

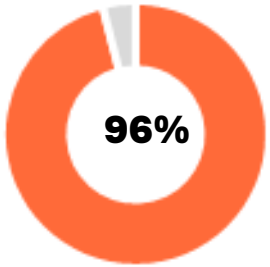
U.S. Drug Shortages: Assessing Vulnerabilities and Informing Systemic Solutions

NOVEMBER 2-4, 2026
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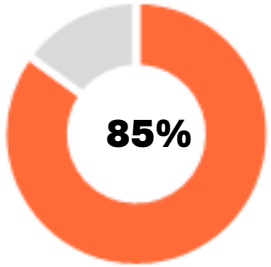
Panel Participants

- **Craig Burton, MBA**
  Senior Vice President, Government Affairs, Fresenius Kabi USA
- **Michael Ganio, PharmD**
  Senior Director, Pharmacy Practice and Quality, ASHP
- **Thomas Roades, MPP**
  Policy Research Associate, Duke-Margolis Institute for Health Policy
- **CDR Emily Thakur, RPh**
  Team Leader, Drug Shortages Staff, OCD, CDER, FDA
- **Moderator: Vimala Raghavendran, MBA**
  Vice President, Informatics Product Development, USP

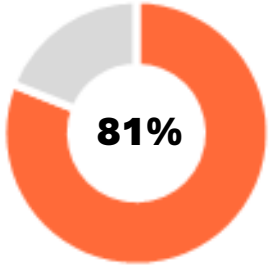
USP Medicine Supply Map creates line of sight for supply chain planning



Finished dosage forms mapped to facilities



API volume mapped to facilities



APIs mapped to KSM country of origin



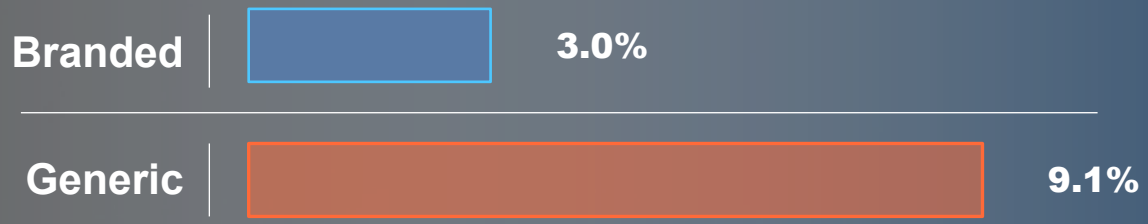
- **94% Rx shortage predictive accuracy**
- **Early shortage detection** - identifies 50% of injectable shortages up to 4 months before they happen
- **Inventory and production optimization**: 5 and 9-month forecasts

Source: USP Medicine Supply Map, 2026, www.USP.org/medicinesupplymap

Shortages hit generics far more than branded drugs



Share of products in current shortage



What the data shows

- Brand shortages are usually driven by demand surges, and makers add capacity to clear them quickly.
- Generic shortages are structural – thin margins, sole-source starting materials (especially for KSMs), and prices that do not support resilience – so shortages persist

N = 627 branded and 1,300 generic finished drug (1,927 total). Current shortage = product listed by FDA (Status = Current, Sep 14, 2026) or ASHP (Active). Sources: FDA Drug Shortages, ASHP Drug Shortages, USP Medicine Supply Map.

Our data shows four factors drive drug shortages

Over 100 factors back tested against shortages recorded by the U.S. Food and Drug Administration (FDA) and American Society of Health-System Pharmacists (ASHP)

USP found four risk categories to be correlated with drug shortages

Geographic concentration

Over-reliance on manufacturing in a limited number of countries or facilities.

Quality concerns

FDA and other regulatory actions like Form 483s, warning letters, and recalls.

Low prices

Economic pressures such as low profitability, limited competition, or declining sales.

