

# Drug Shortages: What Congress Can Do to Minimize Patient Impact

## Background

Drug shortages are an ongoing public health concern in the United States. While the numbers of newly reported drug shortages are much lower than they were at the height of the shortage crisis in 2012, clinicians are still experiencing supply challenges of certain medications. These medications are typically injectable products that are off patent and have few suppliers – and in some cases only one. Causes of these shortages do not appear to have changed, as shortages are in large part the result of quality problems during the manufacturing process, leaving clinicians scrambling to get a supply of the drug, compounding in cases where it is possible, or recommending an alternative therapy if one exists.



Title X of FDASIA was enacted in 2012 requiring that drug manufacturers notify the Food and Drug Administration (FDA) “of any change in production that is reasonably likely to lead to reduction in supply,” of a covered drug in the U.S. – but not the reason for a halt in production or an expected timeline to address it. This advanced warning requirement has played a significant role in reducing the number of drug shortages, but has not altogether solved the problem.

A further complication occurred in the fall of 2017 as a major hurricane struck the island of Puerto Rico, which houses significant drug manufacturing infrastructure. Intravenous solutions have been the most critical shortage experienced as a result of this natural disaster. Confusion over what type of products are produced on the island and the infrastructure needed to resume full production and transportation of products has contributed to the uncertainty over whether more drug shortages will occur, and when these products will be delivered.

## What Can Congress Do?

**Manufacturers should provide the FDA with more information on the causes of the shortages and their expected duration:**

Congress should strengthen Title X of FDASIA to include disclosure of the problem causing the interruption, and an expected timeline to address it.

**Require manufacturers to establish contingency plans and/or redundancies:**

Congress should require that manufacturers establish contingency plans to be used in the event of a shortage, specifically when there are less than three manufacturers producing a drug.

**Manufacturers need to be more transparent:**

Congress should require manufacturers to disclose to the FDA, the location of production, including situations where a contract manufacturer is used

**Examine drug shortages as a national security initiative:**

Congress should require HHS and DHS identify ways that they can support manufacturers and the health care provider community in preparing and responding to future disasters and other supply disruptions

**The Federal Trade Commission (FTC) should include in its review of drug company merger proposals the potential risk for drug shortages.**

Congress could request the FTC consider the potential risk for drug shortages when reviewing drug company mergers and acquisitions, it consider the potential risk for drug shortages.

## For More Information

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