

# HDA Policy Recommendations To Address Drug Shortages

(Updated 9/7/23)

The Healthcare Distribution Alliance (HDA) and its members recognize that drug shortages are a highly complex and nuanced issue, requiring a holistic policy response. Accordingly, HDA collaborates with our members, regulators, policymakers and other healthcare supply chain stakeholders to ensure the availability of safe and effective medicines. While drug shortages are a challenge facing the healthcare industry, it is worth noting that drug shortages peaked in 2011 with more than 250 new shortages.<sup>1</sup> Since then, the number of drug shortages has declined to 49 new drugs in shortage in 2022.<sup>2</sup>

To mitigate drug shortages, distributors continuously work to enhance supply chain resilience (that is, the capacity to prepare for, respond to and recover from planned and unplanned disruptions) and maintain operational resilience (referring to an organization's ability to resist, adapt to and recover from system disruptions that have the potential to hinder its capabilities). Though the causes of various drug shortages may share similarities, each shortage is unique and should be evaluated individually. Healthcare distributors' unique vantage point into the supply chain allows distributors to analyze each shortage, understanding that there is no one policy solution to solving drug shortages.

HDA and its healthcare distributor members understand that drug shortages may pose problems for healthcare providers and patients and have proposed a series of policy recommendations to mitigate them.

## Challenge

Generic drugs represent 90.2 percent of prescriptions dispensed in the United States (2022 data).<sup>3</sup> There are a record number of Abbreviated New Drug Applications (ANDAs) approved for generic drugs by the U.S. Food and Drug Administration (FDA). While a record number of ANDAs approved may increase supply, 16 percent of total approved ANDAs were not launched in 2022.<sup>4</sup> In 2021, 41 percent of ANDAs were not launched.<sup>5</sup>

- **Recommendation:** To encourage the launch of approved ANDAs, the FDA should review the relationship between the number of ANDAs and the number of suppliers currently in the market, specifically for products at high risk of shortage.
- **Rationale:** ANDAs that are not launched may result from market challenges, such as manufacturers not seeing a viable market to make production worthwhile or prices being driven too low if new competition enters the market. The FDA considering what products and suppliers are in the market will mitigate some of the market challenges, such as the market being overly saturated with a specific product.

1. US Food and Drug Administration. "Tenth Annual Report on Drug Shortages for Calendar Year 2022." <https://www.fda.gov/media/169302/download>.  
2. Ibid.  
3. Doug Long, IQVIA. "US Pharmaceutical Trends, Issues & Outlook for HDA." Presented March 13, 2023.  
4. Ibid.  
5. Ibid.

## Challenge

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Some drug shortages result from chronic challenges driven by manufacturing quality issues, such as in the case of generic sterile injectables. Chronic drug shortages within a specific product class often result from manufacturing quality issues and reflect a need for greater investment in robust supply chain resilience practices, which include robust manufacturing processes to mitigate contamination issues.<sup>6</sup>

- **Recommendation:** The FDA should work with the private sector to conduct a focused review of the challenges affecting specific product classes.
- **Rationale:** Each drug shortage, including those that impact a particular class of drugs, is unique and should be examined independently. The review from the FDA will identify what investments may be appropriate for classes of drugs prone to shortages.

## Challenge

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The adoption of broader resilience practices may help prevent drug shortages. Broader resilience practices may include creating additional production capabilities or carrying buffer stock. These practices are often cost-prohibitive and carry a risk of financial insolvency.

- **Recommendation:** Congress and the FDA should examine financial incentives and operational considerations for strategically investing in product development and capacity and work with distributors to build targeted safety stock/buffer stock inventory.

- **Rationale:** Broader resilience practices are necessary to mitigate drug shortages. They will mitigate supply-driven shortages by incentivizing manufacturers to invest in quality measures, such as to prevent contamination. Investing in safety stock/buffer stock will decrease the impacts of both supply-driven and demand-driven shortages.

## Challenge

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Generic drugs represent most prescriptions dispensed in the United States. However, there are barriers to broader adoption of generics and biosimilars. A notable barrier is that pharmacy benefit managers (PBMs) often place a higher-priced product on a Tier 1 formulary for commercial and government-mandated health plans because the PBM receives a larger rebate for higher-cost products. Putting a higher-priced product on a Tier 1 formulary makes it difficult for lower-cost products, including generics and biosimilars, to gain traction in the marketplace. This PBM practice harms patient access and stifles the operational abilities of generic and biosimilar manufacturers.

- **Recommendation:** The Centers for Medicare and Medicaid (CMS) should give preferred formulary positions to new generics and biosimilars.
- **Rationale:** Preferred formulary positions for lower-cost products, such as generics and biosimilars, may incentivize manufacturers of low-cost products to justify the continued production of products that may not generate strong financial incentives.

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

Learn more about the distribution industry's recommendations to mitigate drug shortages from HDA's response to the House Energy and Commerce Committee's [drug shortages request for information](#). Visit <https://www.hda.org/drug-shortages/> for additional information.