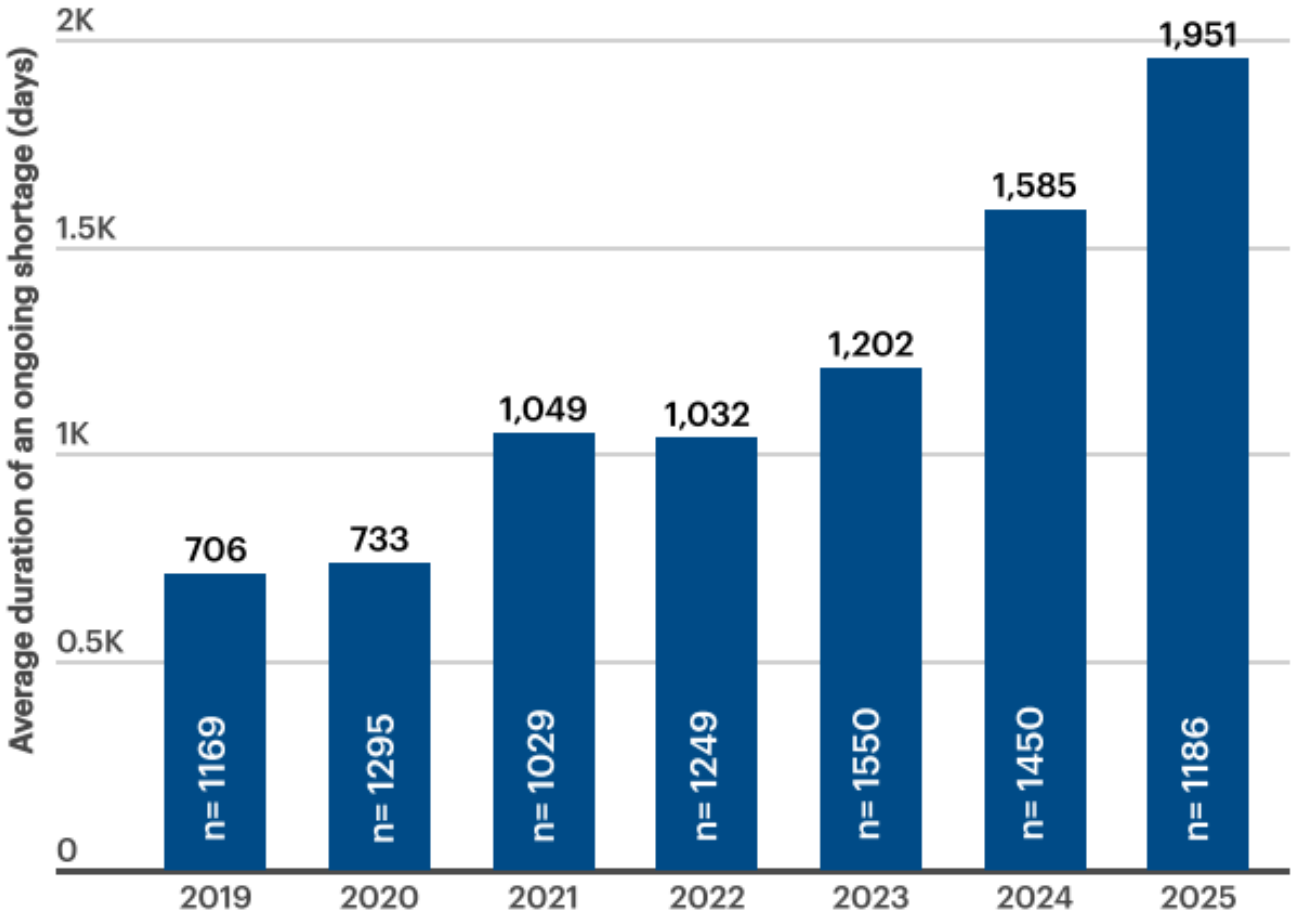
Manufacturing complexity

How difficult a drug is to produce based on formulation, therapeutic class, process type, molecule form etc.

