



Drug Shortages:

America's Physician Groups Deep Dive Webinar Series

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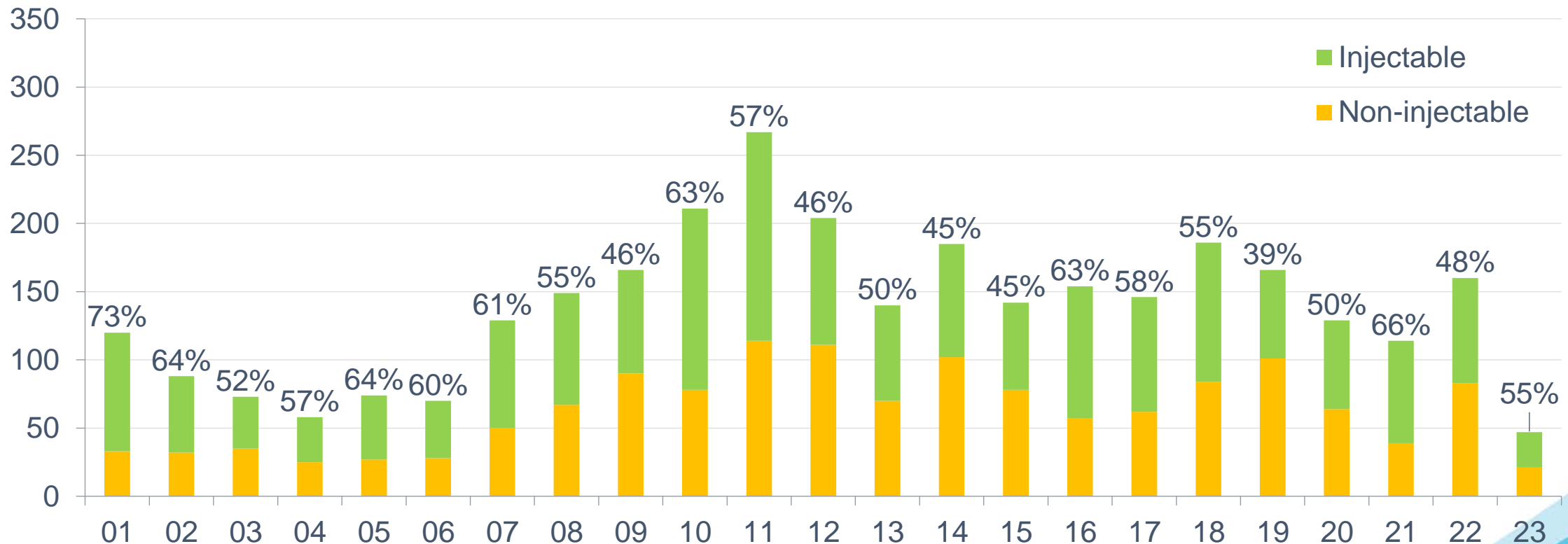
Agenda

- Brief history and current state of drug shortages
- Managing drug shortages
- Root causes and possible solutions

