

We Can't Wait: Obama Administration Takes Action to Reduce Prescription Drug Shortages, Fight Price Gouging
President Issues Executive Order, Backs Legislation to Require Drug Companies to Report Shortages

President Obama today will sign an Executive Order directing the Food and Drug Administration to take action to help further prevent and reduce prescription drug shortages, protect consumers and prevent price gouging. The President's order directs FDA to broaden reporting of potential shortages of certain prescription drugs and to further expedite regulatory reviews that can help prevent or respond to shortages. Under the President's order, FDA will also work with the Department of Justice, which will examine whether potential shortages have led to illegal price gouging or stockpiling of life-saving medications.

In addition to signing the Executive Order, the White House announced the President's support for bipartisan legislation (H.R. 2245 and S. 296) that will build on today's actions to strengthen the FDA's ability to prevent prescription drug shortages.

A small number of drugs in the U.S. experience a shortage in any given year, but the number of reported prescription drug shortages in the United States nearly tripled between 2005 and 2010. While FDA successfully prevented 137 drug shortages between January 1, 2010 and September 26, 2011, prescription drug shortages continue to threaten the health and safety of the American people.

These shortages could lead to price gouging, which has raised serious concerns. For example, the ranking member of the House Committee on Oversight and Government Reforms, when announcing his investigation into so-called gray markets, expressed concerns about a report that a leukemia drug whose typical contract price is about \$12 per vial was being sold at \$990 per vial – 80 times higher. A Premier healthcare alliance report released in August estimated that the typical gray market vendor marks up prices by an averaged 650 percent. At the extreme, a drug used to treat high blood pressure that was normally priced at \$25.90 was being sold at \$1,200 due to a drug shortage.

“The shortage of prescription drugs drives up costs, leaves consumers vulnerable to price gouging and threatens our health and safety,” said President Obama. “This is a problem we can't wait to fix. That's why today, I am directing my administration to take steps to protect consumers from drug shortages, and I'm committed to working with Congress and industry to keep tackling this problem going forward.”

Early notification of potential drug shortages can help prevent a shortage from becoming a crisis by allowing hospitals, doctors and manufacturers to take action to ensure medications remain available. Currently, the FDA can only require drug manufacturers to disclose the discontinuation of a critical drug when the drug is available through a single manufacturer. The President's Executive Order directs the FDA to take additional steps to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances or other actions that could lead to critical shortages. These additional steps to increase early notification

will help achieve some of the goals of bipartisan legislation supported by the President that would require all prescription drug shortages to be disclosed to the FDA in advance and give the FDA new authority to enforce these requirements.

The Executive Order also requires FDA to expand its current efforts to expedite review of new manufacturing sites, drug suppliers, and manufacturing changes to help prevent shortages.

These actions are just some of the steps the Obama Administration is taking to ensure patients have access to the lifesaving medicines they need. Today, the Obama Administration also:

- Sent a letter to drug manufacturers reminding them of their responsibility to report the discontinuation of certain drugs to the FDA. The letter also encourages companies to voluntarily disclose to FDA potential prescription drug shortages in cases where disclosure is not currently required by law.
- Increased staffing resources for the FDA's Drug Shortages Program to address the increased workload that will result from additional early notification of potential shortages by manufacturers.
- Released a report from the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) that assesses the underlying factors that lead to drug shortages, and an FDA report on their role in monitoring, preventing, and responding to these shortages.

While the root causes and many of the solutions are outside of the FDA's authority, including the need for additional manufacturing capacity in the private sector, the Administration will continue its ongoing work with manufacturers and other stakeholders to help address drug shortages.

View a fact sheet to learn more about prescription drug shortages and the Obama Administration's announcements.

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