Source: USP Medicine Supply Map, 2026, www.USP.org/medicinesupplymap

Drug shortages are persistent, with the average duration exceeding 5 years

Average duration of year-end drug shortages, by year (2019–2025)



- 39% of drugs in shortage at the end of 2025 have been in shortage for more than 5 years
- Increased durations of drug shortages are a critical public health risk that can lead to compromised patient care, treatment delays, and unfavorable outcomes

Source: USP Medicine Supply Map, 2026, www.USP.org/medicinesupplymap

History and Current State of Drug Shortages

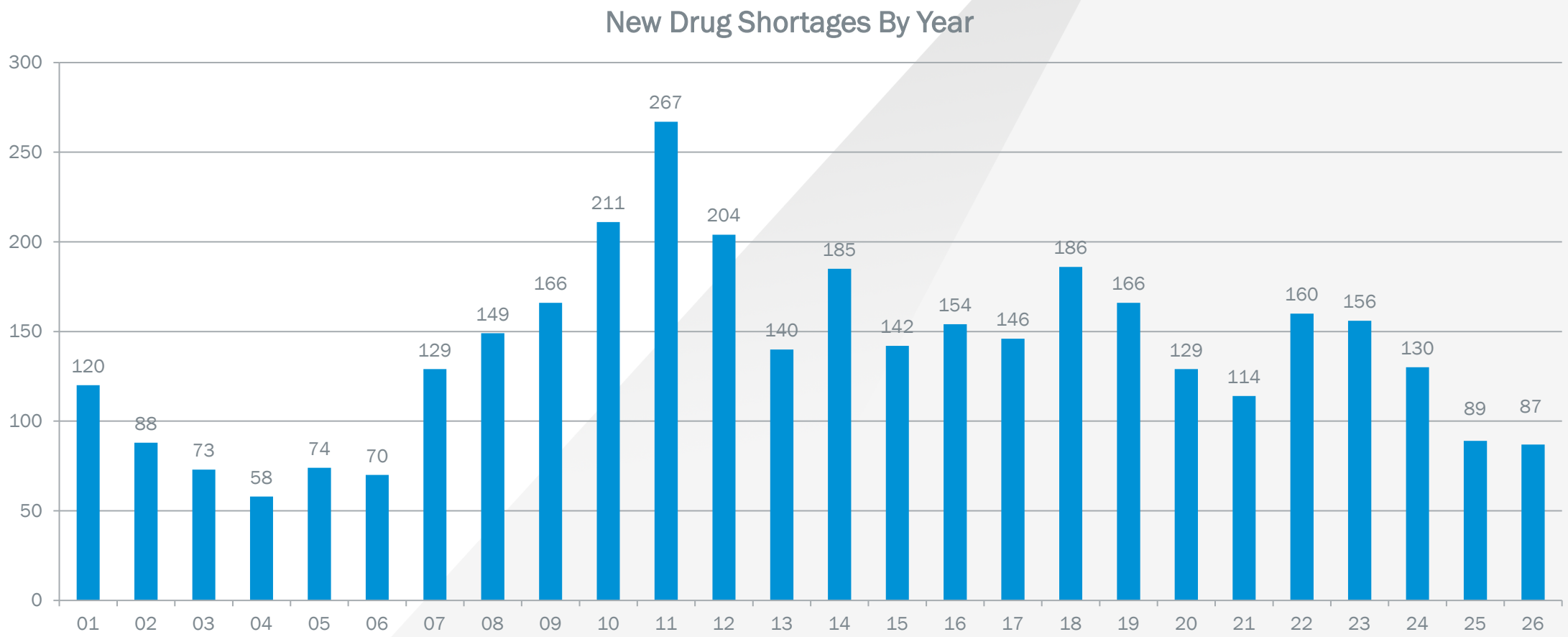
Michael Ganio, PharmD, MS, FASHP

Senior Director, Pharmacy Practice and Quality

ASHP

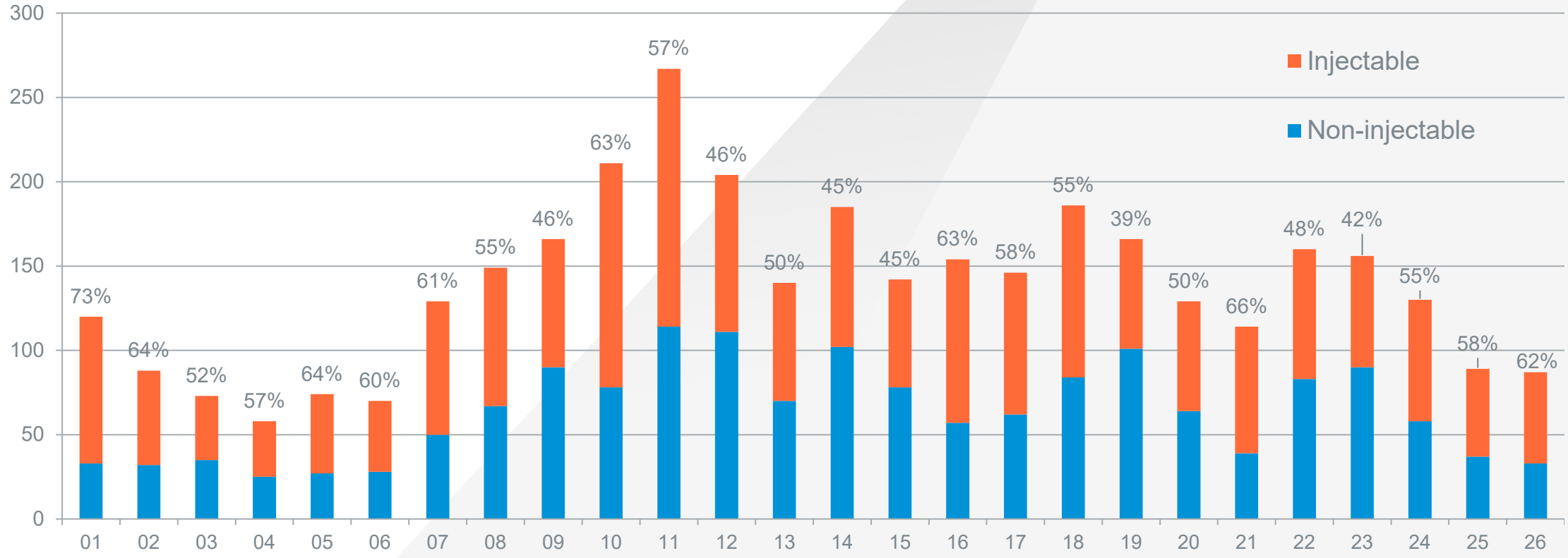
ashp

pharmacists advancing healthcare℠



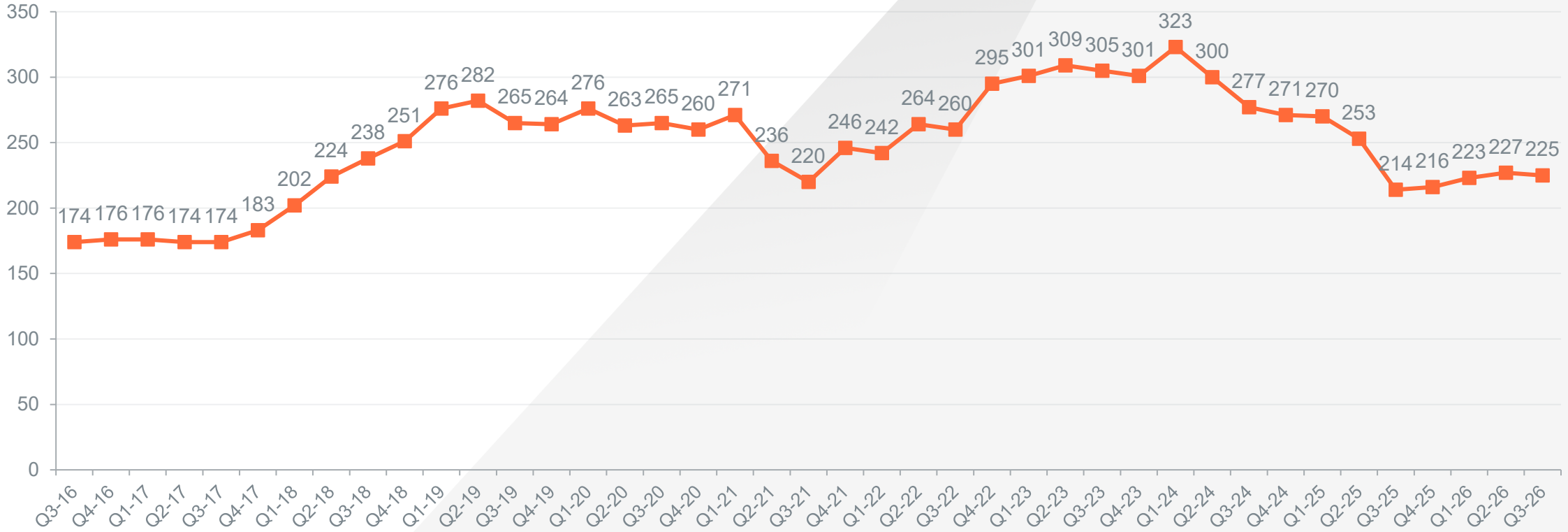
https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

