



Client Alert

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President Obama Issues Executive Order on Drug Shortages

On October 31, 2011, President Obama issued an Executive Order in an effort to prevent drug shortages and price fixing on life-saving prescription drugs. According to the Executive Order, the number of prescription drug shortages in the United States nearly tripled between 2005 and 2010, and shortages are becoming more severe, as well as more frequent. The affected drugs include cancer treatments, anesthesia drugs and other drugs that are critical to the treatment and prevention of serious diseases and life-threatening conditions.

President Obama's Executive Order directs the Food and Drug Administration (FDA) to take action to prevent drug shortages and price fixing. Specifically, the Executive Order directs the FDA to take the following steps:

- Require manufacturers to provide advance notice of manufacturing discontinuities that could lead to shortages of drugs that are life supporting or life sustaining, or that prevent debilitating disease;
- Expand the FDA's efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites and manufacturing changes, whenever it determines that expedited review would help to avoid or mitigate existing or potential drug shortages; and
- Report to the Department of Justice (DOJ) any findings of drug stockpiling and over-charging for scarce drugs.

With respect to reporting to the DOJ, the DOJ will determine whether the activities reported are consistent with applicable law and will coordinate with other state and federal regulatory agencies, as appropriate, to undertake whatever enforcement actions, if any, it deems appropriate. It is unclear whether the provisions of this Executive Order will have any substantial independent effect on the frequency of drug shortages. Currently, 21 U.S.C. § 356c is limited to sole-source manufacturer **discontinuations** of medically necessary drugs. Under 21 U.S.C. § 356c, the FDA cannot require advance notification of other manufacturers, in other circumstances besides discontinuation, or about other types of drug products.

According to a White House press release, the Executive Order is one in a series of steps that will help address the shortage of prescription drugs and ensure patients have access to the lifesaving medicines they need. The Obama Administration also:

- Sent a letter to drug manufacturers reminding them of their legal responsibility to report the discontinuation of certain drugs to the FDA. The letter also encourages companies to voluntarily notify the FDA about potential prescription drug shortages in cases where notification is not currently required;¹
- 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; and
- 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,² and an FDA report on its role in monitoring, preventing and responding to these shortages.³

Administration officials are also calling on Congress to pass more comprehensive legislation to boost the FDA's power to address prescription drug shortages.

¹ The letter is available at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

² The Report is available at <http://aspe.hhs.gov/sp/reports/2011/DrugShortages/ib.shtml>.

³ The FDA Report is available at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

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