

February 26, 2024

The Honorable Ron Wyden

Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Crapo

Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Wyden, and Ranking Member Crapo,

We appreciate the opportunity to provide feedback and offer our perspective to the Senate Committee on Finance's [white paper](#), *Preventing and Mitigating Generic Drug Shortages: Policy Options Under Federal Health Programs*. The Healthcare Distribution Alliance (HDA) is the national organization representing primary pharmaceutical distributors. HDA advocates on behalf of pharmaceutical wholesalers and distributors, leads the sector on relevant policy, and fosters relationships across partner organizations. As the committee continues to examine the issue of drug shortages and potential market-based solutions, HDA and its members welcome the opportunity to continue a dialogue with committee members and staff.

Due to our members' role in the pharmaceutical supply chain, we see the issue of drug shortages as highly nuanced and dynamic. Distributors' unique role in the supply chain provides them with a perspective on the upstream availability of products and the downstream needs of the provider community, including in the hospital, physician and pharmacy settings.

Hospital and Physician Settings

One of the most acute and challenging drug shortages is in the generic sterile injectable (GSI) drug category. These medicines are commonly used in a hospital or physician setting for everyday medical needs such as oncology, emergency medicine, and anesthesiology.¹ There is a need to address the market dynamics for GSIs, recognizing that they are costly and time consuming to produce and generate very little revenue for manufacturers.

HDA is supportive of policies that increase reimbursement for GSIs. Due to the complexity of manufacturing and low returns, these medicines have been subject to chronic shortages². HDA

¹ U.S. Food and Drug Administration. Drug Shortages: Root Causes and Potential Solutions. Published 2019. Updated 2020. <https://www.fda.gov/media/131130/download?attachment>.

² Ibid.

encourages higher Medicare reimbursement to be coupled with higher payments to manufacturers who are willing to support a resilient supply chain. HDA also supports proposed policies to reform Medicare payments by providing reasonable reimbursement increases for these medicines to providers.

In addition to assessing a new payment benchmark for GSIs, the committee has offered perspectives on other policies that could help prevent or mitigate drug shortages in hospital settings. While we will defer to the provider community on many of those suggestions, we have some perspectives on policies to potentially expand stockpiles or create buffer inventories in the hospital setting. Below, you will find our perspectives on hospital shortage and mitigation plans.

What elements should be considered in hospital shortage prevention and mitigation plans?

Distributors understand that hospitals must have access to a continuous supply of medicines to provide patient care and that expanding stockpiles or creating buffer inventories could help insulate hospitals from acute shortages. However, any type of stockpile or buffer inventory plan will require careful consideration to ensure that it will be targeted to specific medicines, be equitable, and not exacerbate existing shortages.

HDA encourages the committee to consider the feasibility of hospitals establishing and maintaining individual buffer inventories. We have previously [expressed concerns](#)³ that buffer inventory programs have the potential to increase demand-induced shortages in the near term. Buffer inventory programs could create challenges for small and rural hospitals that do not have the resources to purchase or store expanded inventories of medicines. Hospital buffer inventory can also impact other healthcare facilities, such as retail pharmacies, because if a buffer inventory product is in shortage distributors will not be able to allocate based on customer need. Any buffer inventory or stockpiling proposal should consider fair distribution for all healthcare facilities (i.e., hospitals, oncology clinics, health-systems, retail pharmacies, etc.), ensuring equitable access to products is maintained. If a buffer inventory program is not carefully executed and transparent, it can exacerbate or create shortages, further inequities, logistical challenges, and waste products.⁴

Any buffer inventory program will require partnership and participation from multiple supply chain stakeholders, including distributors and manufacturers. Distributors and manufacturers are better situated than individual hospitals to view the entire market's needs and develop procedures for building and managing stockpiles that can be made available to the commercial market without exacerbating drug shortages. Plans to identify critical drugs at risk of shortage and how hospitals leverage contracting procedures include should input from supply chain stakeholders, especially manufacturers and distributors.

³ Healthcare Distribution Alliance. HDA CMS Hospital Buffer Stock Proposed Rule Comments. Published 2023. <https://www.hda.org/getmedia/dc5307d1-538b-44b8-92a0-af8990db49a2/HDA-CMS-Hospital-Buffer-Stock-Proposed-Rule-Comments.pdf>.

⁴ Avalere. Drug Shortages: Landscape Assessment of Policy Proposals to Prevent and Mitigate Drug Shortages. Published 2024. <https://avalere.com/wp-content/uploads/2024/01/Drug-Shortages-Whitepaper-1.25.2024.pdf>.

Would it be appropriate to extend similar requirements or incentives to develop such plans to other supply chain stakeholders?

HDA and its members do not support extending similar requirements to develop drug shortage prevention and mitigation plans to other supply chain stakeholders, especially distributors. Distributors already [mitigate and manage drug shortages](#) as part of their everyday business practices.⁵ Distributors mitigate shortages by often sourcing from multiple suppliers in geographically diverse regions and entering into long-term contracts with manufacturers.⁶ Distributors manage shortages using strategies such as a [fair-share allocation program](#), supporting stockpile expansion, and [leveraging national distribution networks](#).

Pharmacy Settings

Distributors recognize that pharmacies are under increasing financial pressure from the pharmacy benefit manager (PBM) and payer sectors. This puts enormous strain on pharmacies' financial viability and often forces pharmacies to purchase the absolute lowest cost products available. This challenging dynamic is why distributors work to create reliability and stability for downstream customers. Without distributors 1,500 manufacturers would have to connect with over 330,000 sites of care, including pharmacies, multiple times a week. Distributor practices reduce operating expenses in the pharmaceutical supply chain, which creates savings for pharmacies.