New Drug Shortages By Year



https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

Active Shortages by Quarter
Q2 2016 through Q2 2026

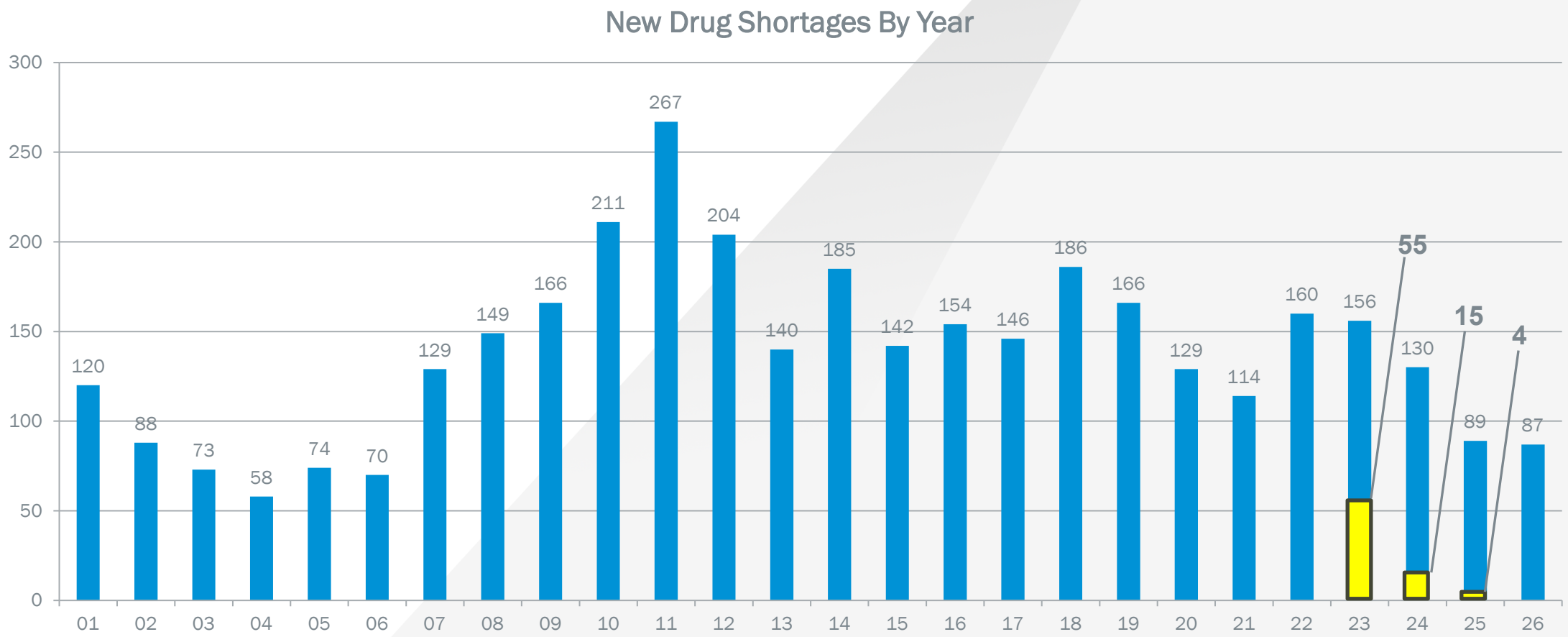


https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

- ASHP
  - Drugs, biologics, some devices
  - Reported through public portal
