

Key Policy Recommendations: Drug Shortage Prevention & Mitigation



The ongoing drug shortage crisis places significant strain on patients and providers across the country. The Healthcare Supply Chain Association represents the nation's leading traditional healthcare group purchasing organizations (GPOs), who work with their healthcare provider members and suppliers to bolster the resiliency of the healthcare supply chain and to ensure that patients and providers have consistent access to the drugs, products, and devices they need. HSCA and its member GPOs understand that solving the ongoing drug shortage crisis is a complex task. To help prevent and mitigate ongoing drug shortages, HSCA proposes the following policy recommendations, several of which build on existing congressional authorities.

Policy Solutions to Address and Minimize Drug Shortages

<p>INVEST IN QUALITY AND BUILDING SECONDARY SUPPLY LINES</p>	<p>Congress, federal agencies, and similar regulating bodies should not only incentivize production, but also investment in quality and capacity, including the addition of secondary supply lines and having alternate or backup sources of active pharmaceutical ingredients (API), to support long-term access to generic medications.</p>
<p>CREATE INCENTIVES TO INCREASE DOMESTIC MANUFACTURING</p>	<p>If Congress elects to create incentives related to domestic manufacturing, incentives should be tied to quality and the amount of product sold in the U.S. to tangibly impact pricing dynamics. This entails greater public-private partnerships; tax incentives and other financial investment aimed at promoting long-term domestic manufacturing growth; and regulatory relief commensurate with quality plus product amount sold domestically.</p>
<p>UTILIZE AUTHORITY RELATED TO THE STRATEGIC NATIONAL STOCKPILE'S (SNS) ABILITY TO ENTER INTO VENDOR CONTRACTS</p>	<p>Policymakers should utilize the authority pertaining to the Fiscal Year 2021 Consolidated Appropriations Act (P.L. 117-328), which authorized the Strategic National Stockpile (SNS) to enter into vendor contracts to assist with the rotation of soon-to-be expired products, so supply chain stakeholders can work collaboratively with agency officials to help identify when and where products should be released.</p>
<p>MAINTAIN AND/OR REQUIRE BUFFER INVENTORY</p>	<p>The federal government, through the Administration for Strategic Preparedness and Response (ASPR) and SNS should create, maintain, and/or require buffer inventory for critical medications and devices.</p>
<p>INCREASE TRANSPARENCY ON BUFFER INVENTORIES</p>	<p>Greater transparency is required regarding buffer inventories, and input from GPOs and other private industry stakeholders should be used to determine which drugs, and if possible, which products should be considered for buffer inventory.</p>
<p>FUND AND IMPLEMENT FDA'S QUALITY MANAGEMENT MATURITY (QMM) PROGRAM</p>	<p>Congress should fully fund FDA's quality management maturity (QMM) program and require manufacturer participation and implementation as soon as possible. FDA should share its QMM ratings with appropriate supply chain stakeholders, including GPOs, to best inform contracting and purchasing decisions.</p>
<p>INCREASE ONGOING VISIBILITY INTO MANUFACTURING LOCATIONS AND ACTIVE PHARMACEUTICAL INGREDIENT (API) SOURCES</p>	<p>Manufacturers should be required to include on their package inserts and boxes the finished product manufacturing location, including for contract manufacturers, and API source(s) on all products.</p>
<p>INCREASE FACILITY INSPECTIONS</p>	<p>Congress should increase funding and encourage the FDA to increase the number of inspections it conducts. Additionally, Congress should encourage FDA to begin unannounced foreign inspections for API suppliers and drug product manufacturers, and inspections should occur at the same time interval for all FDA-registered facilities regardless of location.</p>
<p>ADJUST THE FDA DRUG SHORTAGES LIST FOR PEDIATRIC MEDICATIONS AND REGIONAL SHORTAGES</p>	<p>FDA should adjust its drug shortage list to provide a timely and accurate accounting of pediatric populations and pediatric drug formulations, including the potential for regional shortages.</p>
<p>ENCOURAGE INCREASED PRODUCTION OF AT-RISK PEDIATRIC MEDICATIONS</p>	<p>Policymakers should reduce the risk of pediatric drug and supply shortages by encouraging "readiness to supply," or proactive shortage mitigation plans and/or competition in production of pediatric products that are often under-resourced.</p>