Drug Supply in the Time of COVID-19

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This webinar is being recorded.
Submit your questions using the chat function. It can be found at the left hand side of the window.
COVID-19 Discussion Groups

Register: https://rareaction.org/
NORD COVID-19 Resource Center

https://rarediseases.org/covid-19/

NORD COVID-19 Resources

- Upcoming Webinars
- On-Demand Videos
- On-Demand Webinars
- Advocacy Opportunities and Tools
- Disease-Specific Resources for Patients
- Informational Materials
- NORD COVID-19 Policy Statements
- Resources for Nonprofits

Additional COVID-19 Resources

* Information and links here are not necessarily endorsed by NORD but are shared for your consideration.

- Medical Coverage Information
- Official Resources
- Emergency Preparedness
- Mental Health Support
- On-Demand Videos
- On-Demand Webinars
- Online Events
- Resources for Nonprofits
- Stress Relief
Speakers

CAPT Paras Patel, RPh, MBA
Food and Drug Administration

Sheila Arquette, RPh
National Association of Specialty Pharmacy
Drug Supply in the Time of COVID-19

CAPT Paras M. Patel R.Ph., MBA
Drug Shortage Staff
Center for Drug Evaluation and Research
Food and Drug Administration
Disclosures
CAPT Paras M. Patel, R.Ph, MBA

Financial Relationships:
Employed at the Food and Drug Administration Drug Shortage Staff

Nonfinancial Relationships:
None
Drug Shortage Mission

DSS serves to support FDA’s mission of ensuring that safe and effective drugs are available to patients

- Facilitate temporary and long-term strategies to address shortages
- Coordinate for timely and comprehensive risk/benefit decisions
- Distribute information (web posting, professional organizations)
- Often working across suppliers, facilities, and issues - multiple moving parts, urgency
- Maintain availability while minimizing risk to patients

Brief History

- Part of Drug Shortage Program began in 1999 (FDA’s Center for Drug Evaluation & Research (CDER))
- 2011- President Obama signed Executive Order 13588-Reducing Prescription Drug Shortages
- 2012-Requirements to Industry For Early Notifications Under Section 506C of the FD&C Act
  Food and Drug Administration Safety and Innovation Act (FDASIA)
- CDER Drug Shortage Program (DSP) changed to Drug Shortage Staff (DSS) in 2012
- Moved under the CDER Office of the Center Director in 2014
**Manufacturers** are required to notify the FDA of a permanent discontinuance in the manufacture of a covered drug or an interruption of the manufacture of a covered drug that is likely to lead to a meaningful disruption in the supply of the drug in the United States.

- "At least 6 months in advance of the date of the permanent discontinuance or interruption in manufacturing; or, if 6 months’ advance notice is not possible no later than 5 business days after the...permanent discontinuance or interruption in manufacturing occurs”

- Not limited to medically necessary products

- Regardless of market share, or number of companies marketing, or wholesaler volumes

(From the Food and Drug Administration Safety and Innovation Act (FDASIA))
FDA Drug Shortage Staff - Key Communications

- International Authorities
- Other U.S. Agencies
- Importation Information
- Shortage Information

- Pharmacists
- Patients
- Providers
- Researchers
- FDA Shortages Staff
  - Notification of supply disruption; mitigation strategies and product information

- Manufacturers
- [Other FDA Offices]
Drug Supply Chain – 1st Tier

- **Supplier**
- **Manufacturer**
- **Wholesaler**
- **Pharmacy/Hospital**
- **Patient/Health Care Provider**

**Inventory/Production Data:** Voluntarily Supplied

**Supply Interruptions:** Required per FDASIA

- **Inventory/Supply Interruptions:** Voluntarily Supplied

**Sales/Market Share Data:** Reported to FDA via annual report and other channels

**Public Notifications:** FDA Drug Shortages email account
The Agency’s Approach to Prevention and Mitigation

- Drug shortages cannot always be prevented
  - Unanticipated events occur
    - Manufacturing breakdown, natural disaster (Hurricanes & Floods), Pandemic (COVID-19)
  - Sometimes alternate manufacturer may not make up production shortfall
  - If systemic issues present, the plant may have to close to repair
  - The FDA and the manufacturer can work together to encourage smart distribution (*allocation*)
Role of Industry to Help Prevent and Mitigate Drug Shortages

• Understand the frailties of their supply chain
• Communicate early about potential shortages
• Provide shortage information for posting on FDA website when a shortage is unavoidable
• Provide short term and long term plans for preventing and addressing shortages while maintaining and improving quality
• Work with FDA to minimize shutdowns or slowdowns that will lead to shortages
Coronavirus Disease 2019 (COVID-19)

Along with other federal, state, and local agencies and public health officials across the country, the FDA continues critical work to protect public health during the COVID-19 pandemic. See this “At-a-Glance” resource summarizing the FDA COVID-19 response.

Content current as of:
05/12/2020

Topic(s)
Emergencies

Health Topic(s)
Infectious Disease
Coronavirus
Coronavirus Disease (COVID-19): The FDA continues to take steps to monitor the supply chain. The Drug Shortage Staff within the FDA’s Center for Drug Evaluation and Research (CDER) has asked manufacturers to evaluate their entire supply chain, including active pharmaceutical ingredients, finished dose forms, and any components that may be impacted in any area of the supply chain due to the COVID-19 outbreak. For the latest information from the FDA on COVID-19 see our website at Coronavirus Disease 2019 (COVID-19).

