Improving Drug Safety, Bringing Breakthrough Treatments to Patients More Quickly, Advancing Medical Device Innovation and Avoiding Critical Drug Shortages

Washington, DC – Colorado U.S. Senator Michael Bennet today helped pass a bipartisan Food and Drug Administration (FDA) reauthorization draft bill through the Senate Committee on Health, Education, Labor and Pensions (HELP). The bill includes several Bennet provisions aimed at improving drug safety, bringing breakthrough treatments to patients more quickly, advancing medical device innovations and preventing critical drug shortages. It passed out of committee with broad bipartisan support.

"This bipartisan bill will help bring the FDA into the 21st century, support our bioscience industry and, most importantly, improve care and safety for Colorado patients," **said Bennet.** "As Coloradans and all Americans are facing record recalls and drug shortages, the modernizations and improvements in this bill are more important than ever. I'm pleased to see that this bill moved through committee smoothly and in a bipartisan way, and I hope we can quickly pass this bill in the full Senate."

The FDA Safety and Innovation Act reauthorizes FDA user fee agreements, which began in 1992. FDA's budget largely depends on industry-paid user fees to supplement Congressional appropriations. This year, Congress plans to reauthorize four user fee agreements to provide additional resources pertaining to prescription drugs, medical devices, generic drugs and biosimilars. The FDA Safety and Innovation Act contains these user fee agreements as well as a number of additional policy provisions aimed at updating FDA regulations to improve care for patients and families in Colorado and across the country.

User fee agreements are negotiated between FDA and the affected industries and then sent to Congress for authorization. The prescription drug and medical device user fees included in this bill will expire in September if Congress does not reauthorize them. The generic drugs and generic biologics, or biosimilars, user fees are newly authorized in this bill.

These user fee agreements will provide more certainty to Colorado's growing bioscience industry. About 20,000 Coloradans work at more than 400 companies in the bioscience industry, which amounts to $7 billion in payroll in Colorado alone.

Bennet's provisions in the FDA reauthorization bill include:

- The drug safety component of the bill to secure the supply chain builds upon Bennet's *Drug Safety and Accountability Act*, which he introduced last Congress in response to the record-high number of drug recalls. With 80 percent of the active pharmaceutical ingredients in our U.S. drug supply being manufactured abroad, this 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.

- 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. For patients, this proposal also would allow FDA the ability to move toward more innovative clinical trials, such as minimizing the number of patients enrolled in trials with a placebo and shortening the duration of trials when scientifically appropriate.

- The medical device component of the bill includes Bennet-backed measures to improve innovation and safety in medical devices, including 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.

- 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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