APhA
American Pharmacists Association

AMERICAN PHARMACISTS ASSOCIATION
STATEMENT FOR THE RECORD

BEFORE THE U.S. SENATE COMMITTEE ON FINANCE

DRUG SHORTAGES: EXAMINING SUPPLY CHALLENGES, IMPACTS, AND POLICY SOLUTIONS FROM A FEDERAL HEALTH PROGRAM PERSPECTIVE

MONDAY DECEMBER 18, 2023

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The U.S Senate Committee on Finance
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Chair Wyden, Ranking Member Crapo, and Members of the Committee:

On behalf of our nation's over 310,000 pharmacists, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record to the U.S. Senate Committee on Finance hearing "Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective."

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists and pharmacy personnel 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. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA applauds the Committee's ongoing leadership and recognition of the need to address ongoing drug shortage issues. APhA has recently responded to congressional requests for information, proposed legislation, and the FDA on ways to partner with our nation's pharmacists to address ongoing drug shortages.

APhA also supports the recommendation from today's pharmacist witness, Inmaculada Hernandez, PharmD., Ph.D. for "reforms to the Medicare Part D program to…ensure fair pricing and reimbursement practices, prevent and penalize anti-competitive behavior, foster pharmacy sustainability, guarantee pharmacy access, and promote transparency."

Drug shortages impact 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 and emergency care.

Impact of drug shortages on the vital role of community pharmacies

The effect on community pharmacies of drug shortages, 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. While compounding pharmacies could have alleviated this issue, FDA did not implement APhA's recommendations, which could have mitigated the shortage, including: adding ibuprofen and acetaminophen pediatric oral suspensions to the FDA drug shortage list, issuing temporary guidance for the compounding of acetaminophen and ibuprofen pediatric oral suspensions, and providing enforcement discretion regarding the essential copies and prescription requirement provisions for these products until sufficient supply was available across the country.

Amend the FDCA definition of "drug shortage" and what goes on the drug shortage list to enable faster and broader prevention and mitigation response

The term "drug shortage" is defined in the Food, Drug, and Cosmetic Act (FDCA) in section 506C(h)(2) as: "the term "drug shortage" or "shortage", with respect to a drug, means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug;" FDA's drug shortage response is commendable. FDA can reach into their drug shortage toolbox and use various tools to deflect or mitigate drug shortages. There are many times when a demand exceeds supply throughout the country or in pockets of the country, however, the product does not appear on the FDA drug shortage list. This limits FDA's ability to use some of the effective tools in its toolbox.

The University of Utah/ASHP drug shortages list is broader and more reflective of what's happening in the marketplace. It contains drug shortage information that is reported by healthcare professionals around the country and is investigated and verified before it is added to their list. FDA uses information that is provided by manufacturers to determine whether the product is in shortage or at risk of shortage. Although FDA does query the marketplace, significant reliance on this narrow source of information unnecessarily keeps the bar high for a product to get on the drug shortage list and, consequently, slows prevention and mitigation response efforts.

APhA recommends that the scope of the FDA drug shortage list required under section 506E of the FDCA be broadened to reflect more sources of information. The list should be nimbler and resilient in identifying drug shortages in the U.S., whether widespread or in pockets of the country. Additionally, as experience shows, it takes a while for availability to stabilize across the country. Therefore, we recommend that the definition incorporate a stabilization period to

ensure that the drug shortage has resolved and is not still in a fragile state. For example, the definition of what is reported and what goes on the list could be amended in the following way:

> "the term ''drug shortage'' or ''shortage'', with respect to a drug, means a period of time when the demand or projected demand for the drug, as reported by manufacturers, wholesale distributors, and health care practitioners, within the United States or a region of the United States exceeds the supply of the drug; and continues until six months starting on the day all manufacturers have stabilized market availability across the United States.

