AMERICAN PHARMACISTS ASSOCIATION
Improving medication use. Advancing patient care.

January 11, 2019

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville MD, 20852

RE: Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Public Meeting; Request for Comments

Dear Sir/Madam:

The American Pharmacists Association ("APhA") appreciates the opportunity to respond to the Food & Drug Administration's ("FDA") interest in learning more about drug shortages by hosting a public meeting and issuing the request for comments, "Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions" (hereinafter, "RFC"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with FDA to help identify underlying systemic causes of drug shortages and make recommendations for actions to prevent or mitigate drug shortages. APhA appreciates the opportunity to provide input to help inform the FDA-convened inter-Agency task force report regarding the root causes of drug shortages and encourages continued engagement with pharmacists and other stakeholders.

In addition, as a report is developed, APhA recommends the task force consider which definition of shortage is being used and to recognize there are often circumstances where patient access to medications is limited even when a product is not recognized by FDA as in shortage. APhA encourages FDA to also consider developing recommendations to improve patient access to products that are unattainable for other reasons, including manufacturer-imposed limited distribution policies, excessive price fluctuations, minimum order requirements and payer policies where coverage is limited to products dispensed from specific pharmacies. APhA believes these issues also negatively impact patient care because they increasingly make it more difficult for pharmacists to provide products to the patients they serve.

A. Assessing the Adverse Consequences of Drug Shortages to Patients, Health Care Providers and the Drug Supply Chain

In the RFC, FDA seeks feedback regarding the impact of drug shortages on health care providers. As a health care provider, pharmacists are medication experts who serve patients in a variety of ways, including providing patient care services like medication management services, dispensing medications, maintaining inventory, compounding medications, and providing expertise to pharmacy and therapeutics committees, among other potential functions. Therefore, depending on their role and practice setting, shortages impact pharmacists differently and can have serious negative implications on patients' outcomes by affecting access to treatment and adherence.

i. Inventory Issues and Patient Access

Before modifications are made to a patient's treatment plan, pharmacists often spend significant time trying to find and purchase the needed medication. Should a pharmacist find a distributor selling products in shortage or otherwise difficult to obtain, the products can be significantly more expensive. Additionally, the pharmacist may not typically deal with the distributor, making compliance with other laws, such as the Drug Supply Chain Security Act (DSCSA), more difficult. Alternatively, for medications which are available at another pharmacy and difficult to obtain but not yet recognized as being in shortage by FDA, DSCSA can limit pharmacies' ability to engage in transactions with other pharmacies possessing the needed product. APhA encourages FDA to consider how products in shortage, near shortage or otherwise difficult to obtain can be more easily purchased or compounded by pharmacies.

In addition to identifying purchasing options, identifying different treatments can also be time consuming for pharmacists as it may be unclear what alternative treatments are most effective or readily available, how long the shortage will last, or the cause of the shortage. There is significant variability within health care settings regarding efforts to mitigate risks associated with shortages. For example, some large hospitals or pharmacies may have substantial buying power to help ensure access to medications commonly in shortage or sophisticated systems to track medications, conserve inventory and/or automatically recommend substitutions. This is not the case for all settings. As a result, staff and patients receiving care in settings with less sophisticated systems or staff devoted to shortage issues may be more adversely impacted by shortages.

ii. Patient Care

As FDA is aware, drug shortages may force changes to patients' medication(s) and potentially their behavior (e.g., when to take medications, how the medication is administered). Treatment changes may require titrating new medications to obtain optimal dosage or outcomes. Accordingly, when certain medications are not available, pharmacists also monitor patient responses to medications, consider strategies to preserve medications and counsel patients about new medications. However, these crucial pharmacist-provided care services are not typically covered by payers, including Medicare. APhA encourages the inter-agency report to contain an evaluation of costs, including pharmacists and other providers' time, associated with shortages and recommend payers, such as Medicare, cover these needed pharmacist-provided care services.

