

FastFacts

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Generic Drug Shortages

Introduction

Generic drugs bring down health care costs for patients – if they can access treatment. But sometimes, the demand for certain medications exceeds the supply.

Drug shortages have risen sharply in the past few years. According to FDA data, the average shortage affects at least half a million consumers, with people between the ages of 65 and 85 most likely to be impacted.

Just as the causes of shortages are multifaceted, so too must be the policy solutions. **To ensure patient health, policymakers must make solving drug shortages a top priority.**



Q: What is a drug shortage?

According to the FDA, a drug shortage occurs when demand or projected demand for a drug within the United States exceeds supply for a period of time. When a drug is in shortage, the total supply of all versions of the product, both brand-name and generic, cannot meet the current demand.¹ The FDA, not manufacturers, identifies and communicates which drugs are considered in shortage.

Q: How are drug shortages reported?

Manufacturers are required to notify the FDA of changes in the production of certain drugs. In 2020, the Coronavirus Aid, Relief, and Economic Security Act enhanced FDA's ability to identify, prevent and mitigate possible drug shortages by expanding the notification requirement. Manufacturers now must notify FDA of a discontinuation or disruption six months in advance.²

Another reputable source, the American Society of Health-System Pharmacists, also tracks and reports drug shortages to help keep the public informed.³

Q: What patient populations are most vulnerable to drug shortages?

Significant shortages of chemotherapy drugs mean that cancer patients feel a disproportionate impact.

Shortages are not limited to cancer medications, however. Shortages are being seen across disease states. There are currently more than 300 drugs in shortage – the highest number in over a decade – including commonly used medications such as Adderall, antibiotics, saline and Lidocaine. Patients young and old alike struggle to go about their everyday lives when they can't get the medication they need. Delays in treatment from drug shortages can leave them waiting while their condition worsens.

Q: Why do drug shortages happen?

Different factors can cause a drug shortage, including:



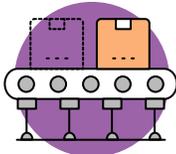
Financial Problems

Inflation and downward pressure on generic drug prices make generic manufacturing of many drugs unsustainable.



Regulatory Challenges

The introduction of new medical guidelines, changes in guidelines or the introduction of new FDA-approved uses for a drug can impact supply and demand.



Supply Chain Issues

Shortages of raw materials can lead to manufacturing delays. The weather, pandemics and other unforeseen events can also disrupt the supply chain and lead to extended drug shortages.



Increased Demand

An unexpected increase in demand can spur shortages. During the period of record-high inflation beginning in 2023, the demand for generic medications, especially the lowest-cost generics, began to outpace the supply.

Q: What are possible solutions?

While there is no single solution to ending the drug shortage crisis or avoiding future shortages, federal policymakers can advance policies that make prescription medications more available and affordable.

These steps include:



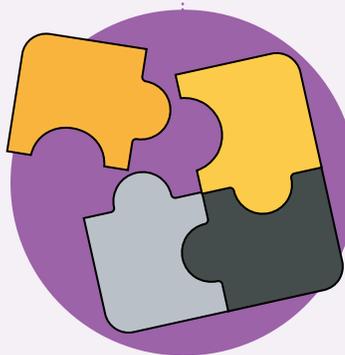
Strengthening Reporting Requirements

The FDA has raised concerns that manufacturers don't always report information about their supply chains or develop risk management plans for more than 4,000 manufacturing facilities in a timely manner. Getting adequate information in a timely manner could help identify and mitigate potential shortages.



Ensuring a Streamlined, Efficient Pathway

An efficient pathway is critical to allow new generic medications to reach the market. This is especially true for complex medicines and first- and second-generation generics.



Raising Awareness

Sharing information about the driving forces behind drug shortages can help make each entity accountable.



Incentivizing Manufacturing

This should be a top priority for generic drugs that are most at risk of or already experiencing significant shortages.

Conclusion

Millions of patients across the country are paying the price of drug shortages. As they wait for treatment, their conditions worsen. It's time that policymakers prioritize solving drug shortages by requiring stronger reporting requirements, ensuring a streamlined pathway, raising awareness and incentivizing manufacturing.



References

1. FDA. *Frequently Asked Questions about Drug Shortages*. <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>
2. Ibid.
3. American Society of Health System Pharmacists. *Drug Shortages*. <https://www.ashp.org/drug-shortages>



ABOUT THE GENERICS ACCESS PROJECT

The Generics Access Project advocates for policies that promote generic competition and efficient approval of generic medicines.

GenericsProject.org