APhA
American Pharmacists Association

July 7, 2023

The Honorable Cathy McMorris Rodgers
Chair
House Energy and Commerce Committee

The Honorable Mike Crapo
Ranking Member
Senate Finance Committee

Subject: Drug Shortages Request for Information (RFI)

Dear Representative McMorris Rodgers and Senator Crapo,

The American Pharmacists Association (APhA) is pleased to submit comments on the House Energy and Commerce and Senate Finance Committee's drug shortage RFI intending to examine drivers of shortages and identify potential policy solutions. We appreciate your efforts to help prevent, mitigate, and end drug shortages.

APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities.

APhA's members and pharmacists across the country know all too well the realities of drug shortages and how devastating and disruptive they are for patient care and the health care system generally. Patients should not have to endure the hardships and resulting fragmented health care that drug shortages create, which is why APhA remains a long-standing advocate for addressing drug shortages. In fact, APhA's nearly 400 person House of Delegates, has passed policies specific to "Drug Supply Shortages and Patient Care" and "Protecting Pharmaceuticals as a Strategic Asset."

> **Drug Supply Shortages and Patient Care (2012)** (JAPhA. NS52(4): 457; July/August 2012).
> 1. APhA supports the immediate reporting by manufacturers to the U.S. Food and Drug Administration (FDA) of disruptions that may impact the market supply of medically necessary drug products to prevent, mitigate, or resolve drug shortage issues and supports the authority for FDA to impose penalties for failing to report.
> 2. APhA supports revising current laws and regulations that restrict the FDA's ability to provide timely communication to pharmacists, other health care providers, health systems, and professional associations regarding potential or real drug shortages.

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3. APhA encourages the FDA, the Drug Enforcement Administration (DEA), and other stakeholders to collaborate in order to minimize barriers (e.g., aggregate production quotas, annual assessment of needs, unapproved drug initiatives) that contribute to or exacerbate drug shortages.
4. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.
5. APhA encourages pharmacists and other health care providers to assist in maintaining continuity of care during drug shortage situations by (a) creating a practice site drug shortage plan as well as policies and procedures; (b) using reputable drug shortage management and information resources in decision making; (c) communicating with patients and coordinating with other health care providers; (d) avoiding excessive ordering and stockpiling of drugs; (e) acquiring drugs from reputable distributors; and (f) heightening their awareness of the potential for counterfeit or adulterated drugs entering the drug distribution system.
6. APhA encourages accrediting and regulatory agencies and the pharmaceutical science and manufacturing communities to evaluate policies/procedures related to the establishment and use of drug expiration dates and any impact those policies/procedures may have on drug shortages.
7. APhA encourages the active investigation and appropriate prosecution of entities that engage in price gouging and profiteering of medically necessary drug products in response to drug shortages.

Protecting Pharmaceuticals as a Strategic Asset (2020) (JAPhA. 60(5) 9; Sept/Oct 2020).
1. APhA asserts that the quality and safety of pharmaceutical and other medical products and the global pharmaceutical and medical product supply chain are essential to the United States national security and public health.
2. APhA advocates for pharmacist engagement in the development and implementation of national and global strategies to ensure the availability, quality, and safety of pharmaceutical and other medical products.
3. APhA calls for the development, implementation, and oversight of enhanced and transparent processes, standards, and information that ensure quality and safety of all pharmaceutical ingredients and manufacturing processes.
4. APhA calls on the federal government to penalize entities who create barriers that threaten the availability, quality, and safety of United States pharmaceutical and other medical product supplies.
5. APhA calls for the development of redundancy and risk mitigation strategies in the manufacturing process to ensure reliable and consistent availability of safe and high-quality pharmaceutical and other medical products.
6. APhA advocates for regulatory and market incentives that bolster the availability, quality, and safety of pharmaceutical and other medical products.
7. APhA calls for greater transparency, accuracy, and timeliness of information and notification to health care professionals regarding drug shortages, product quality and manufacturing issues, supply disruption, and recalls.
8. APhA encourages pharmacy providers, health systems, and payers to develop coordinated response plans, including the use of therapeutic alternatives, to mitigate the impact of drug shortages and supply disruptions.
9. APhA supports federal legislation that engages pharmacists, other health professionals, and manufacturers in developing a United States-specific essential medicines list and provides funding mechanisms to ensure consistent availability of these products.
10. APhA recommends the use of pharmacists in the delivery of public messages, through media and other communication channels, regarding pharmaceutical supply and quality issues.

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Impact

Drug shortages impacts pharmacy teams and patients in all practice settings. Health systems across the country have dedicated staff that focus specifically on addressing and mitigating the impact of potential and current drug shortages. They scour the country for short supply drugs and develop protocols and allocation schemes for precious drugs, such as those for cancer.

The effect on community pharmacies, particularly small independent pharmacies, is often hardest because they lack the buying power that larger chains or health systems have to purchase or stock up on short supply drugs. During the recent amoxicillin and children's fever drug shortages, many chain pharmacies had drugs available for weeks and months after independent pharmacies, who have smaller on-hand inventories, quickly ran out and could not restock. This left many parents scrambling from pharmacy to pharmacy to find medicines for their sick children.

It is beyond APhA's expertise to quantify the economic impact of drug shortages; however, we can confidently say that it is astounding. Drug shortages lead to increased costs for both the patient and the healthcare system. It creates vulnerabilities and risk for medication errors, adverse events, delays in treatment, waste, and overall decreased health outcomes. It creates ethical dilemmas for rationing and allocations, leading to patients going without needed treatment, further complicating their health condition. Additionally, it leads to inefficiencies in workflows as pharmacy teams scramble to deal with a prescription that cannot be filled if the pharmacy is out.

