

For Immediate Release:

October 31, 2011

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Klobuchar-Casey Bipartisan Drug Shortage Legislation Advanced by President's Executive Order

Administration takes action on Klobuchar-Casey early warning system

*Senators' drug shortages working group focused on finding long-term
solutions to critical problem*

WASHINGTON, DC – U.S. Senators Amy Klobuchar (D-MN) and Bob Casey (D-PA) today announced that their bipartisan proposal to address critical drug shortages through early warning notifications will be advanced as part of an Executive Order issued by President Obama. As the President announced the administrative action he gave full support to the senators' legislation, which takes additional steps to address drug shortages. The *Preserving Access to Life-Saving Medications Act* would require pharmaceutical companies to notify the Food and Drug Administration (FDA) of impending prescription drug shortages so appropriate actions can be taken to mitigate such shortages.

"Physicians, pharmacists, and patients in Minnesota and across the nation are currently confronting unprecedented shortages of important medications. These can be life and death situations for families, and we need to act quickly to address this urgent public health crisis," Klobuchar said. **"This Executive Order advancing our legislation will help prevent future shortages and ensure patients continue to receive the best care possible."**

"This action will help ensure that patient care is not jeopardized by a lack of life-saving medication," said Senator Casey. **"Patients and hospitals in Pennsylvania and around the country have experienced an inexcusable shortage of life saving drugs, and I am pleased that the legislation I have been pushing is part of the strategy announced today."**

Klobuchar and Casey's *Preserving Access to Life-Saving Medications Act* would give the FDA the ability to require early notification from pharmaceutical companies when a factor arises that may result in a shortage. These factors may include changes made to raw material supplies, adjustments

to manufacturer production capabilities, and certain business decisions such as mergers, withdrawals, or changes in output. The bill would also direct the FDA to provide up-to-date public notification of any actual shortage situation and the actions the agency would take to address them. The FDA has prevented 99 drug shortages so far this year due to voluntary early notifications from companies, up from 38 in 2010. FDA officials have said that the rise in preventions is due to increased pressure from the senators and other members of Congress.

President Obama today will sign an Executive Order advancing the key provision in the bill, which would require pharmaceutical companies to notify the FDA of impending prescription drug shortages. The Executive Order directs the Food and Drug Administration to (1) push drug companies to notify the FDA of any impending shortage of certain prescription drugs, (2) speed reviews of applications to begin or alter production of these drugs, and (3) work with the Department of Justice to examine whether drug companies have responded to potential drug shortages by illegally hoarding medications or raising prices to gouge consumers.

In addition to the legislation, Klobuchar and Casey are also members of a bipartisan drug shortages working group, which includes Senators Richard Blumenthal (D-CT), Richard Burr (R-NC), John McCain (R-AZ), and Bob Corker (R-TN). The working group is aimed at bringing together patients, doctors, pharmacists, manufacturers, and the FDA to focus on long-term solutions to stop drug shortages. Last month, the FDA convened a public workshop at the request of the working group which brought together patient advocates, industry, consumer groups, health care professionals, and researchers to discuss the causes and impact of drug shortages and possible strategies for preventing or mitigating future shortages.

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