

### *Key Message Points*

- While the Food and Drug Administration successfully prevented 137 drug shortages since the beginning of 2010, the number of drug shortages annually has tripled from 61 in 2005 to 178 in 2010. An important factor in many of the recent shortages appears to be an increase in demand that exceeds current manufacturing capacity.
- We can't wait to act. The shortage of prescription drugs drives up costs, leaves consumers vulnerable to price gouging and threatens our health and safety. While manufacturers are in the process of expanding capacity, one important step is ensuring that the FDA and the public receive adequate advance notice of shortages whenever possible.
- Today, President Obama signed an Executive Order directing the FDA to take action to help further reduce and prevent drug shortages, protect consumers and prevent price gouging. And he announced his support for bipartisan legislation that will give the FDA new tools to prevent drug shortages.
- The President's Executive Order directs the Food and Drug Administration to require drug companies to notify the FDA of an impending shortage of certain prescription drugs. Early notification can help prevent potential drug shortages from becoming a crisis.
- And under the President's order FDA will also 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.
- This is a complex issue and stems from economic, legal, regulatory, policy, and clinical decisions that are deeply interconnected, but the Administration's actions will help prevent drug shortages in the future. We're committed to working with Congress to ensure the American people have access to the lifesaving medicines they need.

- While many of the root causes of drug shortages are outside of FDA's purview, each component of today's announcement will aid FDA in mitigating and even preventing shortages.
- As a report from our Department's Assistant Secretary for Planning and Evaluation that is also being released today makes clear, the underlying problem is that demand for medications is growing while the capacity of manufacturing facilities has not.
- The Executive Order calls for the FDA to expand its efforts to speed up the review of new manufacturing sites, drug suppliers, and changes to the manufacturing process, while maintaining full protections on patient safety. This work is already underway, but we will redouble our efforts.
- While the FDA cannot control the factors that cause these drug shortages, the steps announced today can help counteract them.
- At a time when so many families are struggling, we need to do everything we can to ensure that people can get the medications that allow them to manage their conditions, be without pain, prevent further illness, and in some cases, keep them alive. That's why this Administration is not waiting to act.