Committee on Energy and Commerce
Subcommittee on Healthcare

Hearing on:
Improving Safety and Transparency in America's Food and Drugs

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Statement for the Record
Submitted by ASHP

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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Energy and Commerce Health Subcommittee hearing on "Improving Safety and Transparency in America's Food and Drugs"

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

We applaud the Committee's efforts to address safety and transparency in America's drugs. ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of medication safety and the accessibility of prescription drugs is one of ASHP's highest and longstanding public policy priorities.

Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase. According to a 2019 Kaiser Health Tracking Poll, 29% of adults report that they are not taking their medications as prescribed due to increased cost with 8% of those individuals reporting that their condition has worsened as a result of poor medication adherence.[1]

ASHP has been proactively addressing challenges related to the manufacturing of prescription drugs on several fronts, including implementing proper safety measures and safeguards, and educating members of Congress about the unsustainable burdens drug shortages pose on patients, healthcare providers, and the entire healthcare system.

ASHP is committed to advancing policies that will ensure the manufacturing of prescription drugs is safe and effective, promote open competition in the marketplace, and provide patients with the proper access to care. We appreciate the opportunity to work with you and your colleagues on this issue.

ASHP supports the passage of H.R 4866 the "National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act." Disruptions in the drug supply often stem from quality challenges in the manufacturing of final dosage forms. The U.S. Food and Drug Administration (FDA) has identified continuous manufacturing as a potential alternative to traditional batch manufacturing, which could improve the quality of drug manufacturing. Investment in domestic continuous manufacturing also offers potential to reduce our dependence on highly concentrated foreign sources of drug manufacturing.

We are hopeful that H.R. 4866 will accelerate adoption of continuous manufacturing in the United States.

ASHP also encourages Congress to consider the following additional solutions to reduce the frequency and duration of drug shortages:

1. **Require manufacturers to provide FDA with more information on the causes of shortages and their expected durations and allow public reporting of this information.**

[1] Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 15). KFF Health Tracking Poll – February 2019: Prescription Drugs. Retrieved March 8, 2019, from https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

Current law requires manufacturers to notify FDA when there is a discontinuance or interruption in manufacturing. However, manufacturers are not required to disclose the cause of the interruption or provide a timeline for resolution. Some manufacturers do this voluntarily, but inconsistent information hinders FDA's ability to mitigate shortages. Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) should be strengthened to require these notifications be published in the FDA drug shortages database and include the cause of the interruption and a timeline to address the shortage.

2. **Require drug manufacturers to disclose manufacturing sites, including use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs) to FDA.**

FDA lacks access to key information to assist in preparation and improve resilience of drug manufacturing operations in the face of regional disasters, geopolitical instability, or manufacturing problems at specific sites. The Federal Food, Drug, and Cosmetic Act (FFDCA) should be strengthened to require manufacturers to disclose to FDA the location of drug production, including when a contract manufacturer is used, and sources of APIs. FDA can use this information to more accurately assess the scope and duration of a shortage as well as identify potential supply disruption for related products, including associated medical devices.

3. **Require manufacturers to establish contingency plans to maintain supply of a drug in the event of a manufacturing disruption.**

Manufacturers cannot always predict when a shortage will occur. Manufacturing disruptions can be caused by natural disasters, quality issues, or business decisions which may include discontinuation of a product. Such shortages negatively impact patient safety and access to care. The FFDCA should be amended to include a requirement that manufacturers develop and maintain business continuity contingency plans for future supply disruptions that are reviewed during FDA plant inspections.

4. **Establish incentives to encourage manufacturers to produce drugs in shortage or at risk of shortage.**

Drugs with fewer than 3 manufacturers are at greatest risk for shortages. FDA should recommend incentives to encourage manufacturers to begin producing drugs that are in shortage.

5. **Require the Department of Health and Human Services (HHS) and the Department of Homeland Security (DHS) to conduct a risk assessment of national security threats associated with manufacturing and distribution of critical drugs, their APIs, and associated medical devices used for preparation or administration.**

Relying predominantly on other countries for necessary ingredients to manufacture crucial drugs, APIs, and devices required to safely prepare and administer these drugs presents a potential threat to the stability of the US drug supply. At present, more than 80% of API is produced in China and India – this leaves our supply chain vulnerable to disruption and puts API sourcing at risk. In addition to critical drug products, medical devices necessary for the preparation and administration of drugs are a critical part of healthcare infrastructure. Devices like syringes, needles, and tubing for administration of intravenous drugs have been affected by shortages.

HHS and DHS should 1) conduct a review of priority risks to API and finished pharmaceutical manufacturing and distribution systems, including identification of ways the U.S. government can support preparedness and resilience of critical infrastructure in the pharmaceutical sector, and 2) conduct an assessment of risk for foreign manufacturing of API, finished pharmaceuticals, and medical devices, and 3) establish a standing forum to engage the private sector, including pharmacists, hospitals, physicians and manufacturers, to mitigate these risks.

6. **Require FDA to publish quality ratings for drug manufacturers and 503B outsourcing facilities preparing copies of drug products under the exemption for products on FDA's shortage list or make public such information that would allow purchasers to assess the relative quality of 503B outsourcing facilities**

Drug shortage data indicate that a majority of recent shortages were due to manufacturing quality issues. Hospitals and health systems often make purchasing decisions without any ability to access manufacturing quality data. FDA inspection notices and warning letters describe inspections that are several months old and do not provide timely information of satisfactory resolution of problems identified and do not identify specific products manufactured at that facility. Healthcare personnel need a mechanism to inform purchasing decisions based on manufacturer quality.

FDA should publish manufacturing quality ratings, or make public information that would allow purchasers to compare manufacturing quality when making purchasing decisions. Similar ratings or information should be made public to assess quality of products produced in 503B outsourcing facilities.

7. **Require the Federal Trade Commission (FTC) to evaluate the potential for drug product supply chain interruptions when considering manufacturer consolidations.**

Consolidation in the pharmaceutical industry has disrupted manufacturing lines and created quality issues, resulting in extended duration shortages of critical drug products. To prevent shortages related to mergers and acquisitions, FTC review of proposed consolidations in the pharmaceutical industry should require analysis of potential public health impacts – specifically, the likelihood the transaction will create new and/or exacerbate existing drug shortages.

CONCLUSION

ASHP thanks the Energy and Commerce Committee Subcommittee on Health for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.