Drug Shortages: Brief history and current state

Drug Shortages

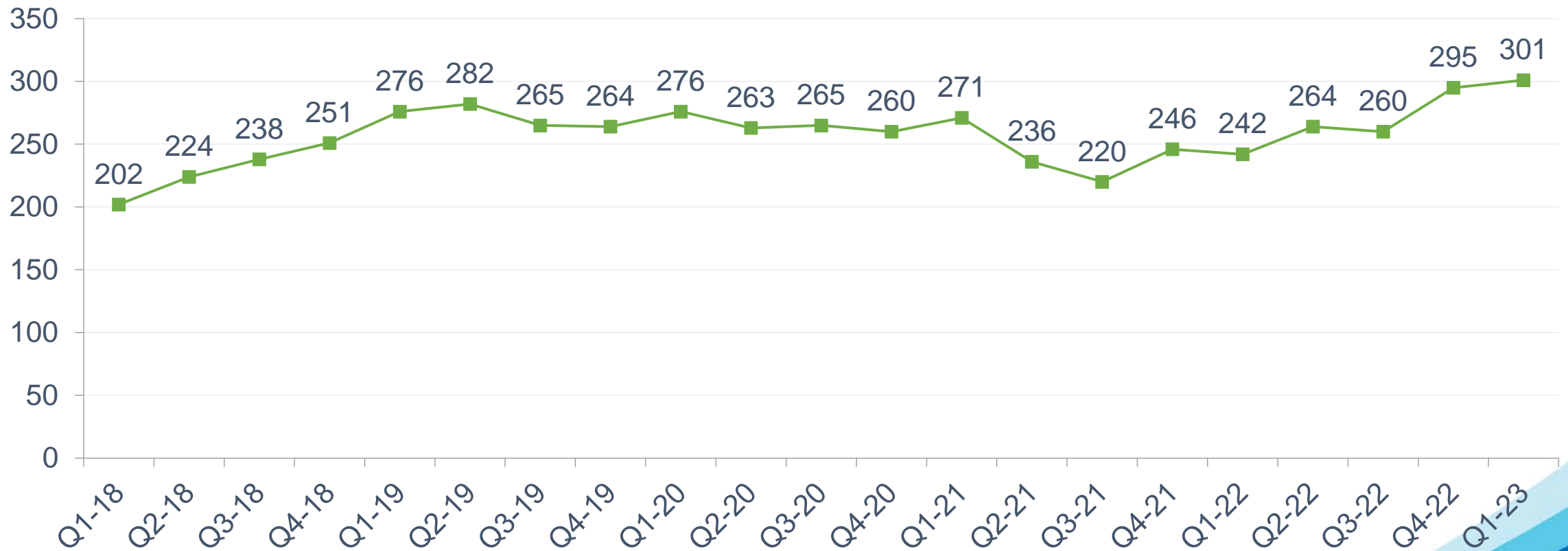
New Shortages by Year January 2001 to March 31, 2023, % Injectable



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

Drug Shortages

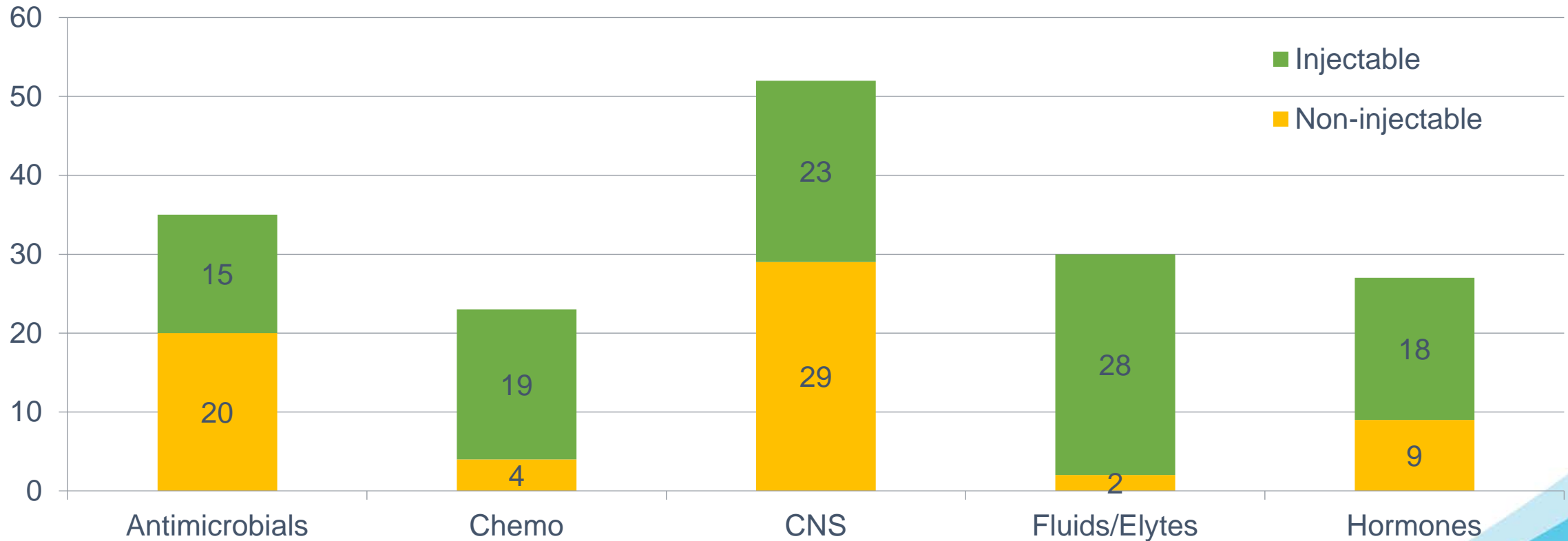
Active Shortages by Quarter: 5-Year Trend