Although drug shortages typically happen with low-cost generic drugs, all drugs are at risk of shortage for one reason or another. It is not just drugs with one manufacturer. Even drugs with multiple manufacturers, whether APIs or finished dosage forms, are vulnerable to shortages. What is devastating is that drug shortages often involve essential drugs for chronic and life-threatening diseases. Examples include: lidocaine (a drug that is used to prevent and treat pain from medical procedures); neuromuscular blockers (a medication used to optimize surgical conditions and assist with mechanical ventilation in patients who have reduced lung compliance); sodium chloride (a drug used to replenish lost water and salt in the body due to certain conditions); and sterile water (used for many procedures and to reconstitute drug products). Recently, pharmacists have been scrambling to find decades-old drugs for cancer, such as vincristine, which is a critical adult and pediatric chemotherapy drug used to treat various types of cancer with no alternative treatment. As vincristine continues to go in and out of shortage, patients are forced to forgo cancer treatment with no alternative treatment. This is just the tip of the iceberg. There are hundreds of other drugs currently in or recently out of shortage.

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Barriers in payment programs

The fundamental way in which hospitals are paid has contributed in part to drug shortages. Hospitals typically are paid based on a diagnosis-related group (DRG) or case rate, whether by Medicare, Medicaid, or most commercial insurances. That has led to the past 25-30 years of hospital pharmacies being "cost centers," with tremendous pressure to decrease drug costs. That also has led to buying groups that work with hospitals and health systems contracting with manufacturers to get the lowest price possible for generic medications. It is a race to the bottom. In the long run that leads to prices that are so low that there are only a few manufacturers who win awards with the major buying groups still left supplying those medications, and if one or more manufacturers have an API or finished product issue it can lead to shortages. The current chemotherapy drug shortages are a prime example, involving carboplatin, cisplatin, fluorouracil (5-FU), methotrexate, docetaxel, paclitaxel and paclitaxel protein bound. One of the major manufacturers in the US of carboplatin, cisplatin, and 5-FU had a major issue at a manufacturing facility in India earlier this year that contributed to shortage of these products. It has resulted in severe disruption treatment and rationing to many cancer patients across the US.

Another barrier is the impact and influence of rebates and pharmacy benefit managers (PBMs). PBMs negotiate with manufacturers to get their drugs on formulary. In doing so, the manufacturers raise prices and provide the PBMs with large rebates, which are kept by the PBMs. This cycle of rebates continues even after a drug loses its patent protection and generics are approved for marketing. By keeping the higher price brand version on a plan formulary, the PBM can continue to get rebates, blocking out generic versions from getting on formularies. This disincentivizes generic manufacturers from producing their version, leading to fewer options and creating greater risk of shortage if there is a problem meeting market demand.

Manufacturing and drug quality

Better transparency and accountability are needed in drug manufacturing and oversight to help prevent and mitigate shortages and help purchasers make appropriate decisions based on quality and reliable availability of drugs. There are numerous recommendations on how to do this, including recently from the Brookings Institution and the Senate Committee on Homeland Security and Governmental Affairs.

FDA inspections show that some manufacturers cut corners and take risks because the cost of complying may be more than the cost of getting caught not-complying. The FDA is still trying to catch up on the inspection backlog that occurred during the pandemic. Relying on the FDA to catch problems and non-compliance is not the solution. There must be incentives in place for manufacturers to upgrade old or failing facilities and create a culture of compliance and accountability. These incentives could come in the form of loans or grants or vouchers.

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Incentivization can also come in the form of a rating system that rates facilities and manufacturers based on the ability to consistently and reliability produce high quality products and meet standards and requirements. FDA's Quality Maturity Model, which has been in development for several years, would create this type of system. FDA should expedite implementation of this system and then purchasers can use it as a basis to buy quality products. Paying more for reliably available, quality products saves money in the long run since the cost of drugs shortages would be significantly higher for a health system, private or government plan, patients, and the health care system as a whole.

Incentives are also needed to diversify manufacturing of low-cost generics and APIs across facilities and geographic areas, particularly in the US., as well as for more robust national strategic supplies or buffer stocks of essential medicines. Discussions about feasible and constructive incentives should include all stakeholders.

Better transparency of what is in the marketplace is also needed. Under new section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act, as added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), FDA receives annual reports of what has been produced at facilities in the past year. This provides a retrospective account of what was produced. Although it may give some indication of what is in the marketplace, only contemporaneous reporting will give a more accurate and transparent account of what is in the marketplace. The costs and benefits of more real-time reporting should be assessed.

FDA funding

FDA needs more resources and funding to increase inspection coverage and review of facilities to ensure compliance with requirements and the ability to reliably produce quality drug products. FDA investigators on occasion find fraud and deceptive practices at facilities. This illegal activity cannot be caught on a paper review of a facility. FDA needs more people to do onsite, in-person inspections to find this egregious activity. Unfortunately, sometimes when this type of activity is found, the quality of the drug products produced at that facility are called into question. FDA needs more funding and tools to more quickly assess compliance and quality of drugs produced in these situations, as well as the ability for personnel working on drug shortage prevention and mitigation to act more quickly to address and avert potential shortages. In addition, additional resources and funding is needed for investigation into price-gouging situations when drugs are in shortage, either by manufacturers or wholesalers.

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Conclusion

APhA is committed to working with Congress, FDA, the drug supply chain, and other stakeholders in addressing and resolving medication shortages in the US. The pharmacy team is critical in managing drug shortages with health systems, providers, payers, and patients, so it is essential that pharmacists and APhA be engaged with you when evaluating policy options. For follow up and any questions, please reach out to APhA's Director of Congressional Affairs, Doug Huynh at dhuynh@aphanet.org or me at ibernstein@aphanet.org.

Thank you for your efforts and service.

Sincerely,

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