MAY 2025

USP Annual Drug Shortages Report:

Long-standing drug shortages persist in 2024

Medicine Supply Map

Executive Summary

For many years, drug shortages have made headlines as disruptions of access to medicines continued to rise and impact patients.

The USP Annual Drug Shortages Report finds that long-lasting shortages make up the majority of the total, despite the decline in the number of total and new drug shortages (11 new shortages in 2024, down from 34 in 2023). More than 40 medicines have now been in shortage for three or more years, with five of those drugs in shortage for 10 or more years. Many of these medicines, such as leucovorin and lidocaine injections, are lifesaving medicines used in critical care settings.

Drug shortages are driven by a combination of factors, including:

low prices

manufacturing complexity

geographic concentration

quality concerns

These risk factors collectively exacerbate shortages and negatively impact patients.

Once a drug is in shortage, the shortage is usually persistent. This analysis found that in 2024:

> There were **98 drug shortages**, 89% carried over from 2023.

> The **average duration of a drug shortage was over four years,** up from approximately three years in 2023.

Improvements did occur in 2024, with this analysis finding:

> A **decrease of the total number of shortages** following a 10-year high in 2023.

> A **decrease in new drugs shortages,** from 34 in 2023 to 11 in 2024.

This report also includes analysis on drug product prices, an important factor for current trade and economic considerations. An overall rise in drug product prices was found from 2023 to 2024. For example:

> The average price of generic injectables **increased 19%** from $75.87 to $90.25.

> The average price of generic oral solids **increased 24%** from $4.10 to $5.10.

This report examines the economic determinants of drug shortages in the United States, aiming to provide policymakers and industry stakeholders with data-driven insights to safeguard patient access to medications. The analysis is based on data from the USP Medicine Supply Map[1], which employs predictive analytics to identify, characterize, and forecast risks within the drug supply chain. In 2024, the USP Medicine Supply Map identified a high shortage risk for 98% of sterile injectable shortages and accurately predicted 100% of new injectable shortages as high risk prior to their occurrence (refer to Appendix A for USP's risk scores).

Introduction

Drug shortages are systemic and have long-lasting impacts on patients, health systems, and future innovation.[2, 3, 4] Using the Medicine Supply Map, USP identified four factors that can increase a medication's risk for shortage:

1. **Low prices:** Drug products, commonly older generics, with low prices have a higher risk of drug shortage.

2. **Manufacturing complexity:** Drugs with higher manufacturing complexity, such as sterile injectables, are more vulnerable to shortage. Certain therapeutic classes are also more complex to manufacture—e.g., certain antibiotics need dedicated facilities, and certain active ingredients require complex chemical synthesis.

3. **Geographic concentration:** Drugs in which the active pharmaceutical ingredient (API) and/or finished dose are made in a single or few locations are at a higher risk of shortages. The risk of drug shortages is particularly acute when a single facility is responsible for producing the entire U.S. market supply for a particular drug. A recent example of geographic concentration risk is the Baxter Marion, North Carolina facility, which was hit by Hurricane Helene in September 2024. Before the hurricane, this facility manufactured roughly 60% of the U.S. supply of IV solutions.[5] This facility had to shut down during and after the hurricane, causing a temporary shortage of these drug products. This is just one example of how geographic concentration anywhere—including within the United States—increases the risk of drug shortages.

4. **Quality concerns:** Quality-related issues that surface after regulatory agency inspections and manufacturer recalls can also inform drug shortage risk and serve as indicators of potential drug shortages.

These four factors are interrelated and, in combination, can impact the supply chain of medicines and drug products. For example, manufacturing complexity increases the cost of making a medicine, which can yield an unsustainable margin when combined with low prices of certain drug products. To improve margins, the manufacturers may try to reduce costs by concentrating production in large facilities that become single points of failure. The low price and low margin dynamic impedes the industry's ability to create manufacturing redundancies and may lead to underinvestment in quality management systems. Likewise, a sudden demand surge or supply disruption can trigger new or worsen existing drug shortages as manufacturers and the market struggle to respond effectively.

Methodology

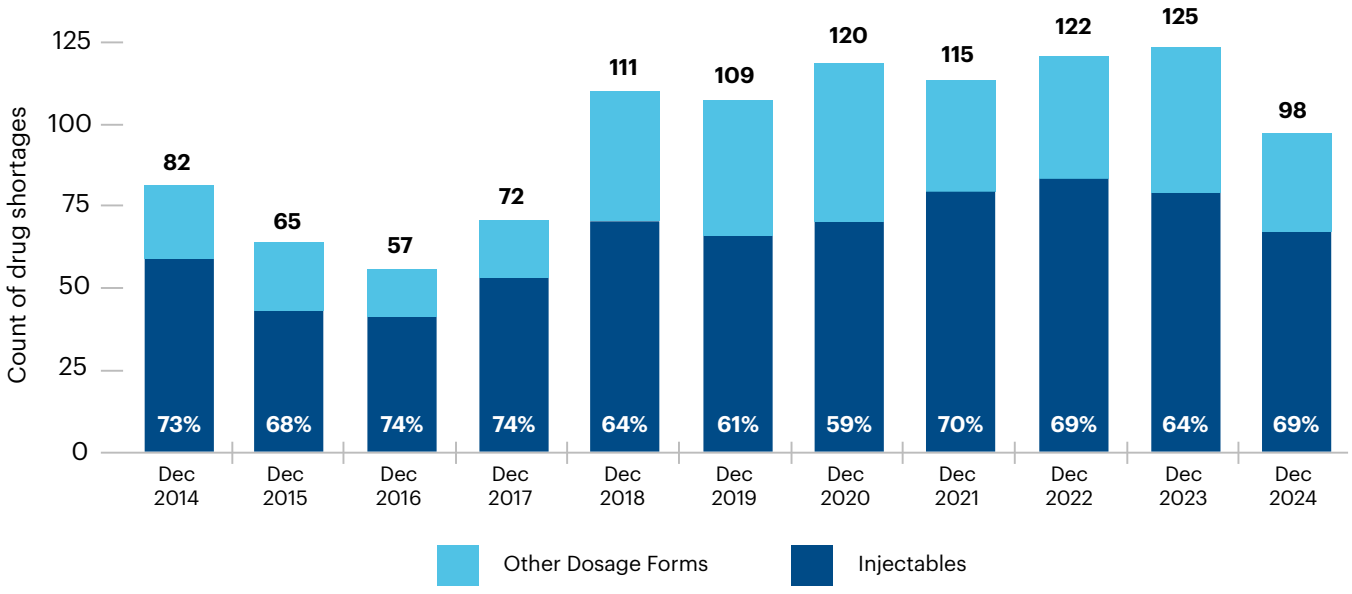
USP analyzed drug products listed on the U.S. Food and Drug Administration (FDA) drug shortages database, focusing on Center for Drug Evaluation and Research (CDER) shortages and excluding biologics tracked by the FDA Center for Biologics Evaluation and Research (CBER). These drugs were mapped to locations, units, prices, and other factors using the USP Medicine Supply Map. For more details, see Appendix B.

