**AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS STATEMENT FOR THE RECORD**

**"Truth in Labeling – Americans Deserve to Know Where Their Drugs Come From"**

**U.S. Senate Special Committee on Aging**

January 29, 2026

Chairman Scott, Ranking Member Gillibrand, and Members of the Special Committee on Aging:

**Introduction:** The American Society of Health-System Pharmacists (ASHP) appreciates the Special Committee on Aging's comprehensive work on creating a more resilient and reliable drug supply chain. For over 20 years, ASHP has worked to strengthen the drug supply chain by publicly reporting drug shortages, providing resources to support patients and clinicians affected by supply disruptions, and advocating for a stronger drug supply chain.

America's drug supply chain is currently challenged by hundreds of ongoing drug shortages and concerns about drug reliability and quality.[1][2][3] These challenges, along with geopolitical risks to our drug supply chain, threaten our national healthcare security. These are decades-old problems with multiple causes.

Every American should have the right to know where their pharmaceuticals are manufactured. Today, that information can be voluntarily provided by manufacturers, but it is not required. While ASHP supports transparency in the pharmaceutical supply chain, including country-of-origin labeling, no single policy will fix the underlying problems that have led to the current fragile supply chain.

Over the last few months, the committee has thoroughly investigated the pharmaceutical supply chain: manufacturers, wholesalers, group purchasing organizations, distributors, and pharmacies. I ask that the committee consider that the drug supply chain in the United States is composed of two distinct supply chains: brand-name, single-source products, and older, generic, multisource products. Financial incentives and challenges separate the two supply chains.

Brand-name manufacturers have a strong market incentive to invest in the resiliency of their supply chains and to produce high-quality drugs. However, price erosion and race-to-the-bottom market

[1] ASHP Drug Shortages Statistics: https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

[2] Written testimony, Peter Baker: https://www.aging.senate.gov/imo/media/doc/ab6519c3-c1ce-3adb-a0a9-0d3992a936d5/Testimony_Baker%2009.17.25.pdf

[3] Are All Generic Drugs Created Equal? An Empirical Analysis of Generic Drug Manufacturing Location and Serious Adverse Events: https://journals.sagepub.com/doi/10.1177/10591478251319691

dynamics result in a brittle supply chain for older, generic products. With slim-to-negative profit margins, generic manufacturers are less likely to invest in resiliency and quality maturity. Generic manufacturers that are capable and willing to make those investments often lose market share due to pricing competition from manufacturers that are unwilling or unable to invest in resiliency and quality maturity. Without a public mechanism to evaluate quality maturity and resiliency investments, purchasers have no information, aside from price, to leverage when buying drugs, reinforcing race-to-the-bottom market dynamics and undercutting market resiliency. The lack of market recognition for these investments reduces incentives for manufacturers to commit to quality and resiliency, contributing to a fragile supply chain and resulting in drug shortages.

While there may be a correlation between country of manufacture and drug product quality, the country of origin alone is not a reliable proxy to evaluate drug product quality. There are many examples of manufacturers, both domestic and overseas, that have faced quality challenges in the recent past. We support public disclosure of where our drugs are made, but we ask that the committee consider additional policies if the intended result is to improve the overall reliability and resiliency of America's drug supply chain. Drug shortages, product quality, and national healthcare security are all related to the resiliency and reliability of our pharmaceutical supply chain (Figure 1). Policies to address each of these risks and vulnerabilities can solve multiple root causes and result in a resilient supply chain of high-quality pharmaceuticals that withstands demand and supply shocks.


*Figure 1: Policies to address drug product quality, national healthcare security vulnerabilities, and drug shortages support a resilient and reliable supply chain*

**ASHP's Role in the Pharmaceutical Supply Chain:** ASHP is the largest association of pharmacy professionals in the United States, representing over 65,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. Our members manage drug shortages in hospitals, ambulatory clinics, and various other healthcare settings. As part of our mission, we have publicly reported national drug shortages for over two decades. We collect public reports of drug shortages from clinicians, patients, and caregivers. Through a partnership with the University of Utah Drug Information Service, ASHP maintains a drug shortages list that includes active and resolved drug shortages.[4] We post every prescription drug shortage report we receive to our database as soon as it is investigated and confirmed with the manufacturer, usually within 24-72 hours. The ASHP Drug Shortages List includes information down to the individual manufacturer and national drug code level and reflects any supply interruption that affects how a pharmacy prepares or dispenses a drug product.