To report a drug shortage please contact the CDER Drug Shortage Staff at: DRUGSHORTAGES@fda.hhs.gov.

Drug Shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Manufacturers provide FDA most drug shortage information, and the agency works closely with them to prevent or reduce the impact of shortages.

Shortage notifications and updates may be reported to FDA at drugsshortages@fda.hhs.gov.
Coronavirus Disease (COVID-19)

- https://www.fda.gov/drugs/drug-shortages/search-list-extended-use-dates-assist-drug-shortages
Contacts:

Current shortage information updated daily at: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

To contact DSS:
Email: drugshortages@fda.hhs.gov

FDA Drug Shortages Homepage:

Drug Shortage Mobile APP
References

- FDA Sixth Annual Report on Drug Shortages for Calendar Year 2018
  https://www.fda.gov/media/130561/download

- FDA Shortages Additional News And information
  https://www.fda.gov/drugs/drug-shortages/drug-shortages-additional-news-and-information

- Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 506C (21 USC 356c)

- Federal Register Final Rule, 80 FR 38915 (July 8, 2015), Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products.

- CDER MAPP 4190.1 Rev. 2, Drug Shortage Management (11/1995; Rev. 1, 9/2006; Rev. 2, 9/2014):

- Executive Order 13588 (October 31, 2011), Reducing Prescription Drug Shortages:

- FDA Strategic Plan for Preventing and Mitigating Drug Shortages:

- Letters of Non-Compliance with Notification Requirement:
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Specialty Pharmacy’s Response

Sheila Arquette, RPh
Executive Director
National Association of Specialty Pharmacy
The mission of NASP is to elevate the practice of specialty pharmacy by developing and promoting continuing professional education and certification of specialty pharmacists while advocating for public policies that ensure patients have appropriate access to specialty medications in tandem with critical services.
What is a Specialty Pharmacy?

Pharmacies that solely or largely provide only medications for people with serious health conditions requiring complex therapies

Most accredited by one or more independent third parties to ensure consistent quality of care

Specialty pharmacies:
Connect patients who are seriously ill with the medications that are prescribed for their conditions and provide high-touch patient care services
Support patients who are facing reimbursement challenges for these highly needed but costly medications
Goals of Specialty Pharmacies

• Ensure appropriate use of medications
• Maximize drug adherence
• Enhance patient satisfaction through direct interaction with healthcare professionals
• Minimize cost impact to patients
• Optimize pharmaceutical outcomes and delivery of information
Specialty Pharmacy was perfectly positioned to support the remote management of patients prior to the COVID-19 pandemic

- Established business model and infrastructure supports:
  - Centralized prescription fulfillment including dispensing and delivery
  - Remote patient and disease management
  - Patient centric care coordination involving all stakeholders

- A high performing SP operates at the intersection of the 5 Ps:
  - Patient
  - Prescriber
  - Payer
  - drug Pipeline
  - Pharmaceutical manufacturer
Keeping pharmacy staff healthy and safe was paramount to ensuring patients continued to receive their medications without interruption

- Immediate evaluation of pharmacy access points
  - Cleaning, disinfection, social distancing
  - Staggered shifts for onsite personnel limiting contact and mitigating risk
- Authorized personnel only
  - Mobilization of patient facing, call center staff to work from home to ensure pharmacy personnel who must be on site are kept healthy, safe and exposure risk mitigated
- Dispensing, shipping, and delivery redundancy
Communication is key to providing the calm reassurance our patients need during such a chaotic time.

- Medication and drug supply experts
- Increased focus on enhancing communication with:
  - Patients
  - Prescribers
  - Payers
  - Manufacturers
  - FDA, federal, state and local officials
Specialty Pharmacy Stakeholder Collaboration

Specialty pharmacy is working collaboratively with the broader pharmacy and supply chain community to ensure patients continue to receive their medications without interruption.

- Medication delivery
- Monitoring drug shortages/clinical trials

- Working with payers to obtain:
  - Early refills
  - 90-day supply of medications where appropriate
  - Prior authorization for new medications, continuation of authorizations for patients stable on therapy
NASP Response

NASP is working diligently to support our members’ needs:

• Education

• Resource Center [https://naspnet.org/covid-19-resources/](https://naspnet.org/covid-19-resources/)
  • Members taking care of Members

• Advocating for Pharmacy DIR reform

• Collaboration with the broader pharmacy community/associations/pharmaceutical supply and payment chain orgs to address and resolve issues

• Working with federal, state and local agencies to identify issues and develop actionable solutions
NASP Response

• Focus on connectivity, self care and mental health
• Looking to the future and using lessons learned to positively impact patient care
• We need YOU!
• Please visit NASPnet.org for more information
Question and Answer Session
Questions?

Submit your questions in the chat box.

Our presenters will answer them in the order in which they came in and based on relevance to the discussion.
Thank you.

Alone we are rare. Together we are strong.

rarediseases.org