

# Weekly Pharmacy Pearl #13 – Drug Shortages

## How is a drug shortage defined and who tracks them?

- **FDA:** An occurrence when a product used to prevent or treat a **serious or life-threatening disease** or medical condition for which there is **no other available source** with sufficient supply of that product or alternative drug available.
- **American Society of Health-System Pharmacists (ASHP):** A supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.
- **In short, ASHP tracks all potential drug shortages while the FDA prioritizes drugs that are medically necessary.**



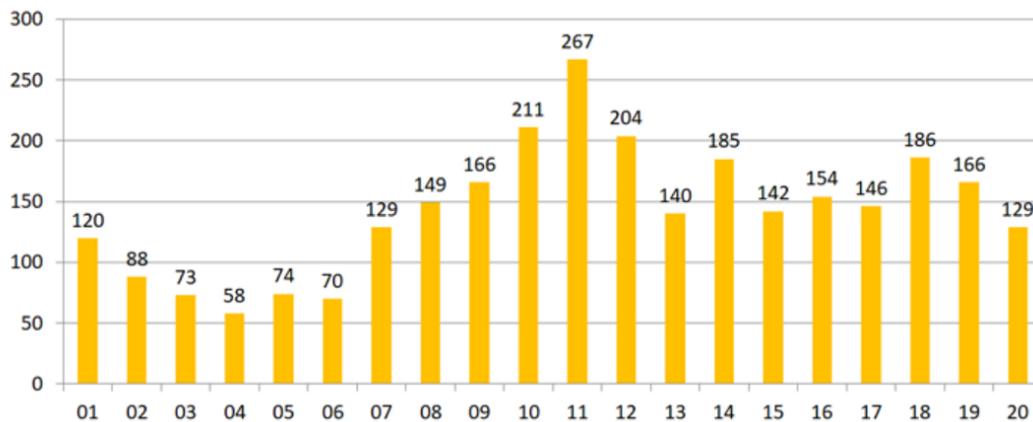
## How big of a problem is this?

- Unfortunately, there have been increasingly frequent drug shortages in the U.S. during the past two decades.
- During 2020 there were significant shortages of analgesics, sedatives and paralytics due to COVID-19

January 2001 to December 31, 2020

Each column represents the number of the shortages identified during that year

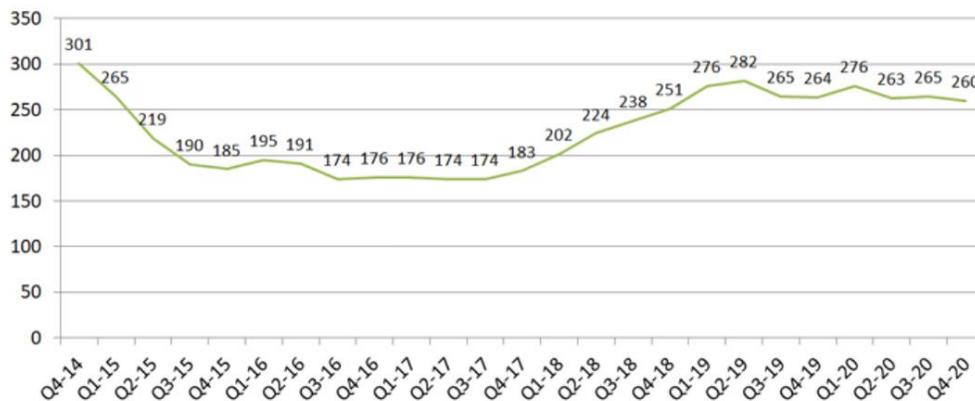
Source: University of Utah Drug Information Service



December 31, 2020

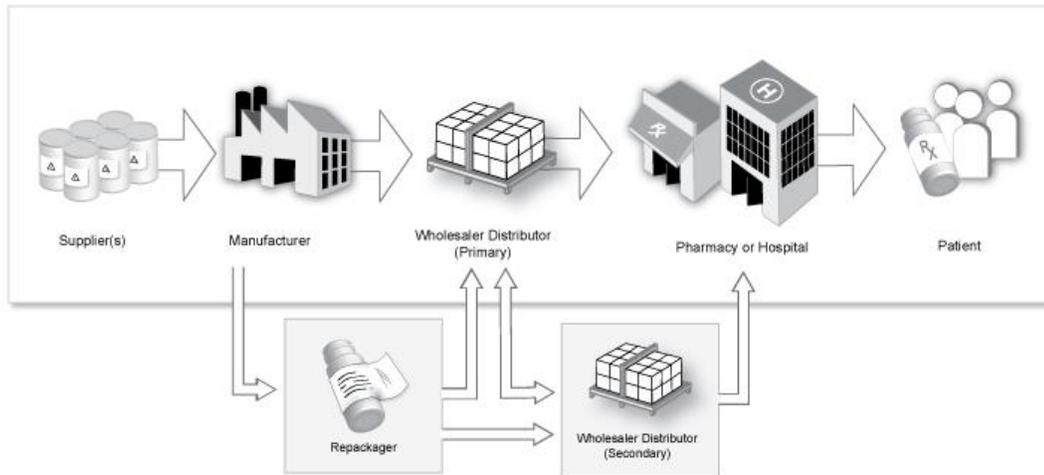
Each point represents the number of active shortages at the end of each quarter

