

Drug Shortages: Impact on Health System Pharmacy

Whitney Hessel, PharmD

Disclosure

- Dr. Hessel has no personal or financial conflicts of interest to disclose.

Learning Objectives

- Define a drug shortage and the contributing factors to current drug shortages.
- Identify root causes and potential solutions of drug shortages.
- Discuss how to manage drug shortages to minimize the impact on patient care.
- Evaluate the role of a pharmacy technician in drug shortages and inventory management.

Why do we care?

- Drug shortages lead to pharmacies continued struggle to provide adequate and appropriate patient care
- Shortages increase the chance of errors
 - Changes in available product sizes
 - Changes in concentrations
 - Need for compounding unavailable doses
- ISMP reported that 21% of pharmacy staff were aware of at least 1 medication error related to a drug shortage
- Increased financial burden of the hospital and responsibilities of pharmacy staff for managing supply and monitoring inventory

Defining a Drug Shortage

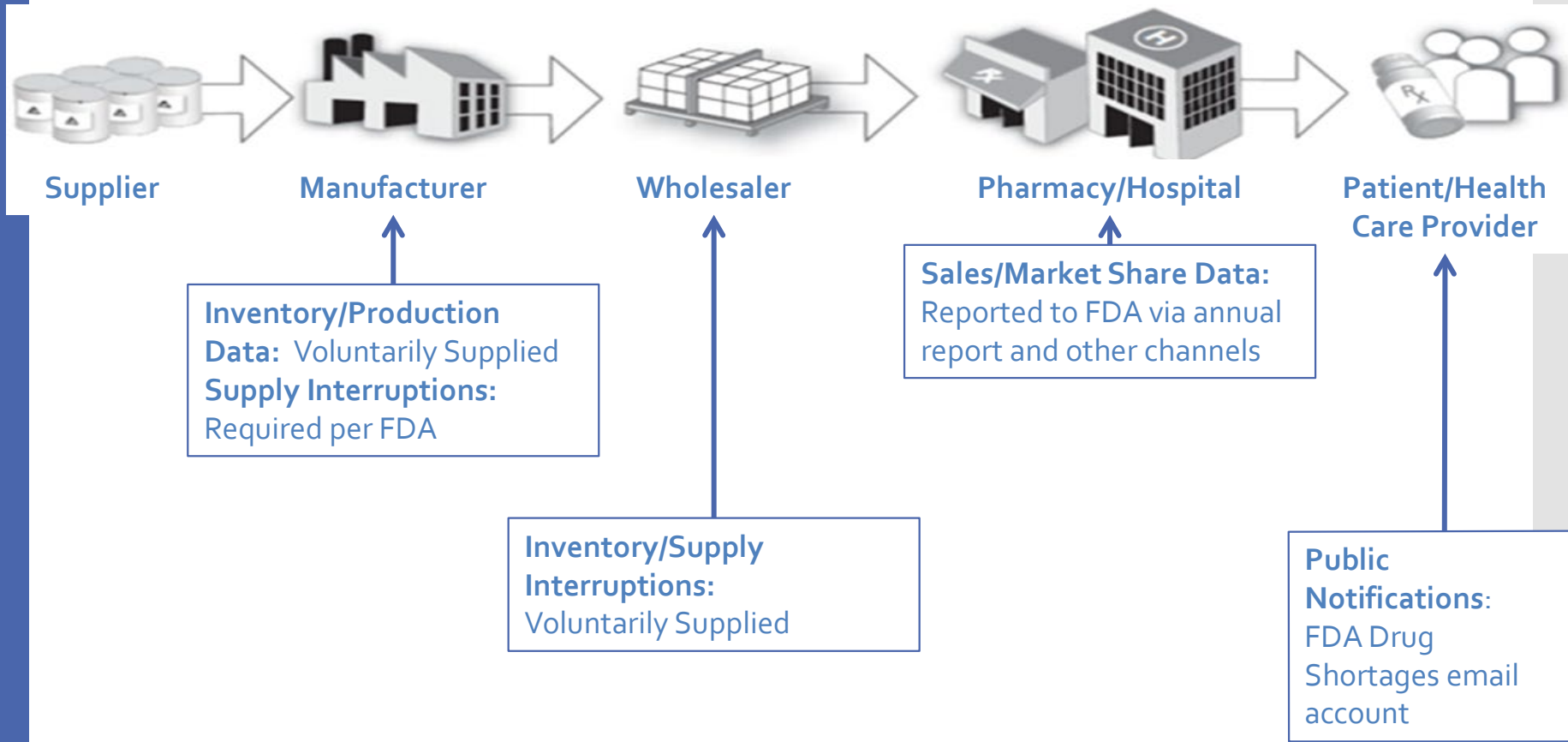
FDA Shortage Parameters

- A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply
- The only criteria to be included on the FDA list is that the manufacturer is unable to meet current market demand
- Manufacturers notify FDA of production disruption and voluntarily provide updates
 - Represents shortage status at drug firm level
 - Reasons provided by manufacturers
- Shortage is considered resolved when one or more manufacturers are in production and able to meet market demand

ASHP Shortage Parameters

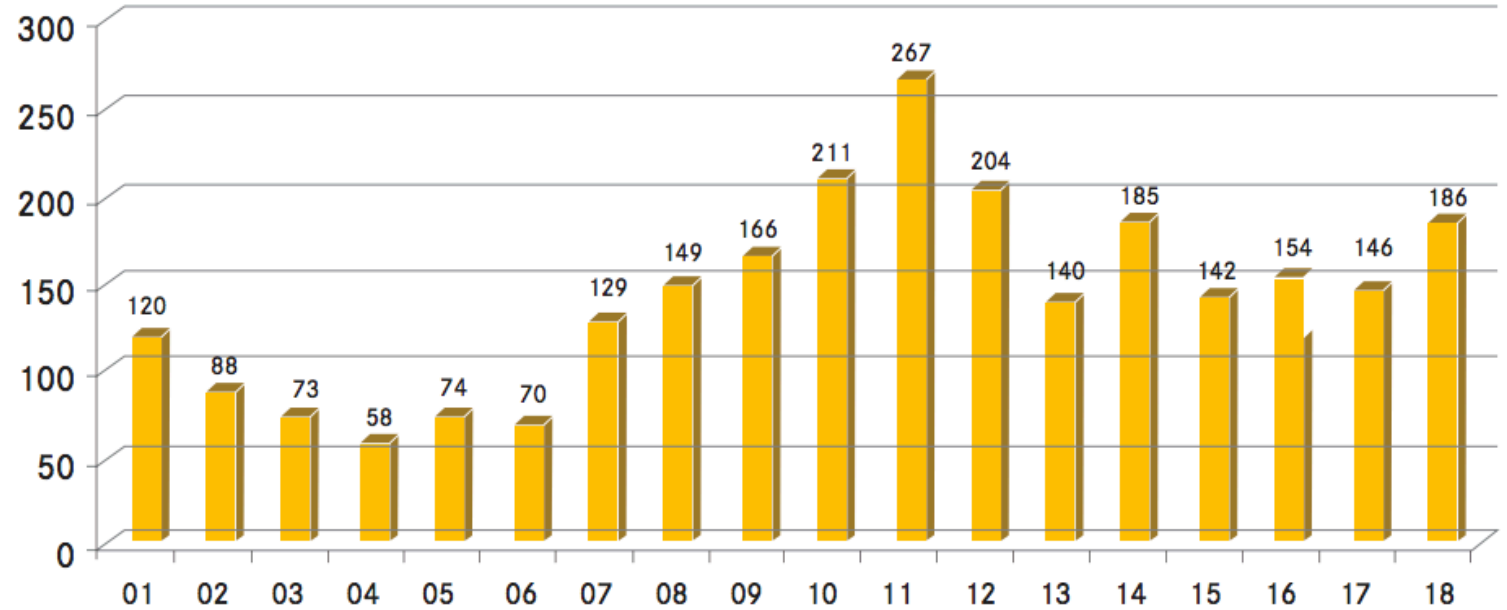
- Provides drug shortage management resources as well as notifications of new shortages and status of ongoing shortages
- Criteria for inclusion on shortage list:
 - Verified by manufacturers
 - Affects pharmacy preparation and dispensing of product
 - Requires use of alternative product which may affect patient care
- ASHP frequently lists more shortages than the FDA
 - All drug and biologic shortages with national impact
 - Information is updated based on projected availability from manufacturers
 - Represents shortage status at healthcare provider level
- Shortage is resolved when all manufacturers are restored to full availability

Drug Supply Chain



Drug Shortages

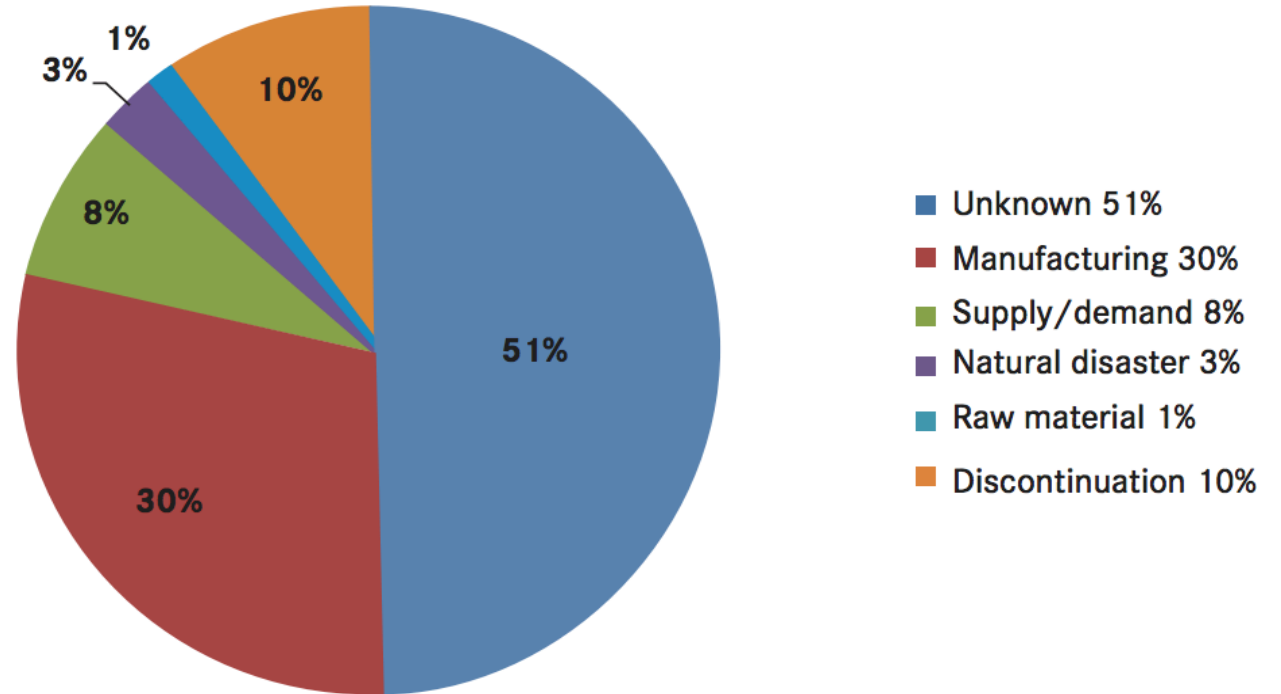
FIGURE 1. NATIONAL DRUG SHORTAGES BY YEAR



Source: The University of Utah Drug Information Service (2019) and the American Society of Health-System Pharmacists Drug Shortages (2019)

Drug Shortages

FIGURE 2. REASONS FOR DRUG SHORTAGES, 2018



Source: The University of Utah Drug Information Service (2019) and American Society of Health-System Pharmacists Drug Shortages Statistics (2019)

What factors are contributing to recent shortages?

- Hurricane Maria in 2017 in Puerto Rico affected 5 of the world's top 10 drug manufacturers and 11 of the top 20 products in the world⁴
- Restrictions on injectable opioids by the Drug Enforcement Administration (DEA) have also affected patient care
- Manufacturers ceasing production of a generic drug
- Inability of other manufacturers to generate additional volumes
- A lack of raw materials can also pose challenges for supply

FDA Root Cause Analysis

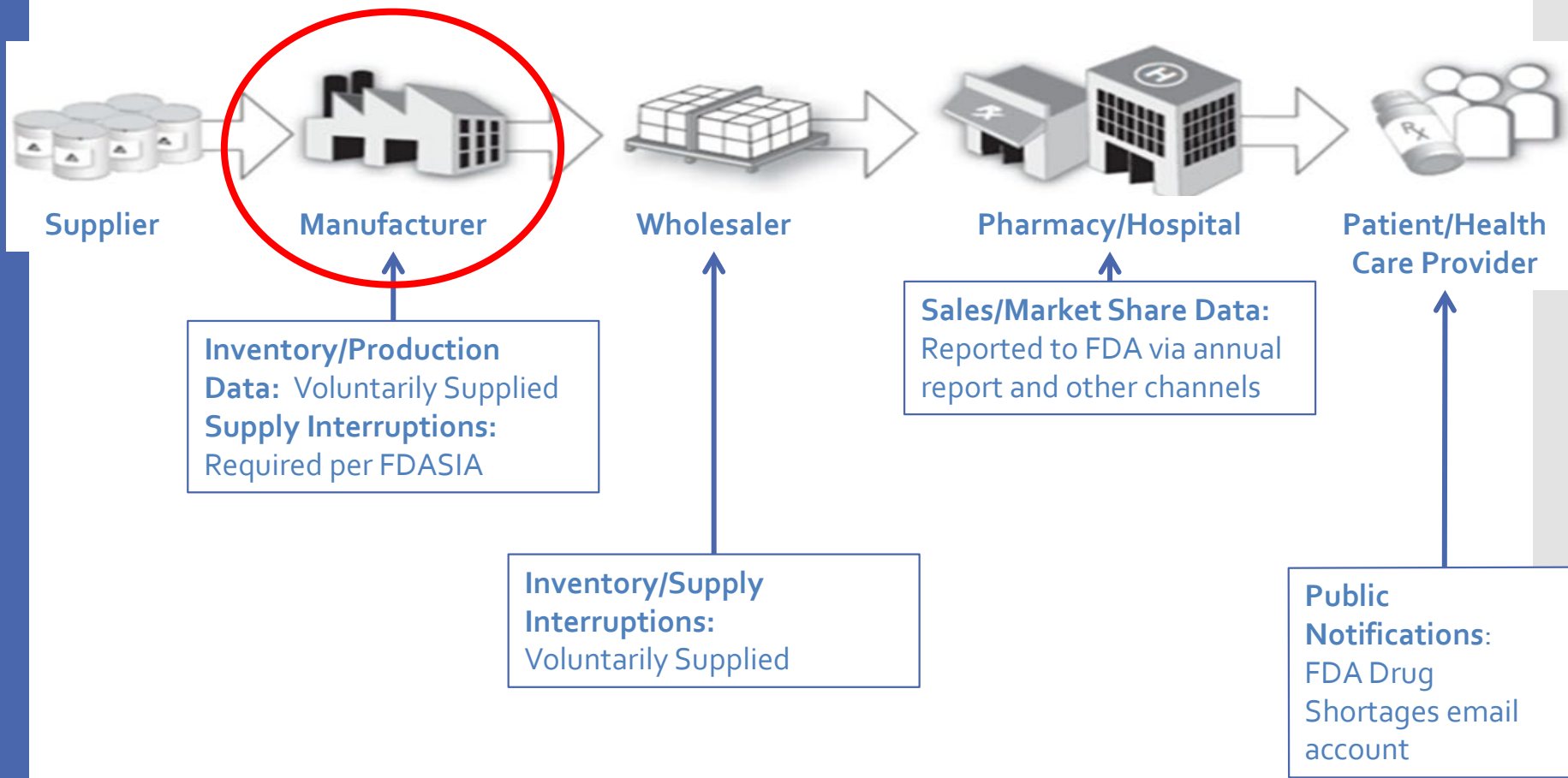
- To help mitigate issues causing the shortages and lessen the impact, the FDA created the Agency Drug Shortages Task Force
- This committee is responsible for investigating the root causes of shortages and proposing long-term resolutions to Congress
- Efforts include:
 - Expediting inspections for manufacturers to increase production in shortages
 - Investigating root causes to prevent future shortages

FDA Root Cause Analysis

Root Cause 1: Lack of Incentives to Produce Less Profitable Drugs

- Market conditions limit manufacturers' profitability
- Manufacturers of older generic drugs face intense price competition, uncertain revenue streams, and high investment requirements
- Current contracting practices contribute to a "race to the bottom" in pricing.

Drug Supply Chain



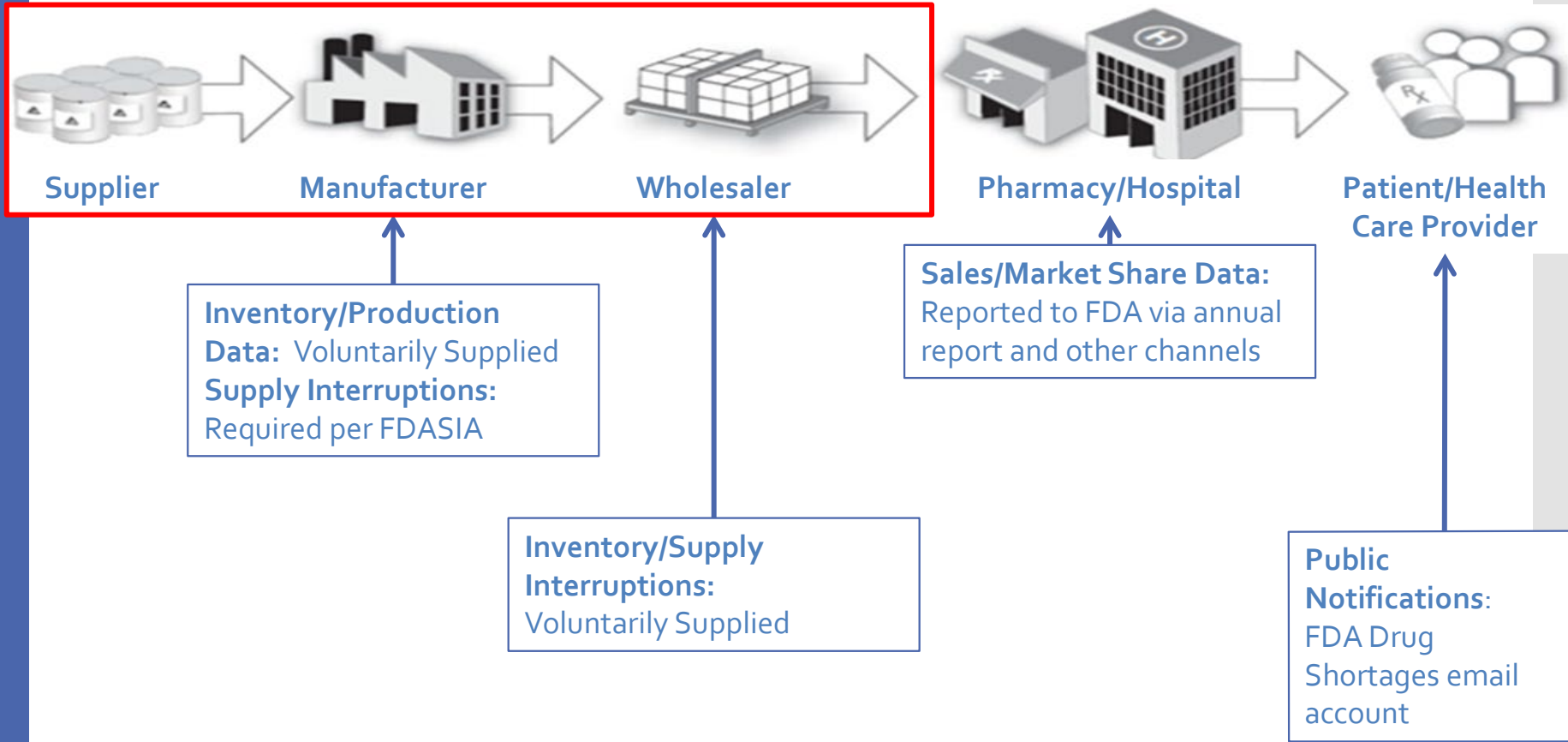
FDA Root Cause Analysis

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)
- Purchasers have only limited information that can be used to assess the state of quality management of any specific facility and the drug products they buy
- The lack of information does not enable the market to reward drug manufacturers that exceed CGMP requirements nor does it penalize manufacturers that fail to implement improvements
- Manufacturers are more likely to keep costs down



Drug Supply Chain



FDA Root Cause Analysis

Root Cause 3: Logistical and Regulatory Challenges Make It Difficult for the Market to Recover After a Disruption

- The drug supply chain has become longer, more complex and fragmented as companies have located more production overseas
- Can limit the ability of drug manufacturers to increase production
- When companies wish to increase production they may have to obtain approvals from many different national regulatory bodies,
- Finding a new source of active pharmaceutical ingredients (APIs)
- New manufacturers that wish to enter the U.S. market and start selling a drug that addresses a shortage, must first develop and file an application with FDA and await its approval

Drug Supply Chain



Potential Solutions

Potential Solutions

Recommendation 1: Create a Shared Understanding of the Impact of Drug Shortages and the Contracting Practices That May Contribute to Them

- Some of the areas most needing attention are the following:
 - Quantification of the harms of drug shortages, particularly those that lead to worsened health outcomes for patients and increased costs for health care providers
 - Better characterization of shortages
 - Greater transparency in private sector contracting practices

Potential Solutions

Recommendation 2: Create a Rating System to Incentivize Drug Manufacturers to Invest in Achieving Quality Management System Maturity

- Measure and rate the quality management maturity of individual manufacturing facilities based on specific objective indicators
- A rating system could be used to inform purchasers, GPOs, and even consumers about the state of, and commitment to, the quality management system maturity of the facility making the drugs they are buying
- Introduce transparency into the market, and provide firms committed to quality management maturity with a competitive advantage, potentially enabling them to obtain sustainable prices as well as grow market share

Potential Solutions

Recommendation 3: Promote Sustainable Private Sector Contracts

- The combination of more complete information about contracting practices and greater transparency of the quality management maturity of specific manufacturing sites would enable payers, purchasers, and GPOs to consider new contracting approaches aimed at ensuring a reliable supply of medically important drugs. The objectives of these contracts should address the first two root causes discussed above by:
 - **Providing financial incentives**
 - **Rewarding manufacturers for mature quality management**

Minimizing Impact on Patient Care

ASHP Best Practice Guideline

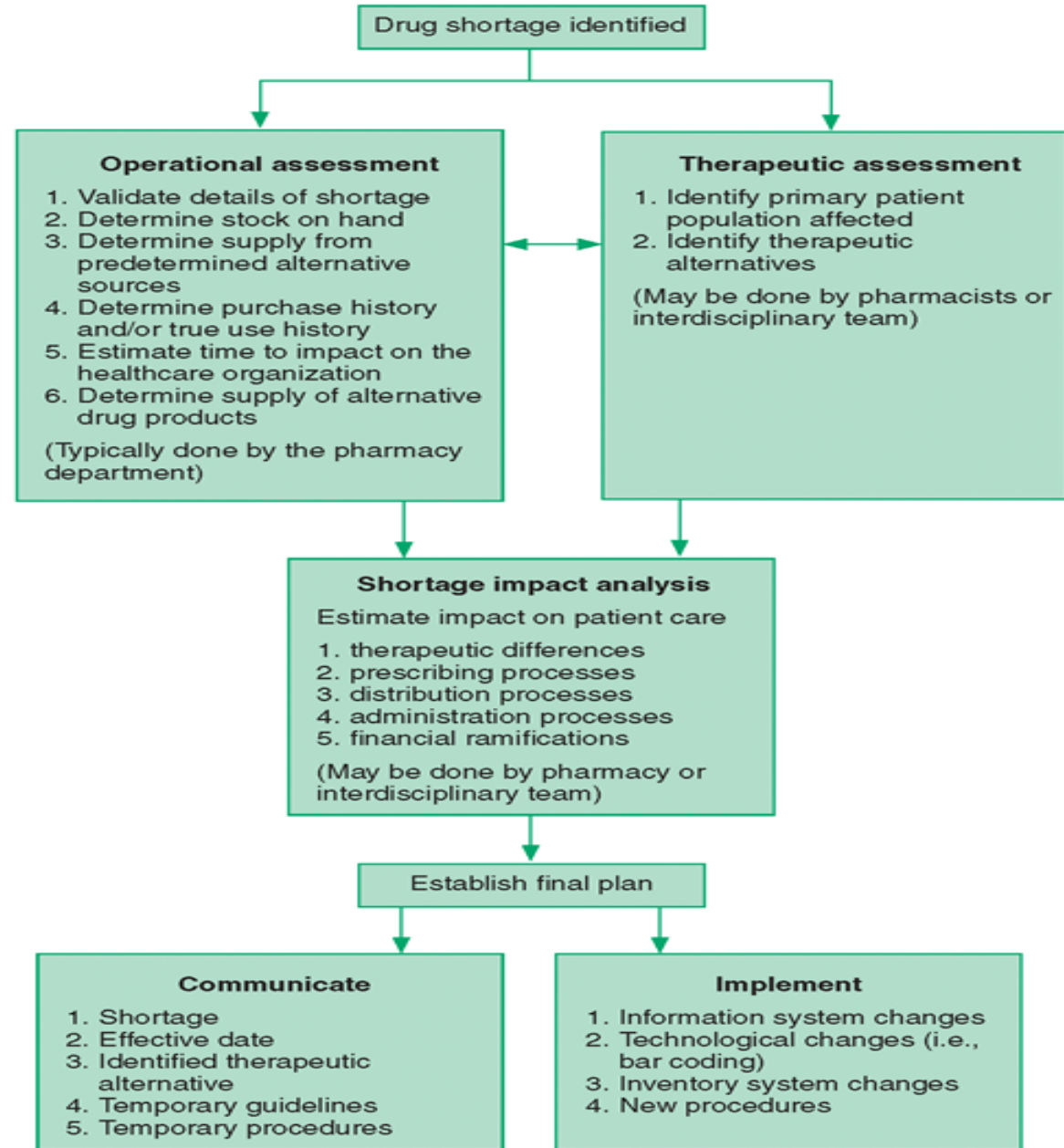
- Pharmacy leaders are at the forefront of educating the healthcare team and organizational leadership
- Drug shortage problems are complex and managing them can be challenging
- The pharmacy department must take a leadership role to:
 - Develop and implement appropriate strategies and processes
 - Inform practitioners of shortages
 - Ensure the safe and effective use of therapeutic alternatives
- Strategic planning is required for managing drug product shortages

ASHP Planning Strategies

Recommended components for strategic planning

- Drug Product Shortage Team
- Resource Allocation Committee
- Process for approving alternative therapies
- Process for addressing ethical considerations

ASHP Framework



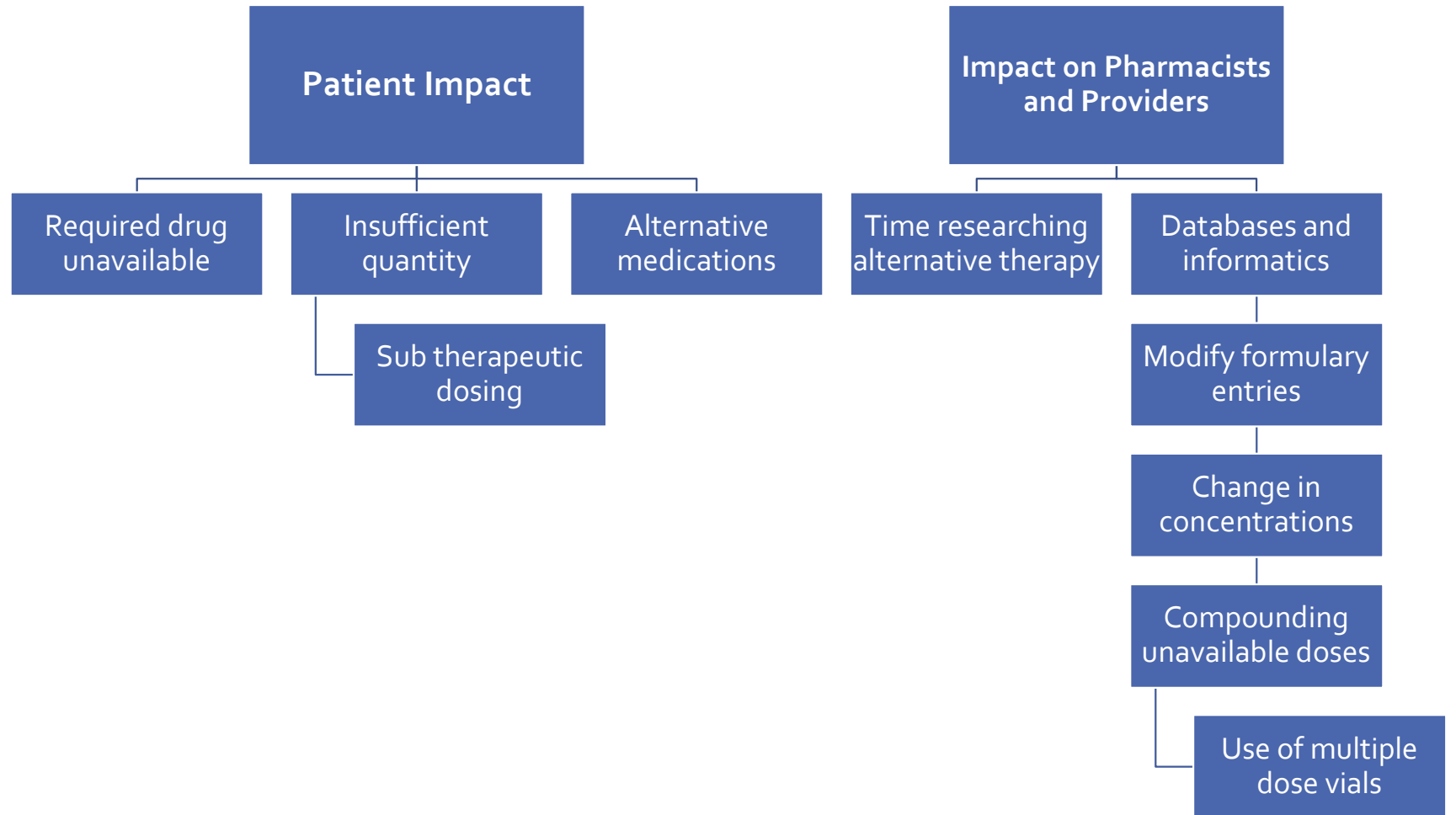
ASHP Framework

- Operational Assessment
 - Details and duration of shortage
 - Inventory on hand
- Therapeutic Assessment
 - Patient prioritization
 - Therapeutic alternatives
- Shortage impact analysis
 - Financial ramifications
- Inventory system changes
 - Stockpiling restraint
 - Purchasing for outside vendors/pharmacies and in-house compounding

Minimizing Impact on Patient Care

- Many of the drugs in short supply are basic products
- Shortages of these types of medications are having a significant effect on patient care
- Current shortages are effecting all areas of the hospital
 - Inpatient
 - Acute Care Clinics
 - Specialties
- Automation in hospitals may create additional burdens when an alternative product must be used:
 - Use of smart pumps
 - Labor-intensive process for changing a drug in the electronic health record (EHR)
 - Workflow changes within the pharmacy department

Impact on Patients and Healthcare Providers



Impact on Health Systems

- Drug shortages increase the financial burden on hospitals
- Maintaining an adequate supply of inventory means that pharmacies must:
 - Purchase greater quantities than needed, which:
 - Increases the chance of outdated inventory
 - Increases the cost of drugs
 - Buyers spend more time on drug shortage management
 - Increase time spent for pharmacists to review alternative therapies
 - Devote time to strategic planning and implementing shortage strategies

Pharmacy Technicians and Drug Shortages

Role of the Pharmacy Technician

- Under the guidance of a pharmacist – pharmacy technicians can take responsibility for the initial management of drug shortages
- The first step is understanding how and why drug shortages occur
- Early identification by pharmacy technicians of impending drug shortages:
 - Backorder notices
 - Partially filled orders
 - Specific strengths of drugs that may be difficult to find
- Collecting information from the manufacturer at the onset of a drug shortage can help with the evaluation of the impact that a particular shortage may have on an institution

Role of the Pharmacy Technician


- Pharmacy technicians have been instrumental in managing supply issues and monitoring shortages for availability
- When a shortage is discovered, technicians help identify inventory levels and predict how long these inventories can maintain supply
- Additionally, technicians are instrumental in identifying alternative sources, including direct supply, other facilities or pharmacies, and secondary wholesalers
- Many technician buyers have templates established within wholesaler accounts to ease the process of frequently ordering items on shortage and creating back orders

ASHP Strategic Planning Framework


Pharmacy technicians can assist pharmacists in managing drug shortages by performing operational assessments of drug products



Operational assessment

1. Validate details of shortage
 2. Determine stock on hand
 3. Determine supply from predetermined alternative sources
 4. Determine purchase history and/or true use history
 5. Estimate time to impact on the healthcare organization
 6. Determine supply of alternative drug products
- 

(Typically done by the pharmacy department)



Role of the Pharmacy Technician

- Technicians can also locate all nursing units with a drug shortage and move inventory to cover areas with more frequent dosing
- Communication to other health care professionals is essential
 - Technicians can help distribute the workload
 - Answer questions
 - Create and distribute updated lists of drug shortages
- Being proactive in monitoring shortages helps facilitate the planning process
- Online resources are available for technicians to stay up to date on drug shortages:
 - FDA Website
 - ASHP Website
 - Professional organizations – email updates to subscribers

Assessment Questions

Question #1

Which of the following is the best definition of a drug shortage provided by the FDA?

- A. When a drug is only available from two manufacturers
- B. Period of time when the demand for the drug exceeds the supply
- C. A lapse in production of an active pharmaceutical ingredient
- D. Inability to order medication from primary wholesaler

Question #2

All of the following can contribute to drug shortages, except:

- A. Natural disasters
- B. Lack of raw materials
- C. New generic drug distributor enters the market
- D. Discontinuation of drug manufacturing

Question #3

ASHP provides planning strategies for managing drug shortages to minimize the impact on patient care. One of these strategies is performing an operational assessment – which can be conducted by a pharmacy technician.

- True
- False

Question #4

Which of the following is NOT a role that may be performed by a pharmacy technician regarding drug shortages?

- A. Providing communication to other healthcare professionals
- B. Contacting the manufacturer for details regarding expected shortage duration
- C. Inventory management
- D. Determine and establish therapeutic alternatives

Question #5

Being proactive in monitoring drug shortages is crucial for the planning process and can be achieved by subscribing to online resources and email updates.

- True
- False

Evaluation

- To receive continuing education credit for this activity, complete the evaluation survey at :

<https://www.surveymonkey.com/r/BN9R7B9>

Password: 3ho4t

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