Key Insights:
Overview

Total drug shortages fell to 98 drugs in 2024

The total number of drug shortages decreased 22% in 2024 from the prior year (Figure 1). Of the 98 active drug shortages, 69% were sterile injectable drugs, 16% were oral solid drugs, and 15% were other dosage forms. Seventeen of the drugs in shortage were Schedule II[6], which can have additional manufacturing and regulatory complexities associated with the Controlled Substances Act; this number remained unchanged from the prior year. Only two new drug shortages were reported and resolved within 2024 (down from four in 2023), highlighting the slow pace at which drug shortages are being resolved.

Figure 1
Count of drug shortages reported by CDER, by year

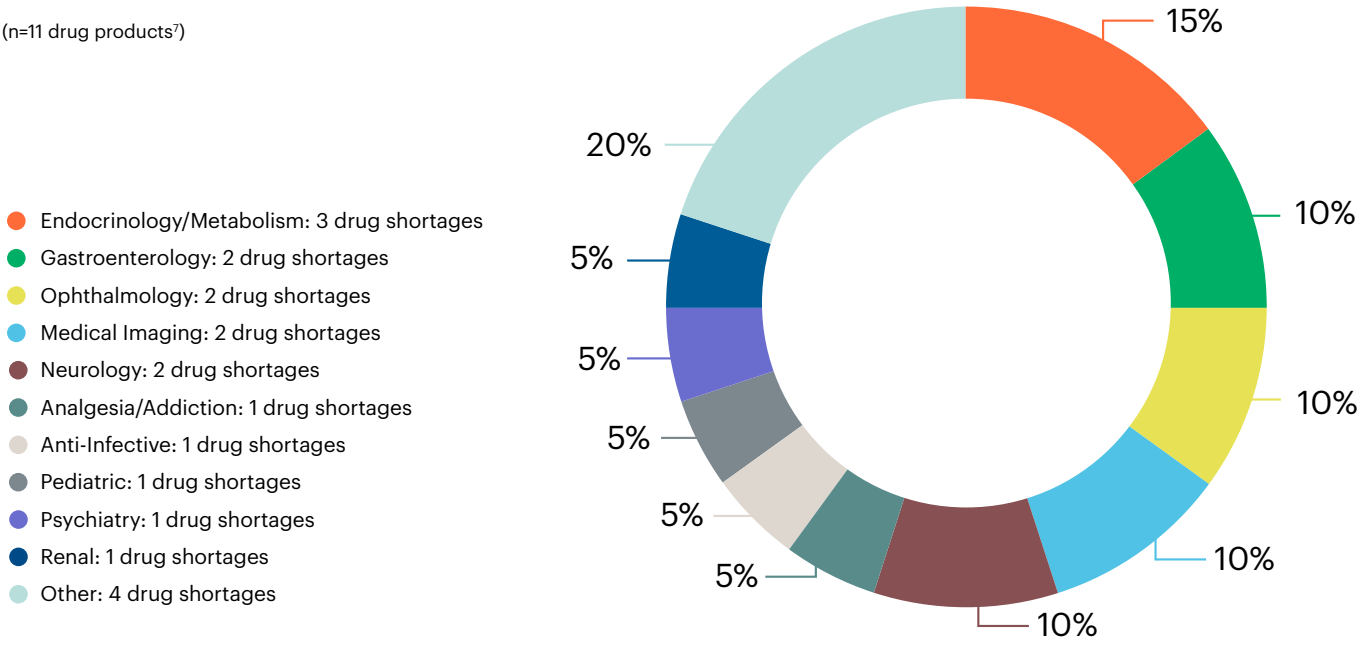


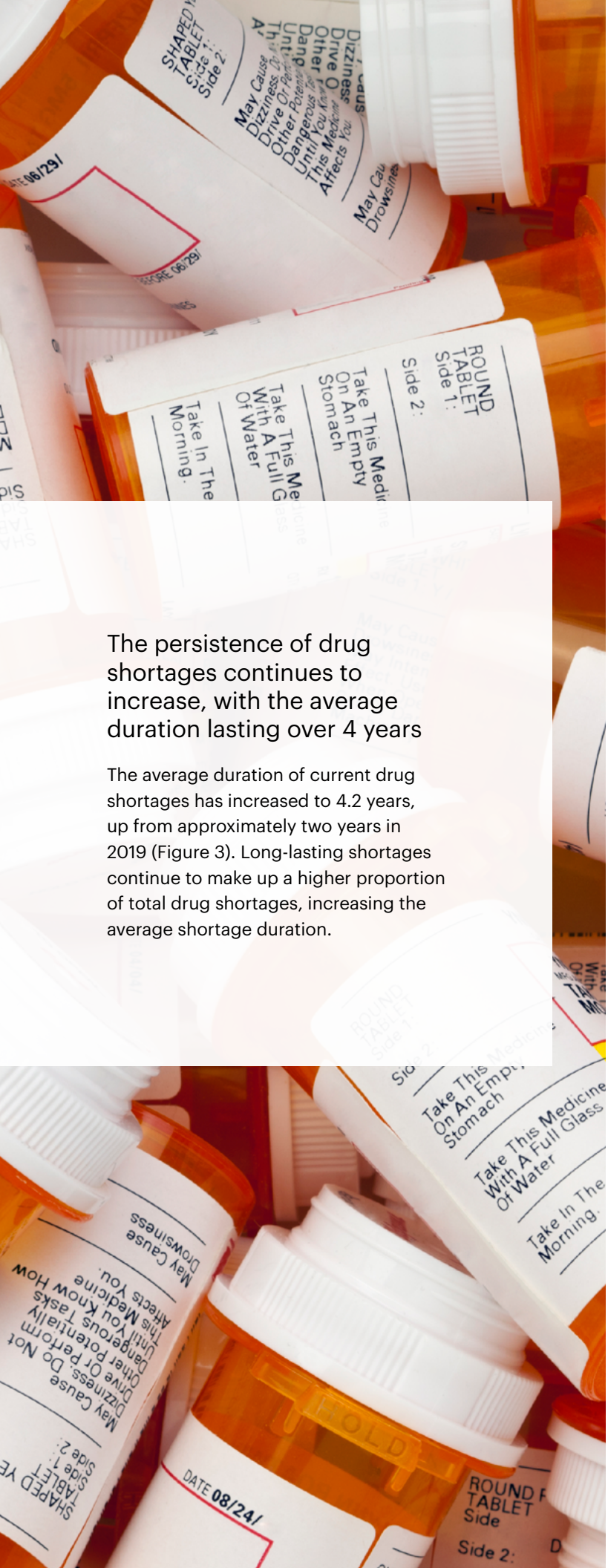
New drug shortages in 2024 impacted diverse drug categories

The number of new drug shortages decreased from 34 in 2023 to 11 in 2024, marking a 68% reduction. New shortages occurred across a wide range of therapeutic classes and disease categories. No one therapeutic class was disproportionally affected, highlighting the widespread patient impact. Five of the new shortages were sterile injectables, with three coming from the Baxter, North Carolina facility impacted by Hurricane Helene in September 2024.

