



July 7, 2023

The Honorable Cathy McMorris Rodgers, Chair
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Mike Crapo, Ranking Member
Senate Finance Committee
239 Dirksen Senate Office Building
Washington, DC 20510

Re: Response to Request for Information (RFI) on Pharmaceutical Drug Shortages.

Dear Chair Rodgers and Ranking Member Crapo:

Thank you for the opportunity to respond to this RFI exploring the regulatory and economic factors that may contribute to pharmaceutical drug supply chain shortages. The American Society of Health-System Pharmacists (ASHP) 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. We appreciate the opportunity to lend our expertise and knowledge to provide effective solutions to address the nation's pharmaceutical drug shortages.

ASHP Provides Widely Used Resources for Tracking and Managing Drug Shortages

Our members manage drug shortages in hospitals and throughout our nation's supply chain. We use feedback from them, in conjunction with the University of Utah, to maintain a drug shortage list that tracks drug availability, including regional shortages, across the nation. ASHP regularly updates the Food and Drug Administration (FDA) regarding emerging shortages. We list every drug shortage reported on our drug shortage database as soon as it is investigated and confirmed, usually within 24-72 hours.¹ We also provide 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.

Status of the Pharmaceutical Drug Supply Chain:

As of June 2023, the United States is experiencing approximately 300 active drug shortages according to ASHP/University of Utah drug shortages database.² Most of these medications are low-cost generics. Sterile injectable generic drugs used in hospital 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.

Causes of Drug Supply Chain Disruption:

While spikes in demand can cause short-term drug shortages (e.g., amphetamine salts for treatment of ADHD, semaglutide), the most severe and persistent shortages are driven by economic factors that undermine investment in manufacturing capacity, manufacturing quality³, and supply chain reliability (e.g., Akorn, Intas). 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

¹ <https://www.ashp.org/drug-shortages/current-shortages>

² <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics>

³ <https://news.nd.edu/news/extreme-price-competition-in-pharmaceutical-industry-may-put-patients-at-serious-health-risk-study-shows>

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 (e.g., Teva⁴).

Manufacturing, supply chain, and regulatory limitations make it difficult for other manufacturers to rapidly increase the supply of a drug when a company exits the market or experiences a manufacturing disruption. Manufacturers may also rely on shared contract manufacturers to produce a given product. While this may be a cost-effective approach to manufacturing, it does not diversify the supply chain. Despite the appearance of diversity in the supply chain, a quality or supply problem at a shared contract manufacturer can disrupt availability of drug products from multiple manufacturers.

340B Is Not a Driver of Drug Shortages:

We have seen no evidence that the federal 340B drug discount program, which is narrowly tailored to help eligible entities stretch scarce resources in a way that supports patient care, contributes to drug shortages. Single-source, brand-name drugs, which account for the majority of 340B savings, rarely experience shortages.

Recommended Solutions:

To effectively address drug shortages, we strongly urge policymakers to focus on the key drivers of generic drug shortages – quality and supply chain issues and larger healthcare marketplace trends that have placed intense economic pressure on the overall cost of generics.

ASHP has developed the following long-term and short-term recommendations designed to directly address the root causes of generic drug shortages. Please note that these are ASHP's recommendations only – we continue to work closely with other national healthcare groups to develop consensus recommendations, which we look forward to sharing with the Committee.

Short-Term:

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.

- We recommend that FDA finalize, and make public, metrics of quality manufacturing maturity (QMM), so that purchasers can buy from manufacturers less likely to experience a shortage.
- In the absence of publicly reported QMM metrics, we recommend 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.

- We recommend that 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 ANDA

⁴ <https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg>

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.

Enforce Existing Shortage Prevention Requirements: Congress previously passed legislation requiring manufacturers to report information about their manufacturing and supply chains to the 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.⁵ This disregards Congress’ intent, increases the risk of manufacturing disruptions, and prevents FDA from responding to shortages.

- We recommend 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.

Long-Term:

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) and the absence of a mechanism to evaluate quality leaves healthcare providers with cost as the differentiating attribute when making purchasing decisions. This encourages healthcare providers and their group purchasing organizations (GPOs) to aggressively negotiate the price of generic drugs. To encourage greater investment in manufacturing capacity and quality, federal policy should provide manufacturers of critical generic drugs who make this commitment 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.

- We recommend 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.⁶
 - 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.

⁵ <https://docs.house.gov/meetings/IF/IF14/20230511/115917/HMTG-118-IF14-20230511-SD006.pdf>

⁶ 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>)

- 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.

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.

- We recommend 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 abbreviated new drug application (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.¹

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.

- We recommend that the federal government provide low- or no-cost financing to encourage private sector maintenance of a buffer inventory of critical drugs.⁷
 - 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.
 - Access to financing should phase in slowly, to minimize the risk of a demand surge that could result in shortages as providers and distributors build their stockpiles.

⁷ 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 SNS. (<https://www.ashp.org/News/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations>)

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ASHP thanks you for your efforts at addressing pharmaceutical drug shortages. We look forward to continuing to work with you to ensure Americans have access to the life-saving medications they need. If you have questions or if ASHP can assist your office in any way, please contact Frank Kolb at fkolb@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tom Kraus', with a stylized, wavy line extending to the right.

Tom Kraus

American Society of Health-System Pharmacists

cc: Senate Finance Committee Chair Ron Wyden, Senate Health, Education, Labor, and Pensions Committee Chair Bernie Sanders and Ranking Member Bill Cassidy, House Energy and Commerce Committee Ranking Member Frank Pallone, Health Subcommittee Chairman Brett Guthrie, Ranking Member Anna Eshoo.