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

Drug Shortages

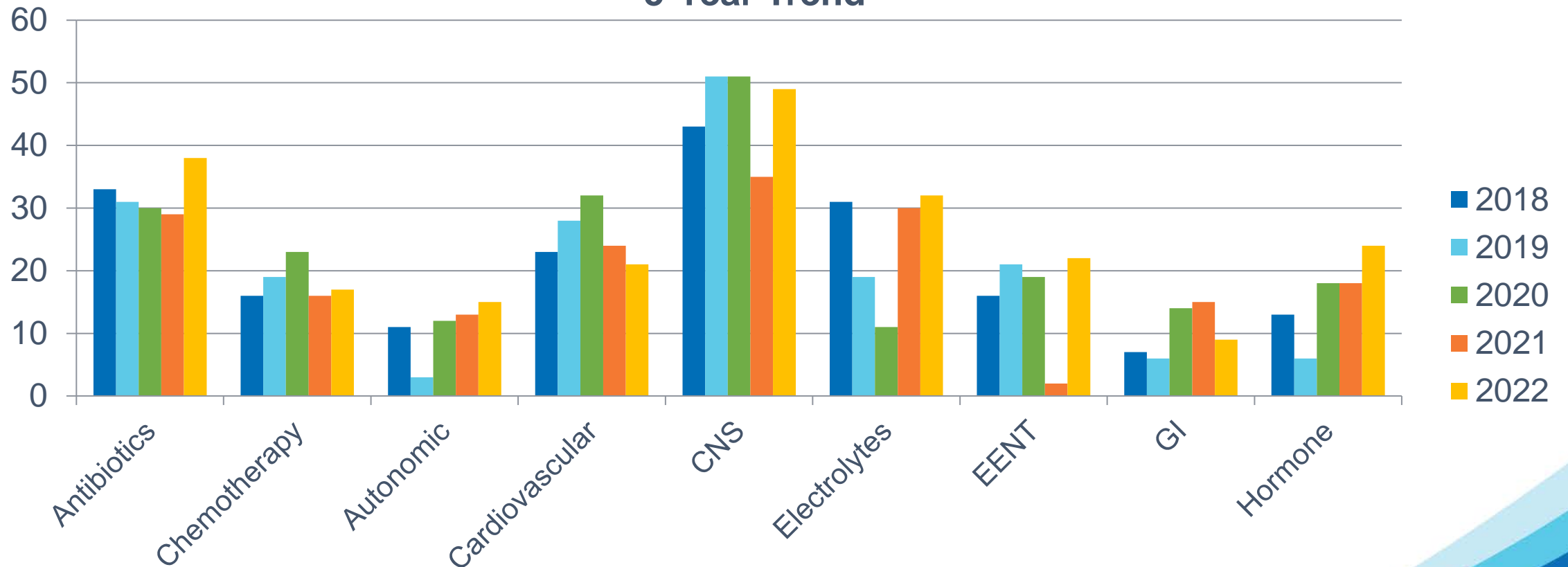
Active Shortages: Top-Five Drug Classes March 31, 2023