Figure 2
Therapeutic class distribution of new drug shortages

(n=11 drug products[7])





The persistence of drug shortages continues to increase, with the average duration lasting over 4 years

The average duration of current drug shortages has increased to 4.2 years, up from approximately two years in 2019 (Figure 3). Long-lasting shortages continue to make up a higher proportion of total drug shortages, increasing the average shortage duration.

Figure 3
Average duration of year-end drug shortages, by year[8]
(whiskers show the 95% Confidence Intervals)

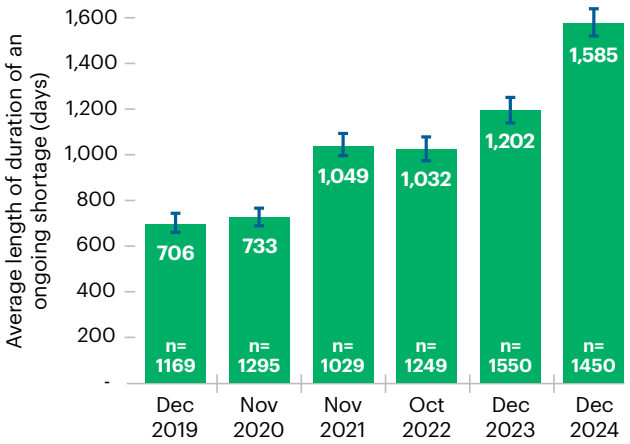
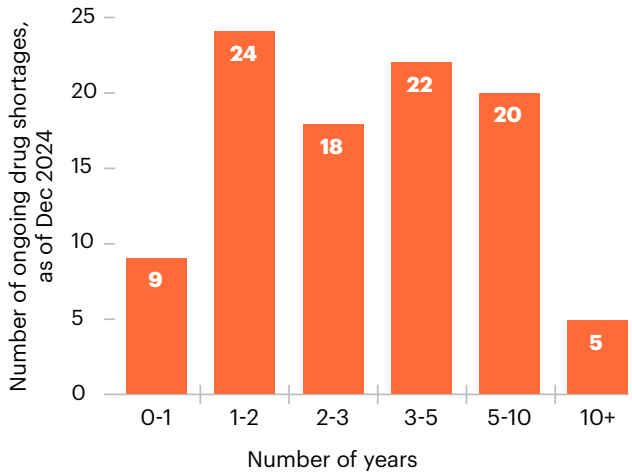


Figure 4
Duration of ongoing drug shortages in 2024



89 of the 98 drugs have been in shortage for over one year

At the end of 2024, nine drug shortages were less than a year old, while the remaining 89 drug shortages (91%) have persisted for over a year. More than 40 life-saving medicines have been in shortage for over three years, and five drugs have been in shortage for ten or more years. All five drugs that have been in shortage for over 10 years are injectables on the FDA and/or World Health Organization (WHO) Essential Medicines Lists and can be used in pediatric settings. Three of these drugs are priced at less than $3 per unit—fentanyl citrate injection, epinephrine bitartrate, and lidocaine hydrochloride injection. Additionally, fentanyl citrate injection, leucovorin calcium injection, and lidocaine hydrochloride injection are identified as vulnerable acute care medicines, per the **USP Vulnerable Medicines List**. In October 2024, epinephrine injection came off the drug shortage list after having been in shortage since April 2012.[9]

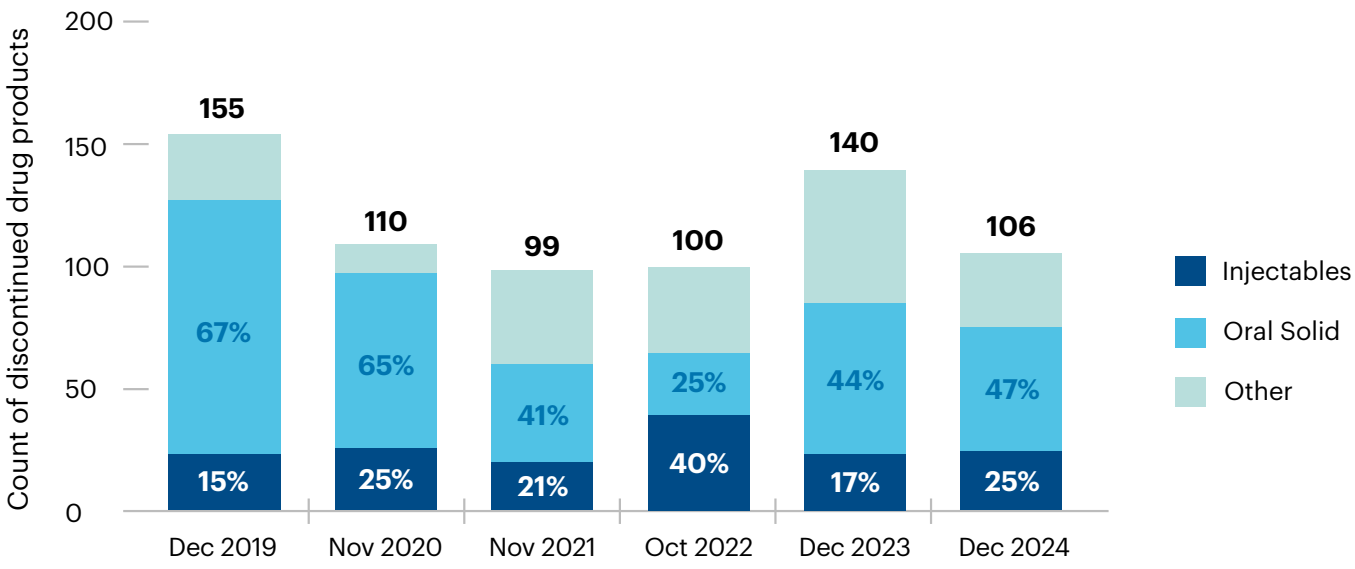
Table 1
Drugs in shortage for over 10 years, as of December 2024

