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POLICY SOLUTIONS TO ADDRESS THE DRUG SHORTAGE CRISIS

Recommendations from ASHP

OVERVIEW

Severe and critical drug shortages continue to pose a significant threat to patient care, resulting in delayed treatment, increased risk of adverse reactions and harm to patients, and unnecessary healthcare costs.

Over 300 active drug shortages exist, according to the ASHP and University of Utah drug shortages database,[1] and most of these medications are low-cost generic drugs. Sterile injectable generic drugs used in hospital treatments and procedures, such as chemotherapeutic agents, are experiencing the most severe and prolonged shortages, with major impacts on patient care. Some of these medications have no alternatives, forcing hospitals and clinicians to ration medication or even delay care. Recent tornado damage to a manufacturing site that produces a large portion of sterile injectable drugs threatens to make these shortages even worse.

While spikes in demand can cause short-term drug shortages, the most severe and persistent shortages are driven by economic factors that undermine investment in manufacturing capacity, manufacturing quality,[2] and supply chain reliability. These economic challenges are driven by extreme price competition among generic manufacturers. When generic manufacturers experience a quality challenge or supply disruption, it may be economically rational for them to shift manufacturing capacity to a more profitable drug, rather than making the investment necessary to continue producing a low-margin product. For example, the lower profitability of generic drug manufacturing has caused companies to completely stop manufacturing certain less-profitable drugs.[3]

To effectively address drug shortages, the United States needs to focus on the key drivers of generic drug shortages, including quality and supply chain issues and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generic drugs. ASHP has developed the following short-term and long-term recommendations designed to directly address the root causes of generic drug shortages.

SHORT-TERM RECOMMENDATIONS

Enforce Existing Shortage Prevention Requirements

Congress previously passed legislation requiring manufacturers to report information about their manufacturing and supply chains to the Food and Drug Administration (FDA), and to develop risk management plans to help prevent disruptions to drug manufacturing. FDA has raised concerns that manufacturers have failed to provide this information for more than 4,000 manufacturing facilities – greater than half of registered facilities.[4] This disregards Congress' intent, increases the risk of manufacturing disruptions, and prevents FDA from responding to shortages.

- ASHP recommends Congress amend section 510(j) of the Federal Food, Drug, and Cosmetics Act to include meaningful penalties for manufacturers that fail to develop risk management plans or report manufacturing and supply chain data as required by this section.

Improve Transparency into Manufacturer Quality

Healthcare providers and pharmacies currently have very little ability to select manufacturers based on the reliability of their supply chain. This undermines their ability to source products from the most reliable manufacturers.

1 https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
2 https://news.nd.edu/news/extreme-price-competition-in-pharmaceutical-industry-may-put-patients-at-serious-health-risk-study-shows
3 https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg
4 https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf

- ASHP recommends that the FDA finalize, and make public, metrics of quality manufacturing maturity (QMM) so that purchasers can buy from manufacturers less likely to experience a drug shortage.
- In the absence of publicly reported QMM metrics, ASHP recommends FDA make unredacted manufacturing inspection reports publicly available so that purchasers have a better understanding of supplier manufacturing challenges and what products are made at facilities with a history of manufacturing quality and compliance problems.

Encourage New Manufacturers and New Manufacturing Sites

Entering the market to manufacture a generic drug is a multi-year process that requires investment in scientific, manufacturing, and regulatory functions. This makes it difficult for new manufacturers to enter the market and increase supply when shortages occur.

- ASHP recommends FDA waive generic drug user fees for generic drugs described in 506C(g) of the Federal Food Drug and Cosmetics Act, for which FDA may prioritize and expedite review of an abbreviated new drug application (ANDA) or related supplement to mitigate a shortage. This fee waiver should only apply to manufacturers that commit to promptly market their generic drug if it is approved.

LONG-TERM RECOMMENDATIONS

Encourage Long-Term, Guaranteed-Volume Contracts

Medicare payment policy for inpatient and provider-administered generic drugs, particularly inclusion of inpatient drug costs in diagnosis-related groups (DRGs) encourages healthcare providers and their group purchasing organizations (GPOs) to aggressively negotiate the price of generic drugs and shift purchase volume to lower-cost manufacturers. To encourage greater investment in manufacturing capacity and quality, federal policy should provide manufacturers of critical generic drugs with greater certainty of their ability to recover their investment and receive purchase volume for these products. Such policy should also give healthcare providers certainty that they can rely on the manufacturer to provide a particular level of supply for the term of the contract.