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

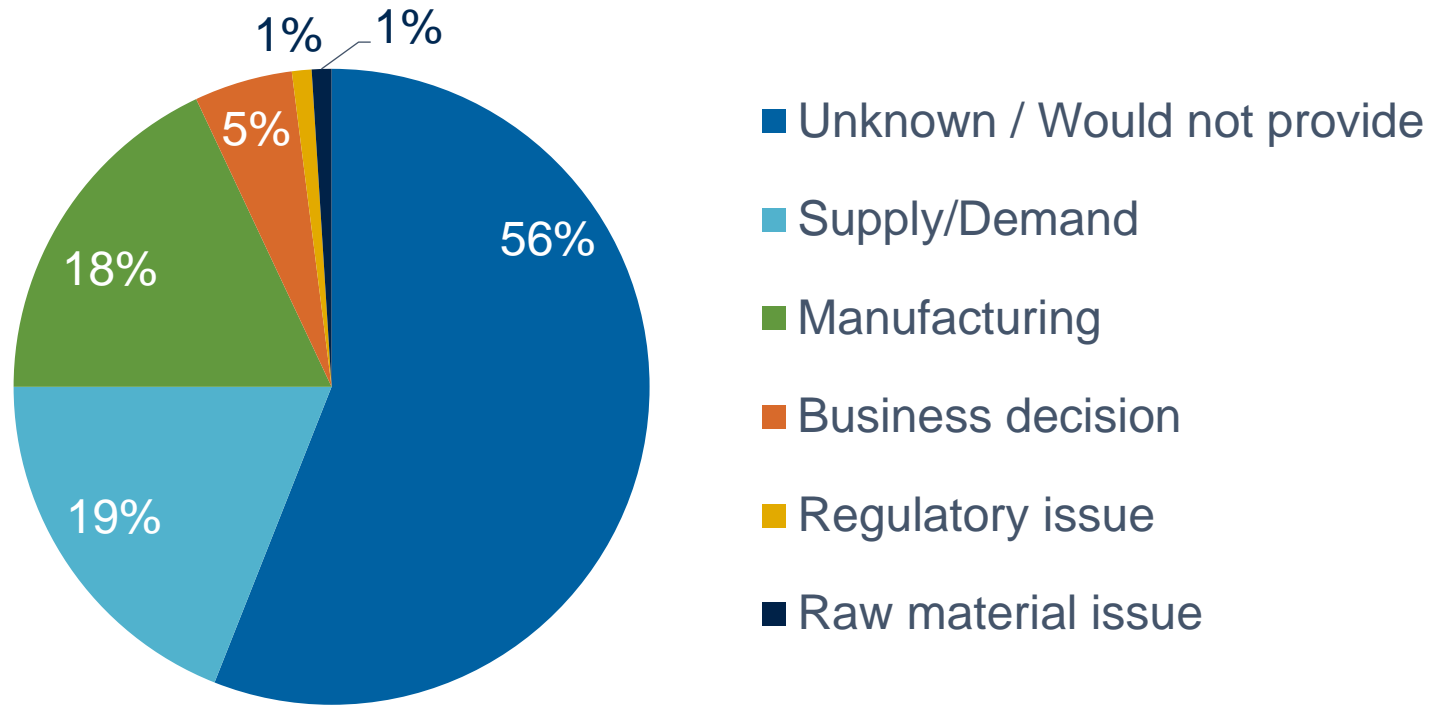
Drug shortages

Active Shortages: Common Drug Classes in Short Supply
5-Year Trend



Drug shortages

Reasons for Shortages as Reported by Manufacturers: 2022



Drug Shortages: Managing drug shortages

Clinical Strategies

- Therapeutic alternatives
- Different routes of administration
- Rationing criteria
- Delay or cancel treatment
- Altering order sets or protocols

Operational Strategies

- Consolidate / centralize inventory
- Use non-formulary sizes or concentrations
- “Insource” internal compounding
- Repackaging
- 503B outsourcing facilities
- Secondary wholesaler

ASHP Guidelines

ASHP Guidelines on Managing Drug Product Shortages

Purpose

Drug product shortages can adversely affect drug therapy, compromise or delay medical procedures, result in medication errors, and cause patient harm.¹⁻³⁸ In addition to these potential problems, healthcare professionals are also increasingly concerned about the tremendous resources required to address shortages, estimated at \$209 million in 2013 for the purchase of more-expensive substitutes alone, which excludes other significant costs (e.g., drugs purchased “off contract,” therapeutic alternatives, added labor).^{39,40}

efficacious, have a worse adverse-effect profile, or require an unusual or difficult dosing regimen. Best practices for managing drug shortages must first consider the potential impact on patient safety. Data documenting patient harm due to drug shortages are limited to case reports and survey data. The Institute for Safe Medication Practices (ISMP) is the leading source of aggregate data.^{13,15,16} A medication-error reporting and review system is an essential component of a medication safety system. Errors and near misses should be reported internally and externally, and analyzed.^{48,49}

<https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.ashx>

Drug Shortages: Root causes and possible solutions

Recent, high-profile shortages



HEALTH INC.