Drug in shortage for over 10 years	Dosage form	FDA therapeutic class [10]	Use	Shortage driver	WHO/FDA Essential Medicines List [11]	Price per unit
Atropine sulfate injection	Injectable	Anesthesia; Neurology; Pediatric	Muscarinic antagonist	Manufacturing delays and amplified global demand for essential critical care medications	Yes	$8.04
Fentanyl citrate injection	Injectable	Analgesia/ Addiction; Pediatric	Pain management	Increased demand	Yes	$1.34
Leucovorin calcium injection	Injectable	Oncology; Pediatric	Antidote to the harmful effects of methotrexate (a cancer medicine)	Manufacturing delays, increased demand	Yes	$20.25
Lidocaine hydrochloride injection	Injectable	Anesthesia; Cardiovascular; Pediatric	Local or regional anesthesia for certain medical procedures	Increased demand	Yes	$1.81
Epinephrine bitartrate	Injectable	Anesthesia; Pediatric	Local or regional anesthesia for certain medical procedures	Increased demand	Yes	$2.45

Drug product discontinuations declined 24% from 2023

Discontinuations declined by 24% from 140 to 106. Of these 106 discontinuations, nearly half (47%) were oral solid products (Figure 6). While discontinuations occur for various reasons, manufacturers typically discontinue drug production when unfavorable market conditions, such as low-profit margins, reduce incentives to remain in or enter the market.

Figure 5
Drug product discontinuations over time, by year

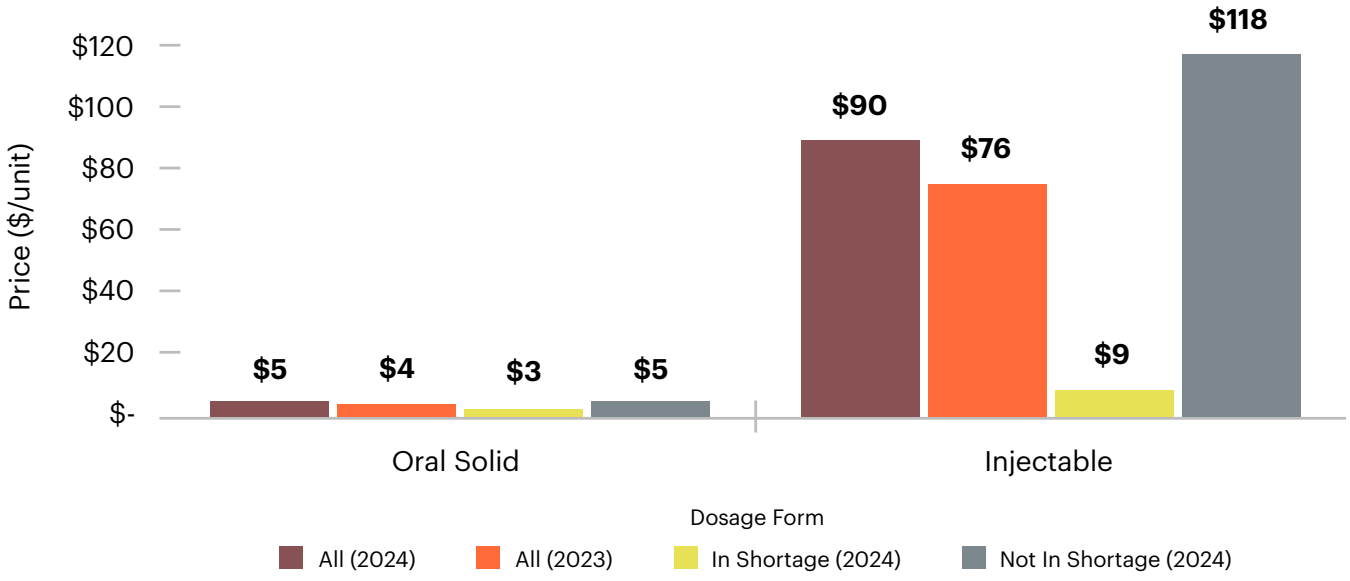


Economic Influence: Price

In this analysis, price refers to the amount paid to a manufacturer rather than the cost to a patient.

The average price of a generic injectable not in shortage ($118) was 13 times higher than a generic injectable product in shortage ($9). For generic oral solid drugs, the average price was $5 for those not in shortage, compared to $3 for those in shortage. From the prior year, the average price of generic injectables rose by 19%, from $75.87 to $90.25, while the average price of generic oral solid drugs increased by 24%, from $4.10 to $5.10.

Figure 6
Average prices of generic approved drug products by dosage form[12]



Nearly one-third of oral solid medicines in shortage are priced below $1 per unit, while nearly half of injectables are priced below $5 per unit

Most oral solid drugs in shortage, 70%, are priced below $4 per unit. The average price of shortage oral solid products increased from $3.40 to $4 between 2023 and 2024 due to four Schedule II drugs with relatively high prices that went into shortage, i.e., flurazepam hydrochloride capsules, lisdexamfetamine dimesylate capsules and chewable tablets, and methamphetamine hydrochloride tablets. Schedule II drugs are associated with more regulatory complexity than non-scheduled drugs. This added complexity can make a response to market signals more difficult, potentially making scheduled medicines more prone to shortage.

In total, 74% of sterile injectables in shortage have a price point below $15 per unit, with 44% less than $5 per unit.

Figure 7
Share of shortage oral solids across per unit price points[13]

(n=16 oral solid drug products in shortage)

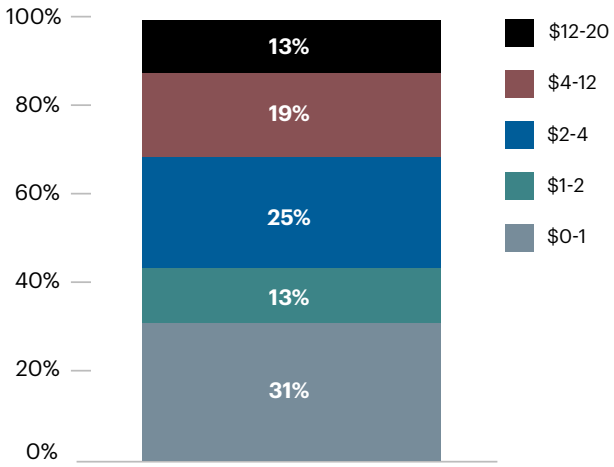
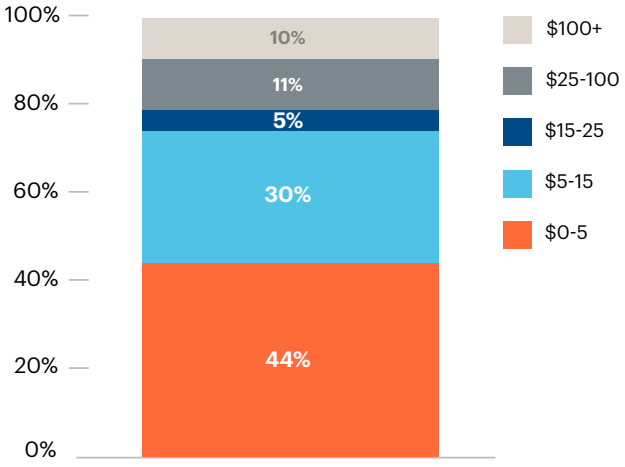


Figure 8
Share of shortage injectables across per unit price points

(n=61 injectable drug products in shortage)



Nearly half, 46%, of discontinued oral solid drug products had a price point below $1 per unit

Low prices disincentivize manufacturers to remain in the market. The median price for discontinued oral solid products was $1.80 per unit, which was nearly $1.00 less than the median price of oral solid products in shortage ($2.76).