[4] ASHP Drug Shortages List: https://www.ashp.org/drug-shortages/current-shortages/drug-shortages-list?page=CurrentShortages

We also provide practitioner-focused resources to help the healthcare community manage shortages. Examples include guidelines for managing drug shortages, specific recommendations and clinical considerations for therapeutic alternatives to drugs in shortage, comparisons within individual drug classes, and safety information to reduce the risk of medication errors during shortages.

**Current and Long-Term Trends in Drug Shortages:** Our current data indicate that drug shortages are improving.[5] Eighty-nine new drugs were added to the ASHP Drug Shortages List in 2025, the fewest additions since 2006. However, we continue to track over 200 ongoing drug shortages, including lifesaving and life-sustaining drugs used in critical care and surgical settings. Solutions targeted at these root causes include promoting quality and transparency, ensuring diversity in the manufacturing base, and directly incentivizing new manufacturing. As noted, a critical component to promoting quality, transparency, and diversity is providing information so manufacturers and purchasers know where the active pharmaceutical ingredients (APIs) and finished products are produced.

**Causes of Drug Shortages:** The causes of drug shortages can range from raw material availability to natural disasters disrupting infrastructure. Most often, shortages are caused by manufacturing delays or declines in manufacturing quality.[6] [7] [8] The root causes behind these shortages are a lack of incentive to produce older, generic drugs with slim profit margins, and limited market recognition of manufacturers with reliable supply chains and high-quality systems.[9]

**Country-of-Origin Labeling Can Improve Transparency and May Influence Purchasers:** Research has shown that patients and pharmacy purchasers prefer to buy drug products manufactured in the U.S. or Canada compared to products from India or China when the country of origin is made available to them.[10] But our research misses key factors that affect purchasing decisions in practice. Choice is often an illusion. Patients receive whichever product is on a pharmacy contract from a wholesaler, pharmacy

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[5] ASHP Drug Shortages Statistics: https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics
[6] National Academies of Sciences, Engineering, and Medicine Building Resilience into the Nation's Medical Product Supply Chains: https://nap.nationalacademies.org/catalog/26420/building-resilience-into-the-nations-medical-product-supply-chains
[7] ASHP Virtual Summit on Safe, Effective, and Accessible High-Quality Medicines as a Matter of National Security: https://academic.oup.com/ajhp/article/78/6/511/6009025
[8] FDA Drug Shortages: Root Causes and Potential Solutions: https://www.fda.gov/media/131130/download?attachment
[9] Ibid
[10] Generic Drug Transparency: Testing a Regulatory Proposal: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4639108

benefit manager, or group purchasing organization. At the pharmacy counter, a patient is likely to receive their prescription in an amber bottle dispensed by the pharmacy and will never see the manufacturer's container. In hospitals, clinics, and surgery centers, medications are prepared and administered without patients seeing them beforehand.

While patient and buyer behavior may not change directly because of country-of-origin labeling, increased transparency about where our drugs and ingredients are manufactured can help government agencies, private investors, and researchers better understand the drug supply chain and decide where to invest resources to address vulnerabilities. With this in mind, we urge the committee to consider requiring disclosure of sources of APIs and key starting material (KSMs) so that agencies have information to identify critical dependencies and vulnerabilities.

While ASHP strongly supports supply chain transparency, we urge the committee to consider the goal of country-of-origin labeling and directly address deficiencies or apply incentives to achieve the desired outcomes. For example, if the goal is to improve overall supply chain quality, consider more transparency in manufacturer quality to provide market recognition for manufacturers with strong quality systems. Strengthening the Food and Drug Administration's (FDA) capabilities to conduct overseas and surprise inspections and enhancing enforcement authority for recalls of adulterated or contaminated drug products can also improve the overall quality of the drug supply chain.