Hurricane Damage To Manufacturers In Puerto Rico Affects Mainland Hospitals, Too


November 15, 2017 • 5:09 AM ET

Heard on Morning Edition

By Alison Kodjak

<https://www.npr.org/sections/health-shots/2017/11/15/564203110/hurricane-damage-to-manufacturers-in-puerto-rico-affects-mainland-hospitals-too>

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Opioid shortages leave US hospitals scrambling

By Pauline Bartolone, California Healthline
Published 5:45 AM EDT, Mon March 19, 2018

<https://www.cnn.com/2018/03/19/health/hospital-opioid-shortage-partner/index.html>

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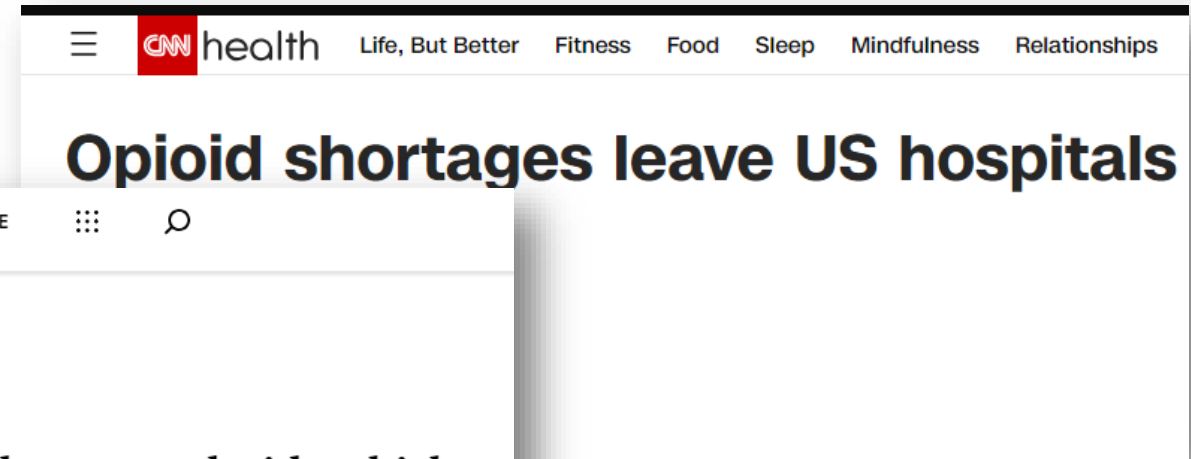
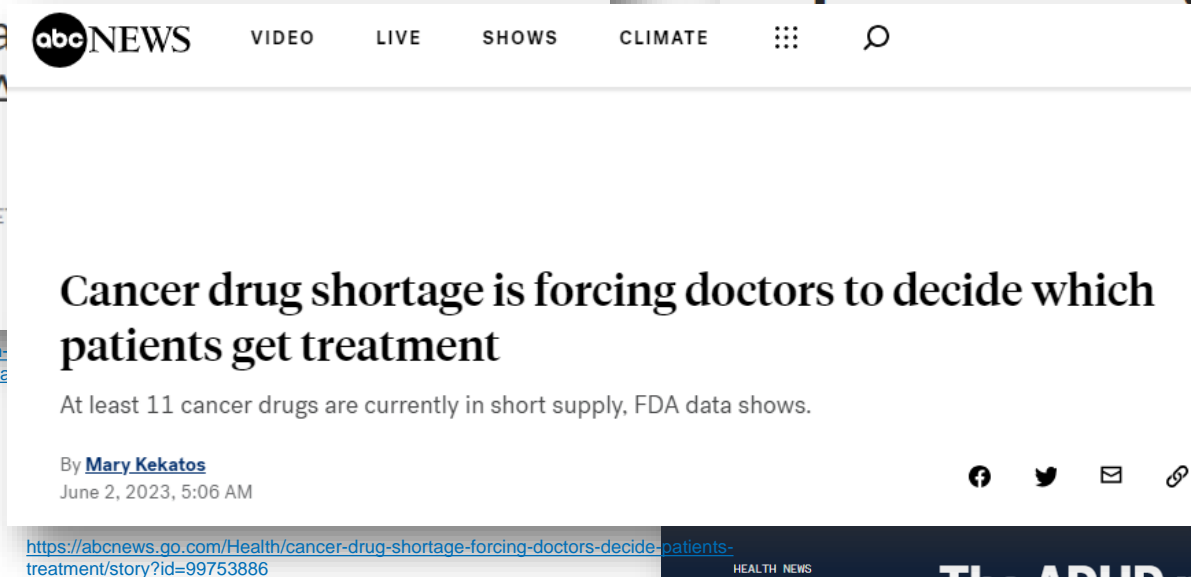
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HEALTH NEWS

The ADHD medication shortage is getting worse. What went wrong?