Figure 10 highlights that 16% of discontinued injectable drugs were priced below $15 per unit.

Figure 9
Share of discontinued oral solids across per unit price points[14]

(n=46 discontinued oral solid drug products)

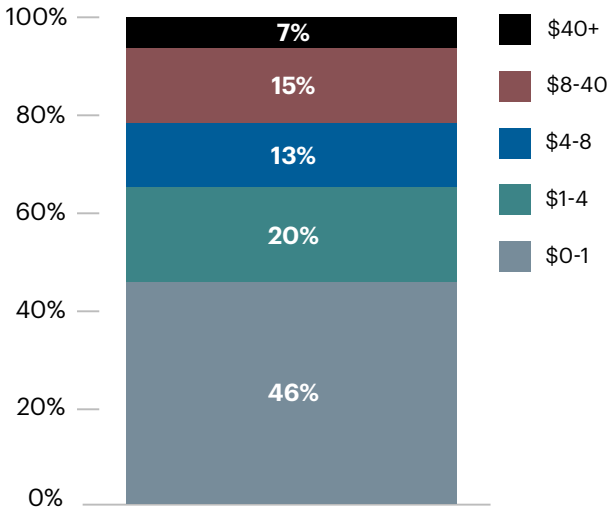
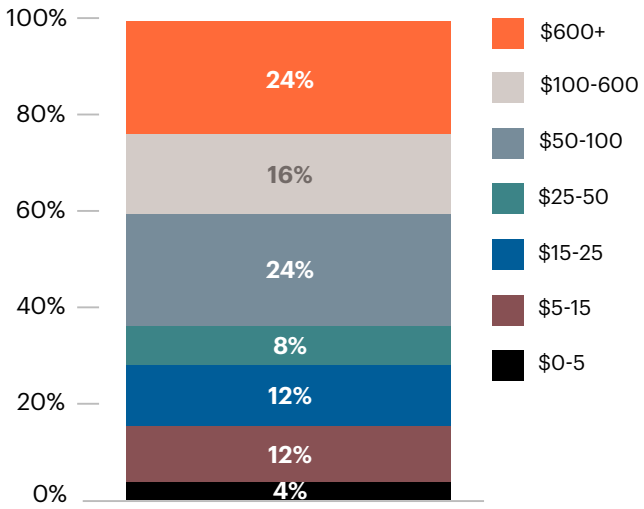


Figure 10
Share of discontinued injectables across per unit price points

(n=25 discontinued injectable drug products)



Economic Influence: Geographic Distribution of Manufacturing

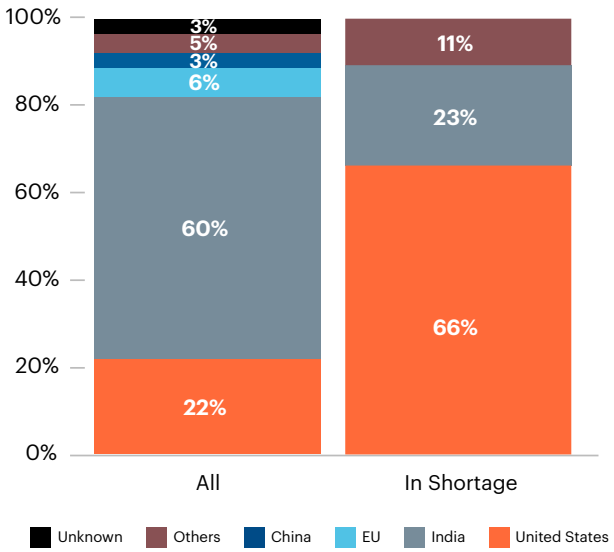
Trade policy discussions have raised awareness of U.S. reliance on other countries for pharmaceutical products and ingredients

Reliance on foreign manufacturing is largely due to race-to-the-bottom pricing dynamics and the pressure to manufacture drugs as inexpensively as possible. This pressure has created longer and more complex supply chains, often with production concentration and reliance on a single or small number of countries that provide markedly lower costs to produce large volumes of key starting materials (KSMs), API, and medicines for the United States. These more complex, fragmented, and clustered supply chains are susceptible to disruptions that can lead to shortages.

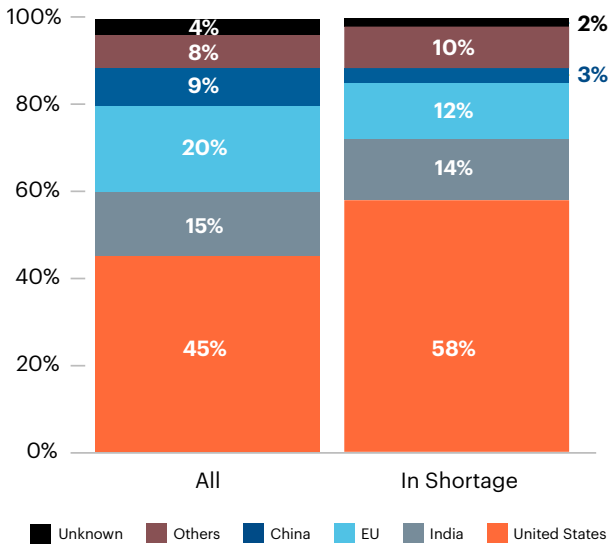
In 2024, the United States produced 22% of all oral solids, and 66% of the oral solids in shortage (Figure 11). In comparison, India produced 60% of all oral solid drugs and 23% of the oral solids in shortage.

Additionally, the Unites States produced 45% of all injectables and 58% of the injectables in shortage (Figure 12). In contrast, EU produced 20% of all injectables and 12% of the injectables in shortage and India produced 15% of all injectables and 14% of injectables in shortage.

