RealClear Health

A Policy Prescription to Help the Next Administration Combat the Drug Shortage Crisis

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Persistent shortages of critical prescription drugs continue to hinder patients from accessing the care they need. As lawmakers, regulators, and industry stakeholders consider measures to bolster resiliency in the pharmaceutical supply chain, success will depend on their ability to address manufacturing quality, transparency, and capacity; increase domestic manufacturing; and create additional buffer inventories of critical medications.

For many patients and healthcare providers, drug shortages are more than just an inconvenience – an out-of-stock medication can create additional costs, treatment delays, and even life-threatening emergencies. During a shortage, patients may be forced to ration prescriptions or forgo treatment altogether while they wait for medications to restock. The effects of drug shortages reach across the healthcare ecosystem, and all stakeholders are impacted by supply chain disruptions. This is particularly true when it comes to the generic sterile injectable drugs used to treat cancer and other conditions.

Moreover, a drug shortage is particularly challenging in pediatric health care, as drugs intended for children are unique. A recent report by the Children's Hospital Association found that more than half of pediatric drugs have only 1-2 manufacturers currently supplying the dosage form pediatric hospitals use most often. Of the essential medication manufacturers utilized by children's hospitals, only 15% of them are pediatric-only suppliers.

As policymakers in Washington consider strategies to prevent and mitigate the impacts of drug shortages, it is critical to first identify the underlying causes. The U.S. Food and Drug Administration (FDA) identifies manufacturing and quality control issues as the primary cause of drug shortages, along with additional factors such as production delays and lack of raw materials. A University of Utah Drug Information Service (UUDIS) survey of drug manufacturers offers additional insight, as more than half of those surveyed (60%) either did not know the cause of a shortage or would not provide the information. Of those manufacturers that responded, supply/demand was the most commonly cited cause (14%).

Overreliance on foreign manufacturing facilities has also increased the strain on the pharmaceutical supply chain, contributing to ongoing drug shortages. The FDA stated that as much as 72% of active pharmaceutical ingredient (API) manufacturers supplying the U.S. market are overseas, and drug manufacturing has increasingly moved out of the United States.

Policymakers must consider several key proposals to mitigate shortages and foster resiliency in the supply chain. First, Congress should create incentives, such as tax subsidies, to encourage domestic manufacturing and reduce over-dependence on foreign facilities. These incentives should be tied to quality, as well as the amount of product sold in the U.S. For incentives to tangibly impact pricing dynamics, they must ensure that quality products are made *and* sold domestically. Moreover, incentives should promote investment in both manufacturing quality and capacity, including the addition of secondary supply lines and having alternate or backup sources of APIs.

Congress should also consider increasing funding for, and the number of, announced and unannounced FDA facility inspections. The FDA should also be encouraged to begin unannounced foreign inspections for API supplies and drug product manufacturers, particularly as the amount of foreign inspections have decreased to below the amount conducted before the onset of the COVID-19 pandemic.

Further, enhanced buffer inventories should play a role in any drug shortage policy solution. The Administration for Strategic Preparedness and Response (ASPR) – the agency responsible for developing medical and public health preparedness – oversees the strategic national stockpile (SNS), which is the national repository for medications and medical supplies to use in case local supplies are at risk of shortage. To fully leverage the potential shortage mitigation benefits of the SNS, policymakers should create, maintain, and require buffer inventory for critical medications through ASPR. Buffer inventories should also be subject to increased transparency, and input from healthcare industry stakeholders, especially providers, should advise which drugs are included in buffer stock.

Pharmaceutical supply decisions must account for more than just price – several factors, including manufacturing quality, are critical components of a resilient supply chain. The FDA's Center for Drug Evaluation and Research quality management maturity (QMM) program encourages drug manufacturers to implement quality management practices that go further than current good manufacturing practices requirements. Lawmakers should fully fund the QMM program, require implementation as soon as possible, and share these ratings with appropriate supply chain stakeholders to best inform sourcing and purchasing decisions.

Drug shortages are a decades-old problem that continue to plague healthcare providers and the patients they serve. Traditional healthcare group purchasing organizations are already taking a number of steps to help hospitals prevent and mitigate shortages, however the entire supply chain needs help from policymakers to address the root causes. Recently, the FDA announced some good news: the shortage of a critical chemotherapy treatment has ended. To help prevent and mitigate additional drug shortages, we urge policymakers to take a holistic approach that addresses manufacturer quality and transparency, provides incentives to increase domestic manufacturing, and creates buffer inventory of certain medications. Patients cannot afford to wait.

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