FDA Facts: Drug Shortages in the United States

Shortages of drugs and biologics pose a significant public health threat, delaying, and in some cases even denying, critically needed care for patients. Preventing drug shortages remains a top priority for FDA.

Although FDA cannot directly affect many of the business and economic decisions that contribute to drug shortages, FDA is well positioned to play a significant role as manufacturers work to restore lost production of life-saving medications.

If notified of a potential disruption in production, FDA can take a number of steps to help prevent or mitigate a shortage, including:

- Determine if other manufacturers are willing and able to increase production
- Expedite inspections and reviews of submissions
- Exercise temporary enforcement discretion for new sources of medically necessary drugs
- Work with the manufacturer to ensure adequate investigation into the root cause of the shortage
- Review possible risk mitigation measures for remaining inventory

However, FDA's ability to take effective action depends on the relevant manufacturer notifying FDA in a timely fashion of a disruption or possible disruption in supply.

Recently, the White House and Congress have taken important and welcome steps to expand early notification of interruptions and discontinuations, enhancing FDA's ability to address drug shortages.

Improvements Seen

Early notification from manufacturers about possible shortages, as requested in the President's Executive Order 13588 of Oct. 31, 2011 and then codified into law in the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), has enabled FDA to work with manufacturers to restore production of many lifesaving therapies.

Since the Executive Order, there has been a 6-fold increase in notifications to FDA. These increased notifications combined with allocation of additional FDA resources have resulted in real progress in addressing shortages—FDA helped prevent 195 drug shortages in 2011 and 282 drug shortages in 2012—almost an additional 100 more since the Executive Order was signed. The total number of new shortages decreased from 251 in 2011 to 117 in 2012.

Provisions of FDASIA

Title X of FDASIA provides FDA with important new authorities that will help the Agency combat drug shortages.

FDASIA:

- broadens the scope of the early notification provision by requiring all manufacturers of certain medically important prescription drugs to notify FDA of a permanent discontinuance or a temporary interruption of manufacturing. Prior to FDASIA, only sole manufacturers of certain drug products for serious conditions were required to notify FDA of a discontinuance of those products. FDA received notifications from other

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manufacturers about potential shortages of other products on a voluntary basis.

- allows FDA to extend, by regulation, the early notification requirement to manufacturers of biologics. A proposed rule, issued on Oct. 2, 2013 by the agency would do so.
- requires the FDA to issue a non-compliance letter to manufacturers who fail to comply with the drug shortage notification requirements and, if the company does not have a reasonable basis for failing to comply, to make the letter and the company's response available to the public.
- directs FDA to establish a task force to develop a strategic plan on drug shortages to submit to Congress

Looking Ahead - Strategic Plan

FDA convened a task force to develop and implement a strategic plan for enhancing the agency's responses to drug shortages, as required under FDASIA. The strategic plan was published and submitted to Congress on Oct. 2. It discusses ways to improve FDA's response to imminent or existing shortages, as well as long-term approaches to addressing quality and manufacturing issues that are the underlying cause of most drug shortages.

For More Information

More on FDASIA, its implementation, and how the FDA works to prevent drug shortages and the Strategic Plan can be found here:
www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/default.htm

Sources

- *www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm*
- *www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/default.htm*

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