Source: University of Utah Drug Information Service



## How does a drug shortage occur?

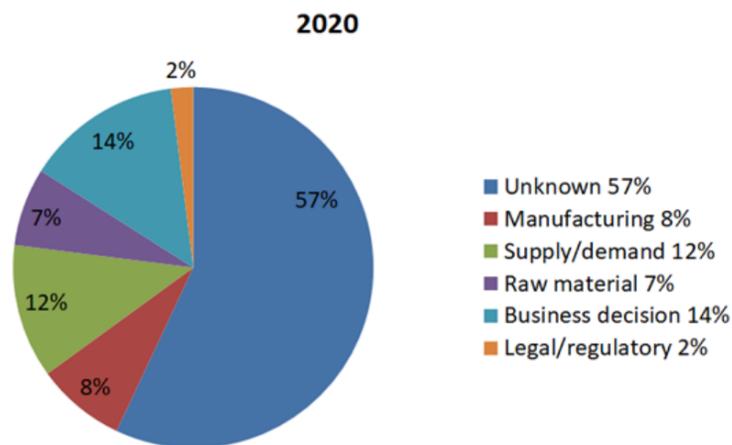
- A shortage can occur due to any disruption in the drug supply chain pictured below



- Common causes of drug shortages:
  - Manufacturing difficulties
    - Old equipment, shift of resources from manufacturing to research and development, loss of production and compliance personnel, limited production capabilities
    - **Example: 2017 shortage of prefilled syringes for epinephrine, sodium bicarbonate, calcium chloride and other emergency medications due to Pfizer manufacturing delays**
  - Shortages of raw materials
    - Disruption in supply of raw or bulk materials delivered to manufacturer
    - Especially problematic with a primary or sole-source supplier of a raw material
    - Issues with obtaining raw materials from other countries
      - Armed conflicts, political upheaval, trade disputes, animal diseases, degradation or contamination during transport, climate changes, decreased crop yields
    - **Example: 2019 heparin shortage due to an African swine fever outbreak in China that killed millions of pigs (yup ...heparin is made from pig intestines)**
  - Voluntary recalls
    - Lack of confidence in safety or reasons such as technical deficiencies in labeling
    - Usually affect specific lots and are temporary
    - **Example: Cisatracurium recall by Meitheal Pharmaceuticals, Inc on 1/27/2021 for vials being mislabeled as phenylephrine**
  - Natural disasters
    - Damage to manufacturing facilities
    - Unexpected demand of meds to treat disaster victims
    - **Example: Shortage of IV saline bags and several medications after Hurricane Maria hit Puerto Rico in 2017**
  - Supply and demand issues
    - Demand can increase due to the approval of a new indication for an existing product, changes in therapeutic guidelines, the spread of disease, etc
    - **Example: Current shortages of paralytics, analgesics and sedatives due to COVID-19 → the reason why you haven't had fentanyl drips in the omnicells and why the talk of 2% propofol is floating around**

- Business and economic issues
  - Pharmaceutical companies love making \$\$\$ → Medication production can be decreased or discontinued due to insufficient profits, introduction of generic formulations, loss of patents, market shares or mergers
  - **Example: 2020 shortage of droperidol when Pfizer discontinued manufacturing it → now only one remaining manufacturer in the U.S.**
- Supply chain issues and healthcare system practices
  - Multiple health care facilities in a geographic area using the same wholesaler
  - Keeping reduced inventories to optimize cash flow
  - Poor ordering practices, drug stockpiling in advance of price increases, hoarding in response to rumors of an impending shortage (seriously, think about the COVID toilet paper crisis but with meds)
  - Drug allocation → limitations on quantities sold to particular sites
  - Delivery delays
  - **Example: Shortage of hydroxychloroquine for lupus and rheumatoid arthritis patients due to drug hoarding for COVID-19**

Reasons for Shortages as Determined by UUDIS During Investigation — 2020



### What are the potential consequences of drug shortages?

- Higher hospital expenses
- Increased labor costs
- Safety risks
  - Compromised clinical outcomes
  - Medication errors
  - Death
- Increases in quality control risks
- Decreased supply of alternative drugs
- Violation of clinical trial protocols due to drug substitutions
- Strained professional relationships

## What strategies do we have for managing drug shortages?

- Verification of a shortage with manufacturers or distributors
- Assessment of hospital inventory to estimate how long a shortage can be endured
- Communication with other sites within the health system → shifting drug inventory among sites
- **Identification of alternative drugs or therapeutic equivalents**
- **Prioritization of patients to receive drugs in short supply**
- Good inventory management practices
- **Modification of clinical guidelines and other policies**
- Development of timely communication systems and strategies

## How can I track drug shortages?

- FDA → <https://www.accessdata.fda.gov/scripts/drugshortages/>
- ASHP → <https://www.ashp.org/Drug-Shortages/Current-Shortages/Drug-Shortages-List?page=All>
- **Ask us!**