<https://www.nbcnews.com/health/health-news/adderall-shortage-adhd-drugs-affected-will-end-rcna66766>

Recent, high-profile shortages



<https://www.nbcnews.com/health/health-news/adderall-shortage-adhd-drugs-affected-will-end-rcna66766>

Root causes

Drug Shortages: Root Causes and Potential Solutions

2019



Executive Summary



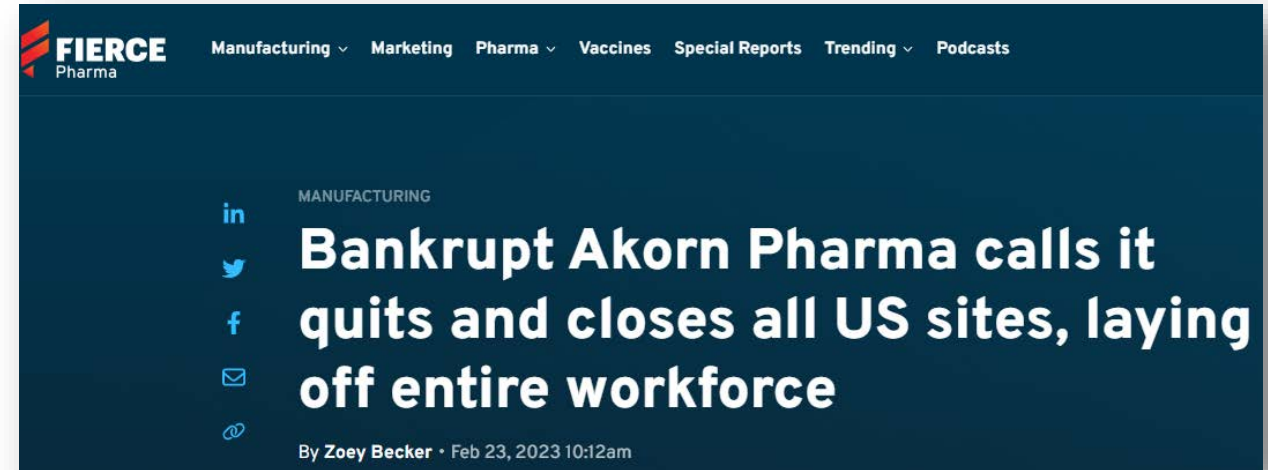
<https://www.fda.gov/media/132058/download>

- **Root Cause 1: Lack of Incentives to Produce Less Profitable Drugs.** When market conditions limit manufacturers' profitability, they reduce a firm's motivation to maintain a presence in, or enter the market for older prescription drugs, and to invest in manufacturing quality and redundant capacity. Manufacturers of older generic drugs, in particular, face intense price competition, uncertain revenue streams, and high investment requirements, all of which limit potential returns. Current contracting practices contribute to a "race to the bottom" in pricing.

- **Root Cause 2: Market Does Not Recognize and Reward Manufacturers for Mature Quality Management Systems.** All manufacturers must meet regulatory requirements for adherence to Current Good Manufacturing Practices (CGMPs), which set a minimum threshold that companies must achieve in order to be allowed to supply the U.S. marketplace. Mature quality management, however, starts with a foundational quality management system that conforms to CGMPs and builds in a performance and patient focus that utilizes technology, statistical process control, and planning activities to ensure a reliable supply of the drugs manufactured at the facility.