Enable compounding pharmacies to help earlier

Currently, under certain conditions, compounded drugs can be made and distributed by state-licensed compounding pharmacies when the drug appears on the FDA drug shortage list. These pharmacies are able to produce products when commercial manufacturers are not able to meet market demand. Because pharmacies compounding under 503A of the law oftentimes compound products for local patients, they are able to more quickly fill in gaps in availability, particularly if a shortage is identified regionally due to specific market demands. For example, if there is misaligned distribution of products across the U.S. because of concentrated cases of an infection, weather, or other acts of nature that surge demand in a region, or during the early or latter stages of a more widespread drug shortage. Unfortunately, current law does not support the ability of 503A pharmacies to fill these gaps. By modifying the definition of "drug shortage," as noted above, the FDA drug shortage list will reflect the dynamics in the marketplace and trigger the ability of 503A pharmacies to compound to prevent or mitigate a shortage.

Reform PBM business practices that contribute to drug shortages

Another cause of drug shortages 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-priced 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 a greater risk of shortage if there is a problem meeting market demand.

Accordingly, APhA strongly supports the Committee's recently passed PBM reform legislation to reign in PBM practices, however, more must be done to mitigate the influence that PBM economic antics contribute to drug shortages by shifting preferences away from lower-cost generic drugs.

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DEA/FDA collaborative forecasting and surveillance

APhA appreciates that the FDA and DEA continue to work closely with hospitals, pharmacists, Congress, and others to prevent or reduce the impact of drug shortages.

For example, on August 1, 2023, the FDA and DEA released a rare joint public letter to provide an update on the recent attention deficit hyperactivity disorder (ADHD) drug shortage. The two agencies announced they are working with multiple manufacturers, agencies, and others in the supply chain to reduce the impact of these shortages and asked drug manufacturers to increase production. FDA is also taking steps to support alternative treatment options while there is a shortage and recommends the use of non-stimulant medications. FDA and DEA also stated that some drug manufacturers have allotted production quota they have not fully used and are on track to fall one billion doses below their allocated quota. Both agencies are asking for unused product quota to be reallocated to manufacturers who could produce these drugs.

On November 1, 2023, the DEA announced changes to its quota allocation process to be more flexible and resilient in allocation management. DEA reduced the amount that manufacturers must keep in inventory to make it easier to relinquish their quote allotments in case they are not able to produce a drug. DEA also took steps to increase manufacturer transparency and receive better real-time data on the status of drug production going forward.

It is essential that FDA and DEA continue with close communication and collaboration in exchanging forecasting and market surveillance data to be nimbler in addressing or mitigating drug shortages. We appreciate that DEA will be moving to a quarterly allocation system, however, by the time quotas are redistributed, it may be too late since manufacturers may not be able to ramp up production fast enough to prevent a shortage.

APhA recommendations to assist in addressing drug shortages

APhA makes the following recommendations to the Committee to assist in addressing drug shortages, including:

- Amend the FDCA definition of "drug shortage" and what goes on the drug shortage list. to enable faster and broader prevention and mitigation response.
- Enable compounding pharmacies to help earlier.
- Reform PBM business practices that are contributing to drug shortages.
- Increasing transparency and accountability in drug manufacturing and oversight to help prevent and mitigate shortages and help purchasers make appropriate decisions based on the quality and reliable availability of drugs.
- Increase incentives to domestically manufacture generic drugs. Congress would also need to provide the FDA with additional funding to increase inspection coverage and review of new manufacturing facilities (e.g., hiring more FDA staff to conduct these

inspections and assess compliance and quality of drugs produced in these facilities, as well as the ability for personnel working on drug shortage prevention and mitigation to quickly address potential shortages).

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APhA appreciates the opportunity to provide this Statement for the Record for the recent hearing to address drug shortages. Pharmacists play a critical role in helping to manage drug shortages for their patients. APhA encourages members of the Committee to leverage the expertise of our nation's pharmacists as you consider solutions for addressing drug shortages for our patients in the United States. Please contact Doug Huynh, JD, APhA Director of Congressional Affairs, at dhuynh@aphanet.org if you have any additional questions or additional information.