

For Immediate Release:

April 25, 2012

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Klobuchar's Bipartisan Provisions to Prevent Drug Shortages, Boost Medical Device Innovation Clear Senate Committee

Provisions included in larger bill that passed Senate Health, Education, Labor and Pensions Committee, paving way for vote in full Senate

WASHINGTON, D.C. – U.S. Senator Amy Klobuchar announced today that her bipartisan provisions to prevent drug shortages and boost medical device innovation have cleared the Senate Health, Education, Labor and Pensions (HELP) Committee as part of a larger bill, paving the way for a vote in the full Senate. Klobuchar's drug shortages provisions would provide early warning notification and give the FDA the tools it needs to stop shortages of critical drugs. Her medical devices provisions would reduce regulatory burdens that unnecessarily delay new, life-saving medical devices from reaching the market without compromising consumer safety.

“This is an important step forward for these critical provisions to help ensure that patients have access to essential drugs and get rid of regulatory red tape preventing companies in Minnesota and across the country from delivering life-saving products to the patients who need them,” Klobuchar said. **“I will continue to push for these common-sense reforms and work to move this legislation forward as quickly as possible.”**

Drug Shortages

The HELP Committee legislation includes a bipartisan drug shortages agreement Klobuchar helped forge that would require prescription drug manufacturers to give early notification to the FDA of any incident that would likely result in a drug shortage. This is the key provision in the *Preserving Access to Life-Saving Medications Act*, legislation Klobuchar introduced with Sen. Bob Casey (D-PA) and cosponsored by Senator Susan Collins (R-ME) and 28 other senators. The FDA prevented nearly 200 drug shortages in 2011 due to voluntary early notifications from companies, up from 38 in 2010. During a recent FDA workshop, FDA officials said that the rise in preventions is due to increased pressure from Klobuchar and other members of Congress.

The agreement also includes two other provisions similar to Klobuchar's legislation: it would direct the FDA to expedite inspections and reviews of manufacturing sites or new products that could be helpful in addressing a drug shortage, and require the FDA to keep detailed records of previous drug shortages and the actions taken to prevent them. It would also establish a task force to create a strategic plan to improve communication within the FDA and with public stakeholders,

as well as commission a report on price gouging and how pricing structures factor into drug shortages.

In January, Klobuchar held a forum in Edina, Minnesota with Federal Trade Commission (FTC) Chairman Jon Leibowitz and Minnesota Attorney General Lori Swanson to discuss the drug shortages crisis and how to ensure patients have access to affordable medications. Klobuchar and Collins also recently took to the floor of the U.S. Senate to urge their colleagues to swiftly pass their legislation.

Medical Devices

The HELP Committee legislation also includes key provisions from Klobuchar's bipartisan legislation, the *Medical Device Regulatory Improvement Act*, that would help streamline the FDA's regulation of medical devices by strengthening FDA's current least burdensome requirements. This would ensure that when making regulatory decisions on medical devices, FDA focuses only on the relevant information during the decision-making process, considers appropriate alternatives to reduce the time, effort, and cost of reaching regulatory decisions, and uses all reasonable mechanisms to reduce review times when making these decisions. The bill also includes Klobuchar's provision to streamline FDA's overly restrictive conflicts of interest requirements.

Over the past few years the FDA's regulation has become increasingly burdensome and less transparent, delaying, and in some cases preventing, new and innovative devices from reaching the market. Recent studies showed that the average time to approve a 510(k) application has increased 43% from the 2003-2007 period to 2010, and the average time to approve a premarket approval (PMA) application has increased 75%. A recent survey of venture capitalist life sciences investors showed that almost 40% of investors are more likely to shift their operations and investments overseas because of FDA's regulatory challenges.

Klobuchar is the chair of the Senate Commerce Subcommittee on Competitiveness, Innovation, and Export Promotion, and has been a leader in the effort to cut red tape that threatens innovation in the medical device industry. After a December 2010 report surveyed over 200 medical technology companies and found that confusing and contradictory regulations are stifling innovation, Klobuchar pushed the Food and Drug Administration (FDA) to reform its slow and inconsistent 510(k) approval process for medical devices to maintain safety, protect patients, and encourage innovation. Klobuchar also founded the bipartisan Senate Medical Technology Caucus to increase awareness about issues facing the industry.

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