  - Verified with manufacturers
  - Consider how drug is prepared or dispensed
  - Maintained until all NDCs are recovered

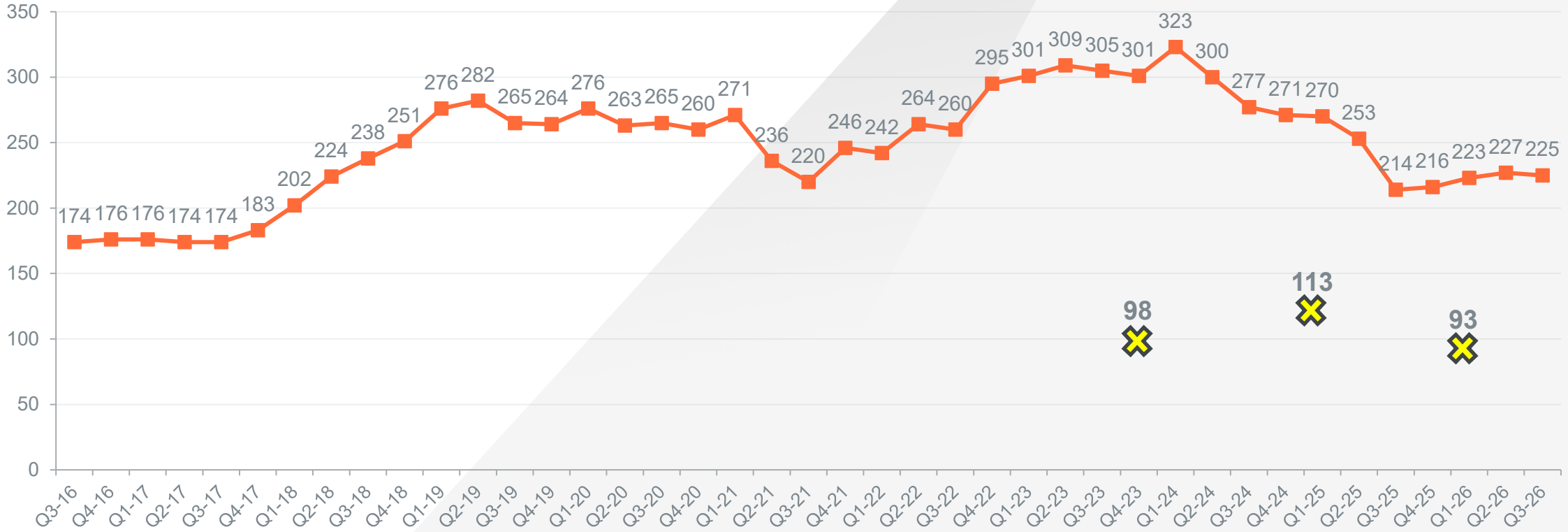
- FDA
  - Drugs and biologics (some devices under CARES Act)
  - Manufacturer reported
  - Overall demand exceeds supply
    - Based on IQVIA data

