Navigating the Pharmaceutical Supply Chain
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Introduction of Speakers

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Agenda

• Welcome
• Introduction and overview
  Greg Burel, Director, Division of the Strategic National Stockpile
• Interconnectedness of the pharmaceutical supply chain
  Erin Mullen, Community Pharmacist & Senior Consultant, Healthcare Ready
• Pharmaceutical supply chain logistics
  Erin Mullen, Community Pharmacist & Senior Consultant, Healthcare Ready
• Case study
  Emily Lord and Erin Mullen, Healthcare Ready
• Recap and closing
Objectives of this Session

• Describe the interconnected nature of the pharmaceutical supply chain.

• Understand some major pharmaceutical topics including third party logistics and just in time inventory.

• Understand the complexities of forecasting demand and allocation.
Interconnectedness of the Pharmaceutical Supply Chain
Pharmaceutical Supply Chain

- 9,309 FDA-permitted sites worldwide
- Drug Discovery
- Advanced Development
- Clinical Testing
- Manufacturing
- Distribution

- 35 full-service distributors
- 157 US-based distribution centers
- Handle ~80% prescription drug volume
- Value of distribution: $33.9B/year

- Over 60,000 community pharmacies
  - Chain 59%
  - Independent / Franchise 36%
  - Govt 3%
- 3.99B prescriptions filled in 2010 (12.9 scripts/person)
- Retail & long-term care =76% of all pharma sales
Pharmaceutical Supply Chain

Suppliers

Manufacturers
Distributors
Pharmacies
Patients

Consumers
Pharmaceutical Supply Chain

**Manufacturers**
- R&D
- Small molecule processing
- Large molecule production
- Clinical trials
- Medical device and supply production

**Distributors**

**Pharmacies**

**Patients**
Pharmaceutical Supply Chain

**Manufacturers**
- R&D
- Small molecule processing
- Large molecule production
- Clinical trials
- Medical device and supply production

**Distributors**
- Wholesalers
- 3PL

Pharmacies  Patients
Pharmaceutical Supply Chain

**Manufacturers**
- R&D
- Small molecule processing
- Large molecule production
- Clinical trials
- Medical device and supply production

**Distributors**
- Wholesalers
- 3PL

**Providers**
- Hospitals
- Pharmacies
- Clinics
- Community Health Centers

Patients
Pharmaceutical Model

Diagram showing the steps of the pharmaceutical model:
1. Raw Materials Suppliers
2. Raw Materials
3. Finished Product
4. Packaging
5. Distribution
6. Pfizer
7. Hospital Clinics/Pharmacies
8. 3rd Party
9. Dispensing

Steps:
- Raw Materials Sourcing
- Manufacturing
- Distribution and Dispensing Logistics
- Dispensing
Pharmaceutical Supply Chain Logistics
During Standard Operations and In Emergencies
During Normal Operations

- Place orders by around 8pm
- Deliveries typically arrive overnight or in the morning on weekdays
- Drug shortages
During an emergency

- If with notice, demand for multi-day delivery in advance
- Increased demand of the supply chain to provide resources for a response
- Possible manufacturing or distributing challenges
- Drug shortages
Other Considerations

3PL – *Third party logistics providers*

- Understanding their critical role in the last mile

**Forecasting demand**

- Adjusting to the changes in demand, based on various external factors

**Allocation**

- Major distributors and the impact of government policies on supply chain operations
• Customers span the healthcare system
  – Chain and independent drug stores
  – Mass merchandisers
  – Chain warehouses
  – Hospitals and HMOs
  – Clinics and long-term care
  – Mail order
• Third-party logistics (3PL)
  – Intermediaries in the supply chain
  – Local transport and deliveries
  – Critical and vulnerable
Limited supply (and sustained demand) causes the price to rise at the distribution level.

Manufacturing constraints impact the availability of product.

Forecasting Demand
Which May Lead to Allocation

“Big 3” (~90% of distributor sales in the U.S.)

- McKesson, AmeriSource Bergen, Cardinal Health

Managing allocation

- Each company has its own protocol to deal with potential shortages
What’s Different in an Emergency?

- Distributor Challenges
- Fuel and access
- Forecasting demand
- Allocation
Distributor Challenges

• Potential damage to facilities
• Issues with staff accessing warehouses
• Transportation halted during emergencies
Fuel and Access

• Facility generators can typically only run for a few days without refueling
• Access to sites for staff and supplies is a critical issue
• Lessons learned from Hurricane Sandy
Governments can decide to use stockpiled resources

It’s messy and is affected by a lot of factors including type of event and location

Allocation programs
Other Influences on Demand

What the federal agencies or states communicate to healthcare has an impact and could lead to spot shortages
Case Study – Doxycycline Shortage
Case Study

This case study will use doxycycline as an example and track during normal operations, and during a shortage.

• Overview:
  – Doxycycline is an option for intervention in response to anthrax exposure
  – Usually prescribed for multiple indications (Lyme disease, malaria, sexually transmitted infections, acne), also a medical countermeasure for anthrax exposure

Source: https://www.nlm.nih.gov/medlineplus/anthrax.html
Case Study

• Normal Supply Chain:

  Process of a pharmacy ordering a drug and receiving it through a wholesaler

  – 14 producers of the products
  – 5 dosing formulations (20 mg – 150 mg)
• Variance in availability will result in periodic shortages
  – (most recent: May 2015)

• Even without emergencies, there can be product shortages
Case Study – Stressed supply chain

• **Stressed Supply Chain:** Same process but let’s review the unique challenges that occur when drug shortage occurs.
Case Study – Stressed supply chain

• Scenario:
  – Doxycycline shortage of June 2013
  – Shortage created by production shortages
    • Interruptions of production at plants, reduced or halted production of doxycycline by multiple manufacturers as a result of raw materials shortages or other products

Case Study – Stressed supply chain

• Implications:
  – Prices for doxycycline surged in response to the shortage
    • $5 price for prescription increased to ~$160
  – Smaller pharmaceutical firms began to produce doxycycline, charging higher prices, to fill the gap
  – CDC recommendation to use doxycycline only when other interventions are not available

Case Study – Stressed supply chain

• Considerations:
  – Impact on patient care
    • Options for prescriptions
    • Cost for insured versus uninsured
  – Concern about supply available in case of a public health threat
  – Additional considerations

• Questions?

Case Study – Stressed supply chain

• Government Actions
  – CDC and SNS can provide resources or product
  – Concern from health agencies prompting outreach to supply chain, nonprofits, and state/federal/local government
  – Overall, there is little they can do to help in the beginning of a shortage
Case Study – Stressed supply chain

• Private Sector Actions
  – Increased production of product under shortage
  – Strategic allocation of product
  – Production of alternative countermeasures, pharmaceutical interventions
Case Study – Stressed supply chain

- Additional Resources
  - FDA shortage list
  - CDC shortage list
  - ASHP shortage list

Source: [http://www.cdc.gov/std/treatment/doxycyclineShortage.htm](http://www.cdc.gov/std/treatment/doxycyclineShortage.htm)
Discussion

Questions for all speakers
Future Webinars – Topics and Dates

- Partnering with the Pharmaceutical Supply Chain
  May 2016
- Principles of Inventory Management
  May 2016
- Principles of Pharmaceutical Regulation
  June 2016

Questions? Email – ContactUs@HealthcareReady.org
Thank You!

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