Reliance on potential geopolitical adversaries can also be addressed more directly. The Agency for Strategic Preparedness and Response has undertaken a Strategic Active Pharmaceutical Ingredients Reserve to build onshore stockpiles of essential medicines.[11] Building buffer inventories of finished dosage forms, APIs, and KSMs can allow critical parts of the supply chain to withstand supply and demand shocks, improving national healthcare security and reducing drug shortages. The United States relies heavily on China for raw materials needed to manufacture pharmaceuticals.[12] Trade tensions and the threat of armed conflict between China and Taiwan may threaten access to these KSMs and other inputs needed to maintain access to life-sustaining and lifesaving drugs. Financial incentives and supply

[11] Ensuring American Pharmaceutical Supply Chain Resilience by Filling the Strategic Active Pharmaceutical Ingredients Reserve: https://www.whitehouse.gov/presidential-actions/2025/08/ensuring-american-pharmaceutical-supply-chain-resilience-by-filling-the-strategic-active-pharmaceutical-ingredients-reserve/

[12] Concentrated Origins, Widespread Risk: New USP Insights on Key Starting Materials: https://qualitymatters.usp.org/concentrated-origins-widespread-risk-new-usp-insights-key-starting-materials

chain transparency can help stakeholders identify vulnerabilities and accelerate the de-risking of supply chains from Chinese sources.

**ASHP's Additional Recommendations to Address Drug Shortages[13]:** We agree with the committee that a comprehensive approach is needed to solve the nation's drug shortages. In addition to labeling transparency and the aforementioned policies, we also make the following recommendations to the committee to effectively address drug shortages through quality, transparency, and direct economic incentives:

- **Enforce Existing Drug Shortage Requirements:** Congress should amend section 510(j) of the Food Drug and Cosmetic Act (FDCA) 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.
- **Improve Transparency into Manufacturer Quality:** Congress should require FDA to finalize and make public metrics of quality management maturity (QMM) so that purchasers can buy from manufacturers less likely to experience a shortage. In the absence of publicly reported QMM metrics, FDA should make unredacted manufacturing inspection reports publicly available so that purchasers have a better understanding of supplier manufacturing challenges and which products are made at facilities with records of manufacturing quality and compliance problems.
- **Encourage New Manufacturers and Manufacturing Sites:** Congress should give FDA authority to waive generic drug user fees for drugs described in 506C(g) of the FDCA, for which FDA may prioritize and expedite review of an abbreviated new pharmaceutical drug application (ANDA) or related supplement to mitigate a shortage. The fee waiver would apply only to manufacturers that commit to promptly market their generic pharmaceutical drug if it is approved.
- **Encourage Long-Term, Guaranteed-Volume Contracts:** Congress should authorize the Centers for Medicare & Medicaid Services to provide an add-on payment to providers for critical generic pharmaceutical drugs determined by the Department of Health and Human Services (HHS) to be at risk of experiencing a shortage, if those providers certify that they have entered an agreement to

[13] ASHP Policy Solutions to Address the Drug Shortage Crisis: https://www.ashp.org/-/media/assets/advocacy-issues/docs/2023/ASHP-Drug-Shortage-Recommendations.pdf

acquire at least 50% of their historical purchase volume for those products via long-term contracts. To ensure investment in supply chain stability and quality, the agreement must include a requirement that manufacturers maintain a six-month buffer supply of finished product as well as meaningful penalties for failure to supply contracted products, including when manufacturing disruptions result from regulatory violations or supplier disruptions. To be eligible for pass-through payments, providers must demonstrate that their suppliers participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[14]

- **Diversify the Manufacturing Base:** Congress should require the federal government to use its purchasing power to encourage greater diversity and redundancy in the supply chain by spreading purchase volume from federal agencies across at least three different manufacturers with approved ANDAs for any critical generic pharmaceutical drug determined by HHS to be at risk of experiencing a shortage. Federal purchasers should require that manufacturers not rely on the same contract manufacturers, as this would do little to diversify the manufacturing base. Federal contracts should require manufacturers to maintain a six-month buffer supply of finished product and include meaningful penalties for the failure to supply, including when manufacturing disruptions result from regulatory violations or supplier problems. As noted earlier, to ensure quality and transparency, federal agencies should give preference to manufacturers that participate in FDA's QMM program and voluntarily make their QMM metrics publicly available.[15]

ASHP greatly appreciates the Senate Special Committee on Aging's leadership in working to ensure America's seniors have access to safe and effective drugs without hindrance or delay. Such efforts are critical to ensuring patients have continuity of care. We look forward to working with the committee to provide greater transparency into the drug supply chain and ensure patients and providers have ready and uninterrupted access to safe and effective drugs required to ensure optimal patient care.

[14] Healthcare Groups Release Drug Supply Chain Recommendations: https://news.ashp.org/news/ashp-news/2021/12/16/healthcare-groups-release-drug-supply-chain-recommendations
[15] Ibid

Thank you for the opportunity to appear before this committee.

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