CARES Act: Coronavirus Aid, Relief, and Economic Security Act
https://www.ashp.org/drug-shortages/current-shortages/fda-and-ashp-shortage-parameters



https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics

Active Shortages by Quarter
Q2 2016 through Q2 2026



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Reasons for Shortage

- Lack of impacted manufacturer redundancy
- Lack of manufacturers in a market
- Inability of other manufacturers in a market to increase supply
- Hoarding
- Lack of alternate sources of KSM, API, or components
- Regulatory submission and review
- Lack of a risk management plan

Our Toolbox

- Communicate possible shortage concerns to other suppliers
- Prompt manufacturers to look at supply and demand
- Regulatory flexibility and discretion
- Expedite review of proposals and regulatory submissions
- Expiry extension
- Temporary importation of an unapproved product

Role of Industry to Help Prevent and Mitigate Drug Shortages

- Understand the frailties of their supply chain
- Communicate early about potential shortages
- Provide shortage information for posting on FDA website when a shortage is unavoidable
- Provide short term and long-term plans for preventing and addressing shortages while maintaining and improving quality
- Work with FDA to minimize shutdowns or slowdowns that will lead to shortages
- Hold safety stock
- Allocate product when possible
- Adopt more mature quality management practices

A Broad Portfolio Supporting Patient Care

High-quality and affordable products for the therapy and care of critically and chronically ill patients in hospital and outpatient care

Biopharma



MedTech



Nutrition



Pharma



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Fresenius Kabi is committed to U.S. Production



> **4,000** employees in the US

5 production sites, **3** R&D centers

+1B USD invest in the U.S. since 2017 in production and supply capacity

60% of the Essential Medicines List*

72% of our medicines are filled and finished in U.S.

#1 in Injectable IV Drugs in the U.S.

90% of manual **blood collections** supported by our products

* Based on the 2022 ASPR Essential Medicines Supply Chain and Manufacturing Resilience Assessment

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Reducing Shortages Requires Understanding Shortages

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Key therapies

25% of drug shortages are within two fields—oncology and neurology—where patients require consistent and timely access to necessary medications

84%

Generics

Shortages disproportionately affect generic drugs

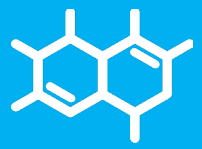
75



Distinct molecules with active shortages

Down from 98 in 2024

13



Cancer shortages

13 oncology molecules are in shortage, with the vast majority (N=12) being sterile injectables

69%

Injectable

Sterile injectables are the majority of shortages

56%

Products in shortage are typically low-price, with 56% of molecules in shortage priced at $1 per unit or less

Source: AAM Savings Report, 2026, using IQVIA data

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The Duke-Margolis ReVAMP Drug Supply Chain Consortium's

Framework to Address Chronic Drug Shortages

Six Priority Areas



Federal Coordination on Drug Shortages

Create a coordinating mechanism for federal roles and responsibilities, data sharing, and supply chain expertise.



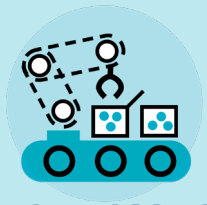
Supply Chain Measurement

Scale reliability assessments that help purchasers identify more reliable supply chains.



CMS Payment Reforms to Prevent Drug Shortages

Use Medicare payment tools to reward purchasing from reliable manufacturers.



Advanced and Modernized Manufacturing Technologies

Accelerate adoption of equipment, processes, and technologies that improve reliability, monitoring, and quality assurance over time.



Address Geopolitical Risks in Drug Supply Chains

Assess product-level vulnerabilities and tailor interventions to mitigate supply chain risks.



Leverage International Collaboration

Coordinate with partner governments to harmonize approaches and strengthen trusted supply chains.

Panel Discussion

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