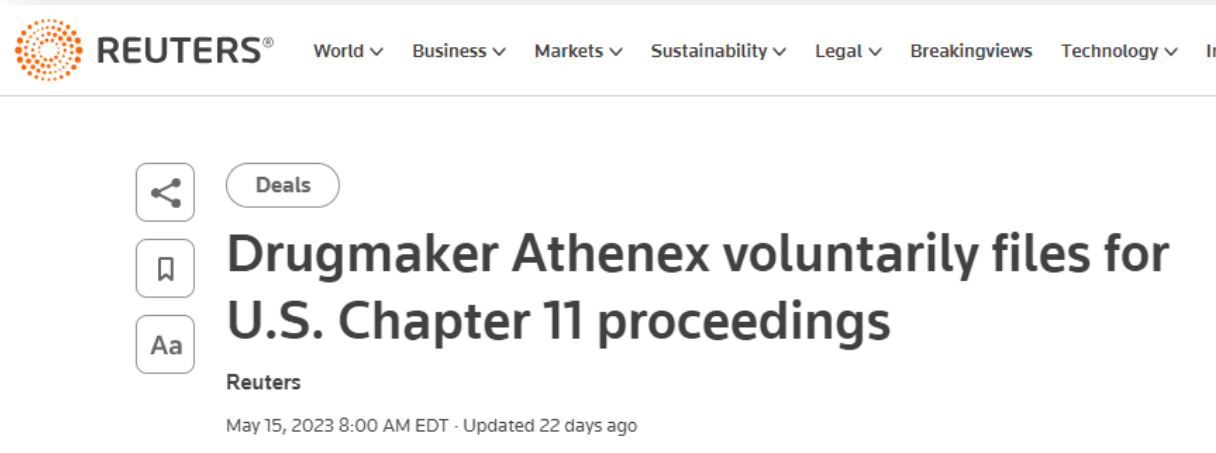
Currently, purchasers have only limited information that can be used to assess the state of quality management of any specific facility and have little information linking the drug products they buy with the facilities where they were manufactured. The lack of information does not enable the market to reward drug manufacturers with price premiums for mature quality management, back-up manufacturing capabilities, or risk-management plans, nor does it penalize manufacturers that fail to invest in modernization of manufacturing equipment and facilities to ensure a reliable supply. Thus, manufacturers are more likely to keep costs down by minimizing investments in manufacturing quality, which eventually leads to quality problems, triggering supply disruptions and shortages.

Recent examples



<https://www.fiercepharma.com/manufacturing/akorn-pharma-bankrupt-calls-it-quits-closes-all-us-sites-and-cuts-entire-workforce>

Recent examples







<https://www.reuters.com/markets/deals/drugmaker-athenex-voluntarily-files-us-chapter-11-proceedings-2023-05-14/>



<https://www.fiercepharma.com/manufacturing/akorn-pharma-bankrupt-calls-it-quits-closes-all-us-sites-and-cuts-entire-workforce>

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   **Deals**

Drugmaker Athenex voluntarily files for U.S. Chapter 11 proceedings

Reuters

May 15, 2023 8:00 AM EDT · Updated 22 days ago

<https://www.reuters.com/markets/deals/drugmaker-athenex-voluntarily-files-us-chapter-11-proceedings-2023-05-14/>

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MANUFACTURING

Bankrupt Akorn Pharma calls it quits and closes all US sites, laying off entire workforce

By Zoey Becker · Feb 23, 2023 10:12am

<https://www.fiercepharma.com/manufacturing/akorn-pharma-bankrupt-calls-it-quits-closes-all-us-sites-and-cuts-entire-workforce>

Bloomberg

Markets

Teva Plans to Cut Back Generic Drug Production Even As Shortages Intensify

- Drugmaker will focus on new, branded products to fuel growth
- Manufacturing reductions will not harm market supply: CEO

<https://www.bloomberg.com/news/articles/2023-05-18/teva-plans-cuts-to-generic-drug-production-amid-shortages#xj4y7vzkg>

Recent examples



The screenshot shows the FIERCE Pharma website header with navigation links: Manufacturing, Marketing, Pharma, Vaccines, Special Reports, Trending, and Podcasts. The article is categorized under 'MANUFACTURING' and features a vertical list of social media sharing icons (LinkedIn, Twitter, Facebook, Email, Link, Print) on the left. The main headline is 'Burn after reading: FDA blasts Intas for 'cascade of failure' after investigators find heaps of shredded documents'. The byline reads 'By Fraiser Kansteiner • Jan 20, 2023 10:17am'.

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MANUFACTURING

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Solutions

- Address the root causes – incentivize investment in quality maturity
- Mitigate the impact – reimagine the strategic national stockpile
- Build better systems – adopt newer manufacturing technologies
- Improve transparency – identify vulnerabilities so they can be addressed

Drug Shortages – Discussion





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