- ASHP recommends that the Centers for Medicare & Medicaid Services (CMS) provide an add-on payment to providers for critical generic drugs determined by the U.S. Department of Health and Human Services (HHS) to be at risk of experiencing a shortage if those providers certify that they have entered a contract to acquire at least 50% of their historical purchase volume for those products via long-term contracts.
    - » To ensure manufacturers invest in supply chain stability and quality, the contract must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions.
    - » To receive add-on payments, providers must ensure that they enter long-term supply contracts with manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[5]
    - » Providers and manufacturers could attest to meeting these requirements rather than providing proprietary contract information to HHS.
    - » Providers should be free to delegate long-term supply contracting to their GPO to meet these requirements.
    - » To minimize the administrative burden, add-on payments should be made based on the provider's total Medicare spend on the contracted drug product, rather than requiring per beneficiary accounting for medication use.

5 Recommendations from ASHP and other healthcare providers in 2021 called for FDA to make these metrics public. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

Diversify the Manufacturing Base

The federal government should use its purchasing power to ensure that at least a minimum number of manufacturers remain in the market and maintain active manufacturing capacity for critical medications. While this would not prevent any given manufacturer from experiencing a supply disruption, it would increase the likelihood that another existing manufacturer would be able to respond, in the medium term, when a shortage occurs.

- ASHP recommends the federal government encourage greater diversity and redundancy in the supply chain by spreading purchase volume from federal agencies across at least three different manufacturers with approved ANDA for any critical generic drug determined by HHS to be at risk of experiencing a shortage.
  - » The federal government could leverage its purchasing through the Department of Veterans Affairs, the Department of Defense, the Indian Health Service, the Bureau of Prisons, and the Administration of Strategic Preparedness/the Strategic National Stockpile.
  - » Federal purchasers should ensure that manufacturers under this program do not rely on the same contract manufacturers, as this would not actually diversify the manufacturing base.
  - » To ensure manufacturers invest in supply chain stability and quality, the federal contracts must include a requirement that the manufacturer will maintain a six-month buffer supply of finished product, and include meaningful penalties for the failure to supply, including when manufacturing disruptions result from a regulatory violation or supplier disruption.
  - » Federal agencies should give preference to manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.

Finance Private Sector Buffer Supplies

Encouraging healthcare providers and their distributors to maintain a buffer supply of critical medicines would reduce the impact of manufacturing disruptions on patient care.

- ASHP recommends that the federal government provide low- or no-cost financing to encourage private sector maintenance of a buffer inventory of critical drugs.[6]
  - » Providers and distributors should continue to have discretion to determine what products they stockpile.
  - » Providers should continue to be free to contract with GPOs, drug distributors, or manufacturers to manage storage and rotation of drugs stockpiled on their behalf.
  - » Private sector buffer supplies should be phased in slowly to minimize the risk of a demand surge that could result in shortages as providers and distributors build their stockpiles.

6 Recommendations from ASHP and other healthcare providers in 2021 called for incentivizing the creation of private-sector reserves of essential medicines, medical devices, and supplies not adequately provided by the Strategic National Stockpile. (https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations)

About ASHP and Drug Shortage Tracking and Monitoring Systems

ASHP (American Society of Health-System Pharmacists) is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies.

ASHP has led efforts to minimize and prevent drug shortages for more than 20 years. As part of that work, ASHP and the University of Utah maintain a drug shortage database that tracks drugs availability, including regional shortages, across the nation. ASHP updates the drug shortage database with every drug shortage reported as soon as it is investigated and confirmed, usually within 24-72 hours.[7] ASHP works closely with officials in the FDA's Drug Shortages Program and regularly updates FDA staff, Congress, and other policymakers on emerging shortages. ASHP also provides practitioner-focused resources to help the healthcare community manage shortages. Examples include information on unapproved drugs and unlabeled uses (when well-researched and reported to be safe and effective); recommendations for therapeutic alternatives; drug-to-drug comparisons and comparisons within individual drug classes; and safety recommendations.

For more information, visit ashp.org/drug-shortages.

7 https://www.ashp.org/drug-shortages/current-shortages