In addition, when products are difficult to obtain but not yet in shortage, the pharmacy may refer the patient to another pharmacy. Such a referral impacts coordinated care and can cause the patient to pay more for their medications, especially if using an out-of-network pharmacy or paying out-of-pocket. While DSCSA provides flexibility for certain transactions, such as drug shortages caused by a public health emergency, APhA is concerned confusion within states and among pharmacies regarding the permissibility of pharmacy-to-pharmacy transfers and exemptions to the term transaction persist and effectively prevents these transactions from occurring. APhA recommends FDA provide flexibility to pharmacies engaging in transactions, including trades, to prevent gaps in care and maintain patient access to medications for products in shortage or those that are otherwise difficult to obtain (e.g., minimum order requirements, price spikes).

iii. Compounding

Often, compounding medications can help alleviate patient access issues caused by drug shortages. However, pharmacists face several challenges when working to meet patient needs through compounding. APhA's members indicate it takes too long for a drug to appear on FDA's shortage list and there is limited information available about the shortage to help inform their business decision to compound. According to FDA guidance documents,[1,2] a compounded drug product is not considered essentially a copy of a commercially available drug if it is on FDA's drug shortage list. While our members appreciate this allowance, pharmacists have difficulty meeting patient demands before and during the period a product is recognized by FDA as being in shortage because they are unaware how long products will be in shortage and face restrictions dictating when they may compound, distribute, or dispense the product. APhA encourages FDA to develop policies which more efficiently and effectively communicate the details of a shortage, allow for the compounding of near shortage products, and enable compounding for short periods after a product is no longer recognized as being in shortage. APhA believes FDA's development of such policies will help ensure the financial viability for the compounding of otherwise unavailable but needed medications.

B. Identifying the Root Causes and Drivers of Drug Shortages

Often, pharmacists will not know the specific cause of a drug shortage. However, pharmacists will be among the first health care practitioners who are aware a medication is unavailable or inaccessible. APhA's members indicated access issues may stem from manufacturers refusing to sell products broadly (e.g., limited distribution product), price spikes, or demand fluctuations. Some distributors may also impose minimum order requirements limiting pharmacies' abilities to obtain needed medications. For pharmacists, it is not unusual to

[1] Food & Drug Administration (January 2018). Guidance for Industry, Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under 503B of the Federal Food, Drug, and Cosmetic Act (January 2018), available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510153.pdf

[2] Food & Drug Administration (January 2018). Guidance for Industry, Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under 503A of the Federal Food, Drug, and Cosmetic Act (January 2018), available at: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM510154.pdf

learn that a difficult to obtain medication is not recognized as being in shortage by FDA. Yet, the implications to patients are the same.

Pharmacies' inabilities to access these hard-to-acquire medications can persist without any of the regulatory flexibility that exists when FDA recognizes a product in shortage. In addition, the lack of availability of these products is not viewed as a public health issue, unlike when a product is in shortage. However, like when a product is in shortage, patients' use of needed medications will be delayed or alternative, potentially less effective, treatment options provided. APhA encourages FDA to identify and study different supply chain issues preventing pharmacies and other health care entities from obtaining needed products despite those products not being identified as in shortage.

C. Identifying Strategies for Preventing or Mitigating Drug Shortages

APhA appreciates FDA's efforts to identify strategies to prevent or mitigate drug shortages, but reiterates the need to ensure all manufacturer, distributor and repackagerer marketed prescription drugs used in patient care have been FDA-approved as safe and effective and meet DSCSA requirements. APhA is concerned drug shortages and issues obtaining costly medications will result in policies, such as unnecessarily broad importation policies, which weaken the safety and security of the U.S. pharmaceutical supply chain.

APhA has adopted the following policy statements related to drug shortage responses for FDA to consider when identifying strategies for preventing or mitigating drug shortages:

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.

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.

APhA appreciates FDA's efforts to address drug shortages and identify solutions to improve patient access to needed medications. We look forward to reviewing the task force's report and recommendations. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,

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Executive Vice President and CEO

cc: Stacie Maass, BSPharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs