



FDA Drug Shortages Workshop

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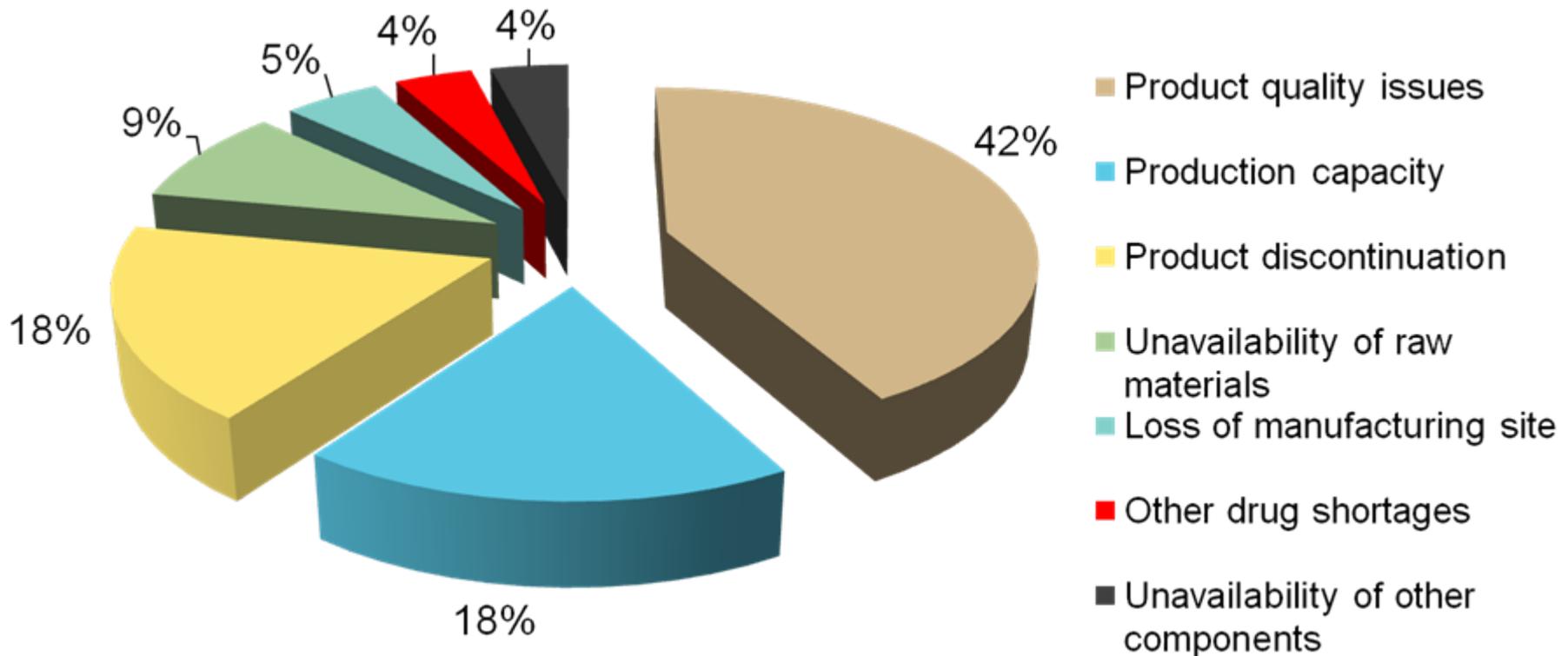
Urgent situation:

- Frequency, duration of drug shortages are at record levels.
- Patient care, patient safety are being negatively affected.
- Shortages are caused by *manufacturing* issues (raw materials, quality and regulatory issues, etc.).
- All stakeholders need to focus efforts on solutions that have the **most impact on patient care**.

Goal: Mitigate impact

- **Communication + coordination are key:** early-as-possible, consistent, accurate information about product shortages, from manufacturers and/or FDA.
- **Cardinal Health role:**
 - Dynamically allocate **available** product to providers;
 - Communicate available information to customers;
 - Protect supply chain integrity.

Reasons for drug shortages



Source: FDA Drug Shortages Program, Jan thru Oct 2010
Note: Information not reported as drug-specific

U.S. Pharmaceutical Supply Chain: Manufacturer, Distributor, Provider Roles



Manufacturers:

- 1,400+ manufacturers
- 50,000+ products

Role:

- Physically manufacture pharmaceutical products
- First to know of raw material shortages, quality and regulatory, other issues that impact supply.
- Most complete view of cause and duration of shortages

Cardinal Health:

- 22 distribution facilities
- 7.4 MM deliveries/year
- >80% of generic injectables sold to hospitals are governed by 'contract' price

Role:

- Just-in-time, 'next day' delivery of medications to points of care.
- Protect security and integrity of supply chain

Health Care Providers:

- 24,000 retail pharmacy locations
- 2,650 hospitals
- 4,000+ physician office and surgery center locations
- 150 mail order locations

Role:

Order, receive and dispense medication to patients.

Best-in-Class measures: Cardinal Health Suspicious Order Monitoring (for Controlled Substances); Cardinal Health Know Your Customer Sales Force Training; Cardinal Health Wholesaler Safe Practices Program

Enhanced measures: HDMA Distributor Guidelines; Authorized Distributor of Record

Licensing, Quality and Regulatory: State Board of Pharmacy, Drug Enforcement Administration Licenses, FDA manufacturing requirements

Drug Shortages: What we're doing to mitigate the impact

- **Work with manufacturers to get product availability information as soon as it available**, so we can immediately notify customers.
 - Scorecards that measure quality of communication
 - Regular communication, monthly reviews to discuss gaps
- **Daily updates to customers.**
- **Dynamic allocation system:** sophisticated process allocates product to customers based on past buying behaviors.
- **Make product available to customers as soon as we receive it.**
- **Manage inventory of alternate items** in anticipation of demand shifts.
- **Leverage National Logistics Center**, highly responsive distribution network to quickly get product to those in need.

Drug Shortages: What we're doing to mitigate the impact

Protect supply chain integrity:

- **Encourage providers to buy direct** from distributors who buy direct from manufacturers.
- **Only sell medications to entities** that have required licenses (State Boards of Pharmacy, DEA).
- Require health care providers to **confirm medications are for their own use to dispense or administer to patients.**
- Require all licensed wholesaler customers to **participate in Cardinal Health Wholesaler Safe Practices Program.**

Manufacturers and/or FDA to provide *faster, more accurate, consistent* information about shortage cause, duration.

FDA, AHRQ, ASHP, appropriate clinical organizations could identify appropriate clinical alternatives to products in short supply.

Early-as-possible communication

Supply Chain Integrity

Appropriately, immediately allocate available product to providers

Distributors should allocate product to providers in 'fairest' manner possible, based on past buying behaviors.

Encourage dialogue + coordination between FDA + Manufacturers.



Thank you!