HDA defers to the pharmacy community about the potential for bonus payments and performance incentives. However, we urge the committee to consider the reimbursement pressures pharmacies face from the payer and PBM communities. Any incentives or bonuses should flow directly to the pharmacies and not be contingent on assessments or performance ratings determined by the payers. Also, any pharmacy reimbursement reform should work to alleviate the financial strain that pharmacies experience.

Below, you will find answers to the questions about drugs dispensed in retail settings and the Medicare Part D prescription drug benefit.

What strategies and business practices do stakeholders in the retail prescription drug supply chain (e.g., pharmacies, wholesalers, plans, PBMs, manufacturers) currently use to help prevent, mitigate, and manage drug shortages?

HDA's members [mitigate and manage drug shortages daily](#), whether [supply-driven](#) or [demand-driven](#). Distributors source generic medicines from multiple suppliers in geographically diverse regions whenever possible to guard against potential natural disasters or geopolitical unrest. Distributors often enter long-term arrangements with manufacturers to ensure a steady and reliable supply of medicines.⁷ When supply disruptions occur, distributors employ strategies such as a [fair-share allocation](#), to supporting stockpile expansion, and [leveraging national distribution networks](#).

⁵ Healthcare Distribution Alliance. Mitigating and Managing Drug Shortages: The Role of Healthcare Distributors. Published 2023. <https://www.hda.org/getmedia/984131d4-5163-411a-b74b-f3467113146b/Mitigating-and-Managing-Drug-Shortages.pdf>.

⁶ Healthcare Distribution Alliance. HDA RFI Submission Drug Shortages. Published 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

⁷ Healthcare Distribution Alliance. HDA RFI Submission Drug Shortages. Published 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

Distributors understand that certain products are at a higher risk of experiencing market failure due to the low number of manufacturers and low reimbursement levels⁸. We encourage the committee to examine products at a high risk of experiencing market failures due to a low number of manufacturers, the complexity of manufacturing, or a potential for a sharp increase in demand for such products. HDA encourages the committee to recommend that the National Academy of Medicine review the impact of current policies to lower drug prices, increase the number of generic medicines in the market, and determine whether these policies contribute to the “race to the bottom” in pricing. We also encourage the committee to consider the need for increased federal investment for the FDA to conduct foreign inspections of generic facilities.

Policies addressing generic drug shortages must acknowledge the financial strains stakeholders face in the generics market. Current market dynamics are affected by policies that lower drug prices while other policies have increased the number of generic manufacturers in the market. These policies have been overly successful, creating a commoditized market. Distributors recognize the challenges in the generics marketplace, and they focus on creating stability and reliability for both upstream manufacturers and downstream customers. Despite the good faith actions distributors take, they operate at the mercy of a generics commoditized market like all other stakeholders.

What policy options would create incentives for pharmacies and wholesalers to purchase from generic manufacturers that invest in quality and reliability?

Distributors have existing robust processes, such as contracting with generic manufacturers to create sustainability and reliability, when sourcing generic drug products. The criteria distributors look for in their manufacturing partners are to ensure a dependable, resilient supply of medicines for the benefit of healthcare providers and patients. Once distributors onboard a manufacturer trading partner, they often maintain long-term contracts with those manufacturers.⁹

Since the passage of Hatch Waxman in 1984, generic manufacturers have operated in a very complex and rapidly changing environment driven largely by companies entering and exiting the marketplace. The main criteria for any Abbreviated New Drug Approval (ANDA) to be approved is the assurance of bioequivalence and quality.¹⁰ Once approved a manufacturer may enter the market as the first generic alternative to an innovator product, or as a subsequent entrant to an already existing generic marketplace. When generic manufacturers do enter the market, the only way they can gain market share is to compete with existing manufacturers on price. Often the last generic entrant on a particular molecule will lower the existing market price to gain market share.

In addition to this dynamic, providers and pharmacies face downward financial pressure from payers, causing them to seek lower generic drug prices. That then creates upstream pressure for drug manufacturers to lower their prices, in addition to the pressures stemming from other generic manufacturers. As a result of these pressures, manufacturers face unrelenting market

⁸ Avalere. Drug Shortages: Landscape Assessment of Policy Proposals to Prevent and Mitigate Drug Shortages. Published 2024. <https://avalere.com/wp-content/uploads/2024/01/Drug-Shortages-Whitepaper-1.25.2024.pdf>.

⁹ Ibid.

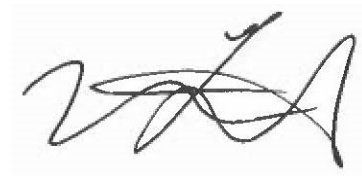
¹⁰ U.S. Food and Drug Administration. Generic Drug Facts. Published 2021. <https://www.fda.gov/media/107601/download>.

dynamics that often result in decisions to leave the market, or failures to maintain Current Good Manufacturing Practices (CGMPs) and Quality Assurance (QA) standards that are often the leading causes of regulatory interventions and subsequent disruptions in supply. Any policy incentives that seek to promote investing in quality and reliability should not interfere with current practices that create reliability and sustainability in the pharmaceutical supply chain.

Conclusion

HDA and its members thank the Senate Committee on Finance for its thoughtful work on market-based solutions to prevent drug shortages. We stand ready to provide our continuing perspective on the complex dynamics associated with drug shortages and our [policy recommendations](#) on the matter. If you have any questions or would like additional information, please contact Dr. Nicolette Louissaint by email at nlouissaint@hda.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'N. Louissaint', written over a light gray rectangular background.

Nicolette Louissaint, PhD, MBA
Senior Vice President, Policy and Strategic Planning