Figures 11 & 12
Geographic distribution of oral solid and injectable drug product manufacturing, by shortage status



(n=1239 oral solid drug products, n=16 drugs in shortage)



(n=633 injectable drug products, n=69 drugs in shortage)

Prices can vary across geographies due to product portfolio complexity and cost of manufacturing

Figures 13 and 14 focus on generic drug pricing. For generic drugs, the United States and EU have the highest price points across all regions studied. These variations could be due to differences in product portfolio, manufacturing costs, and/or competition and there was a minor difference in price across regions for drugs in shortage.

Figure 13
Unit Price per Country

(All Generic Injectables and Generic Injectables in Shortage as of Dec 31st, 2024)

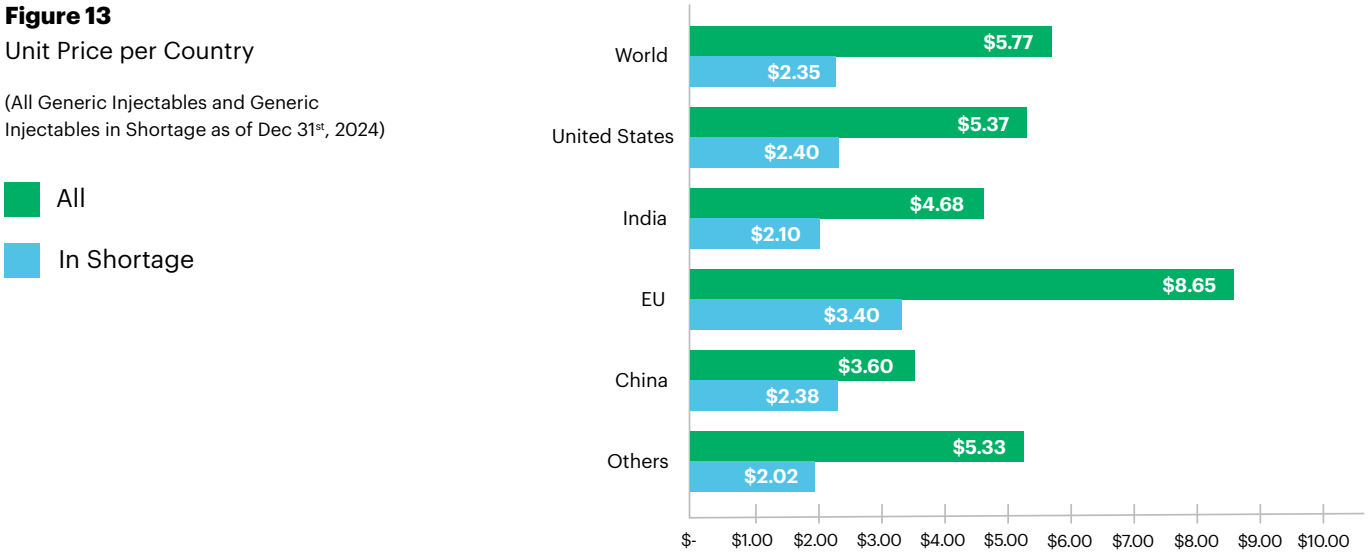
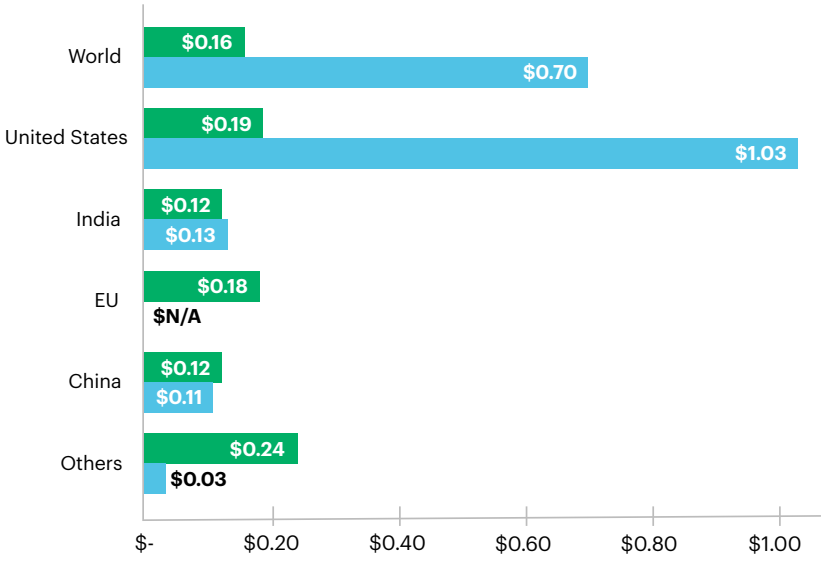


Figure 14
Unit Price per Country

(All Generic Oral Solids and Generic Oral Solids in Shortage as of Dec 31st, 2024)



Other Influences: Inspection Metrics

Facilities where drugs in shortage are made are more likely to have had inspection issues

Issues with quality management maturity and product integrity can also lead to drug shortages. Quality management maturity is synonymous with a company's "culture of quality." Quality management issues may refer to process challenges that result in production delays rather than the quality of an individual product itself; yet, compounded over time, poor quality management processes may lead to product quality challenges, as well. Medicines that do not meet quality requirements must be withheld from the market and may face recall. When manufacturing quality and product integrity issues arise, supply disruptions often follow.

FDA conducts risk-based surveillance inspections of drug manufacturing establishments to help ensure inspected facilities can consistently manufacture acceptable quality medications and to minimize the risk of exposing the public to potentially ineffective or harmful drugs that can result from serious quality deficiencies.[15] Inspections resulting in "no action indicated" (NAI)[16] connote that FDA did not observe objectionable conditions or practices related to current good manufacturing practice (cGMP) compliance during the inspection, but they should not be interpreted to suggest a strong and robust quality culture, or a high level of quality management maturity.[17] "Voluntary action indicated" (VAI) means that objectionable conditions were found and documented, but inspectors are not prepared to take, or do not recommend any regulatory action. "Official action indicated" (OAI) means that objectionable conditions were found, and regulatory action should be recommended.

During the period 2020-2024, facilities that manufactured drugs in shortage as of December 2024 were more likely to receive OAIs from inspections compared to facilities that manufactured drugs not in shortage as of December 2024; the difference is statistically significant. Facilities that received OAI outcomes account for 5% of the total production of drugs in shortage, up from 1% in 2023.

The USP Medicine Supply Map identified 11 facilities that received OAI outcomes from inspections in the last five years. 15 drugs made at those facilities subsequently went into and are currently in shortage.

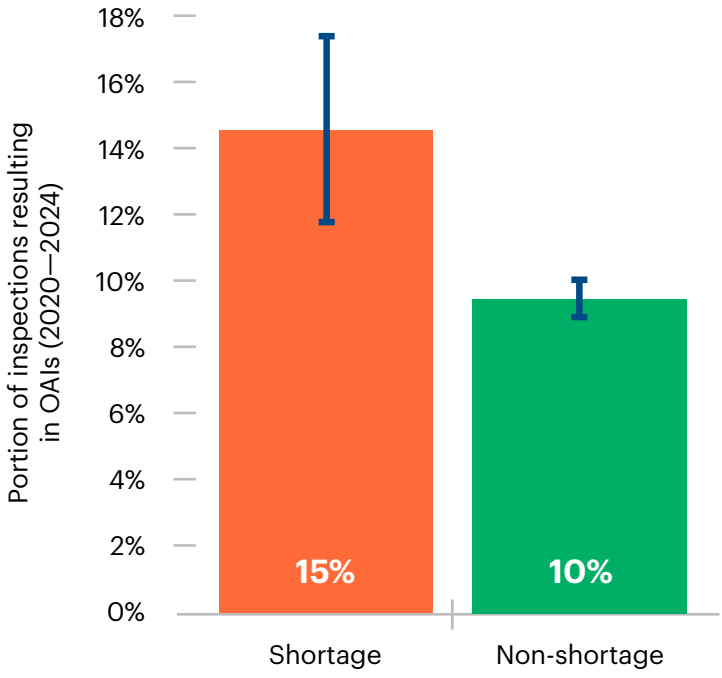


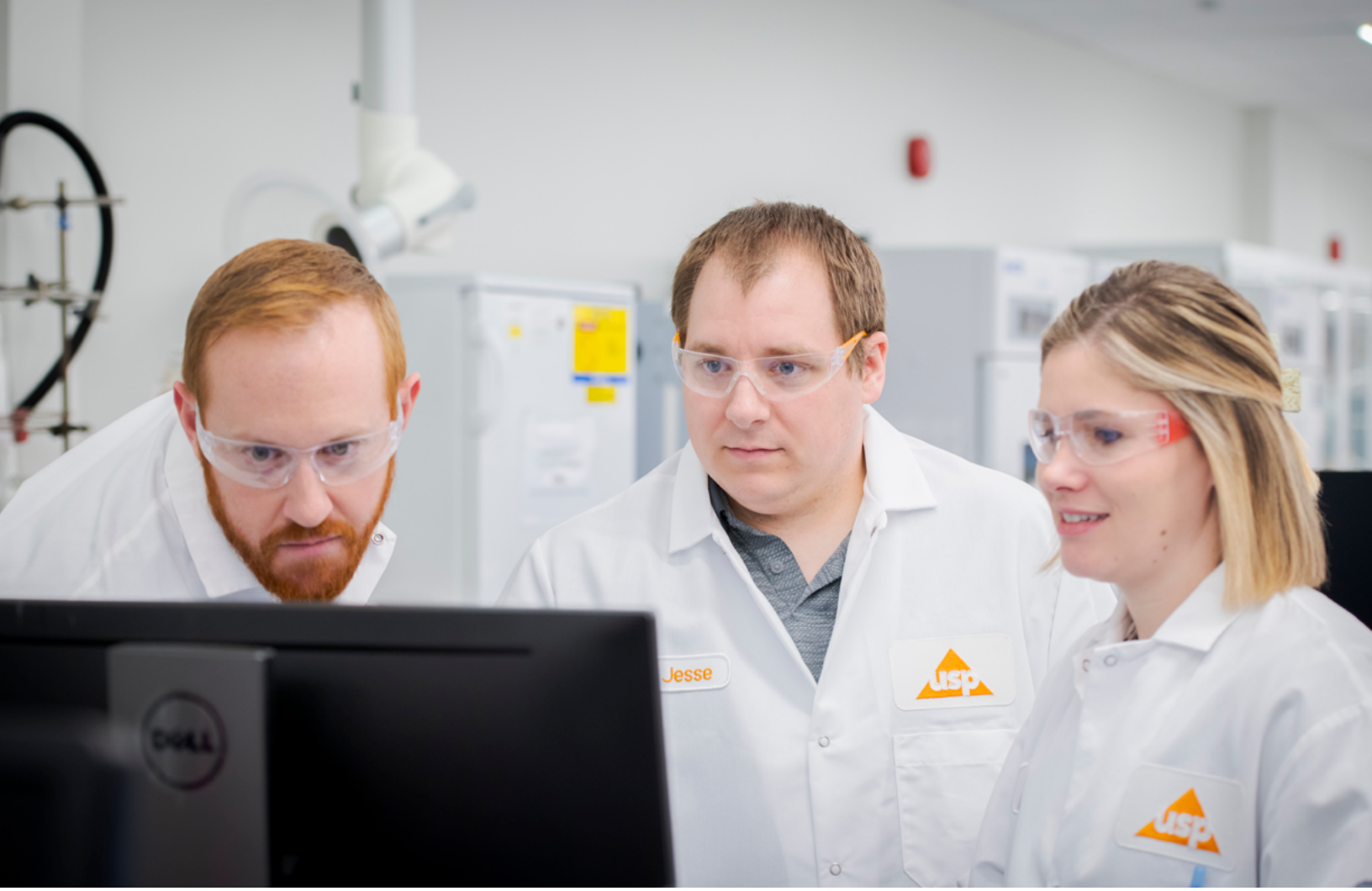
Figure 15
Inspection outcomes for drugs in shortage vs. non-shortage in the last 5 years (whiskers show the 95% Confidence Intervals)

Conclusion

This year's analysis of drugs shortage in 2024 found that there were improvements, but systemic issues persist

Drugs go into shortage and often remain in shortage because of the four identified risk factors—low price, manufacturing complexity, geographic concentration of manufacturing and quality concerns. These risk factors are often interrelated and can exacerbate economic challenges for manufacturers of low-margin drug products. Increased risk of supply chain disruption can also be caused by vulnerabilities related to other external factors or unexpected shocks including trade policy changes, natural disasters, and geopolitical tensions, among others. Additionally, potential tariffs may change the dynamics in the near future. Experts believe that, in the short-term, tariffs could exacerbate drug shortages and discontinuations for generic sterile injectables as supply chains adjust.[18] Further analysis of persistent shortages may provide insight into which of the four factors—or which combination of factors—predominantly cause these drugs to remain in shortage.

Drug shortages have significant impacts on patients, including increased mortality, adverse events, medication errors, treatment delays, and increased out-of-pocket costs.[19, 20, 21] They can also impede daily operations in a healthcare setting and contribute to increased labor costs and workforce burnout. While there is an encouraging trend in declining drug shortages, the public and private sectors must continue to act to address drug shortages and ensure patient access to necessary medical treatments.



About USP

The U.S. Pharmacopeia (USP) is an independent, scientific nonprofit organization focused on building trust in the supply of safe, quality medicines, dietary supplements, and foods, through setting public quality standards in its various compendia.

Appendix A:
MSM risk scores for new injectable drug shortages in 2024

Note: The risk scores are updated monthly and predict the chances of drug products going into shortage. Risk scores range from 0% to 100%. The threshold that MSM Shortage Model employs to identify severe risk of shortage for injectables is 40%.

Drug Product	MEDICINE SUPPLY MAP risk score one month prior to the shortage
Dextrose injection	91%
Hydroxocobalamin injection	61%
Lactated Ringer's injection	45%
Potassium chloride in lactated Ringer's and dextrose injection	45%
Vitamin A injection	74%

Appendix B: Methodology

USP used the FDA drug shortages database to identify drug shortages. This analysis focused on Center for Drug Evaluation and Research (CDER) drug shortages, as those are the most common drug shortages impacting U.S. patients. New shortages in 2024 were defined as those drug products with earliest "initial posting date" in the FDA drug shortage database is in 2024 or those that began and were resolved in 2024. This approach may not account for all drug shortages since the FDA drug shortage database primarily lists medically necessary products. Also, according to the FDA, "shortages that are expected to be resolved quickly, shortages that involve only a particular strength or package size, and shortages where a substitute strength(s) or package size(s) is available are not usually the focuses of FDA's program."

Volume analysis was done using the IQVIA National Sales Perspectives (NSP) dataset. Unless specified otherwise, in this analysis, the volume of injectable drugs is quantified using "eaches" which counts individual items such as vials or syringes. For oral solids, "extended units" is used as the smallest saleable unit, like a tablet, ensuring a consistent basis for comparison by normalizing pack size differences. Prices are calculated using the IQVIA NSP dataset and dividing revenue by total units sold. IQVIA reports revenue based on the invoice price, which does not include post-invoice rebates such as 340b.

Drug products were mapped to facilities and locations using the USP Medicine Supply Map.

Reference and Notes

1. www.usp.org/medicinesupplymap. The Medicine Supply Map uses multiple sources of information to identify worldwide sites of pharmaceutical ingredients and finished dose medicine manufacturing. Datasets from USP, U.S. Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services, European Medicines Agency, World Health Organization, and private sector sources are utilized by the Medicine Supply Map platform. The model is also informed by insights on the use of USP quality standards in most FDA-registered finished dose and API manufacturing facilities. These data are enriched with information about risk drivers such as price and ingredients and cover 92 percent of FDA-approved generic prescription drugs.
2. McBride, A., Hudson-Disalle, S., Pilz, J., Hamm, M., Boring, B., Buie, L., & DeRemer, D. (2022). National Survey on the Effect of Oncology Drug Shortages in Clinical Practice: A Hematology Oncology Pharmacy Association Survey. JCO Oncology Practice, 18, e1289–e1296. https://doi.org/10.1200/OP.21.00883
3. U.S. Food and Drug Administration (2020). Drug Shortages: Root Causes and Potential Solutions. Retrieved from https://www.fda.gov/media/131130/download?attachment
4. Which Data Analytics Tool Should We Use to Evaluate Risk in Upstream Drug Supply Chains? American Medical Association Journal of Ethics. (2024, April 1). Retrieved from: https://pubmed.ncbi.nlm.nih.gov/38564745/.
5. AHA to president urging the administration to take action to address IV solution supply shortage as a result of Helene: AHA. American Hospital Association. (2024, October 7). Retrieved from: https://www.aha.org/2024-10-07-aha-president-urging-administration-take-immediate-action-address-iv-solution-supply-shortage-result-helene#:~:text=The%20AHA%20and%20its%20members,impact%20of%20the%20plant%20closure.
6. Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. Citation: https://www.dea.gov/drug-information/drug-scheduling#:~:text=Schedule%20II%20drugs%2C%20substances%2C%20or,drugs%20are%20also%20considered%20dangerous.
7. A drug product can be associated with multiple therapeutic categories. For this analysis, all therapeutic categories were included.
8. n is the count of approved drug products corresponding to the National Drug Code (NDC), which is a unique, three-segment numerical identifier assigned to every medication approved for sale in the United States by the FDA. The NDC identifies the labeler, product, and package size, thereby aiding in the regulation, distribution, and inventory management of drugs.
9. FDA Drug Shortages Database https://dps.fda.gov/drugshortages/resolved/epinephrine-injection-syringes
10. Note: Since a drug can be associated with more than one therapeutic class, the therapeutic class distribution reflects multiple occurrences for some new shortages.
11. U.S. Food and Drug Administration (2020). List of Essential Medicines, Medical Countermeasures, and Critical Inputs. Retrieved from: https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs
12. The average prices shown are based on 16,222 oral solid and 3,870 injectable approved generic NDCs in 2024. Among these, 391 oral solids and 969 injectables were in shortage, while the remaining 15,831 oral solids and 2,901 injectables were not in shortage. For comparison, in 2023, there were 14,827 oral solid and 3,633 injectable approved generic NDCs.
13. This analysis includes both brand and generic medicines that were in shortage. Percentages do not total 100% due to rounding.
14. This analysis includes both brand and generic medicines that were discontinued.
15. U.S. Food and Drug Administration (2023). Overview of Drug Manufacturing Inspections. Retrieved from https://www.fda.gov/media/172786/download
16. Within about 90 days from completion of a drug surveillance inspection, FDA classifies the inspection results according to a three-tier system based upon the seriousness of any observations made during the inspection:
    - No action indicated (NAI) means that no objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).
    - Voluntary action indicated (VAI) signifies that objectionable conditions were found and documented but the agency is not prepared to take or recommend regulatory action.
    - Official action indicated (OAI) means that objectionable conditions were found and regulatory action should be recommended.
17. U.S. Food and Drug Administration (2023). CDER's Quality Management Maturity (QMM) Program: Practice Areas and Prototype Assessment Protocol Development. www.fda.gov/media/171705/download?attachment.
18. Wosińska, Marta. "Will Pharmaceutical Tariffs Achieve Their Goals?" Brookings Insitution, 18 Apr. 2025, www.brookings.edu/articles/pharmaceutical-tariffs-how-they-play-out
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20. Postma, D.J., De Smet, P.A.G.M., Notenboom, K. et al. Impact of medicine shortages on patients - a framework and application in the Netherlands. BMC Health Serv Res 22, 1366 (2022). https://doi.org/10.1186/s12913-022-08765-x
21. U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE). Report to Congress: Impact of Drug Shortages on Consumer Costs (2023). Retrieved from: https://aspe.hhs.gov/sites/default/files/documents/87781bc7f9a7fc3e6633199dc4507d3e/aspe-rtc-costs-drug-shortages.pdf