Agenda

- Background and AHA Advocacy: Roslyne Schulman, Director, Policy

- FDA Update on Drug Shortages: CAPT Valerie Jensen R.Ph., Associate Director, Drug Shortage Staff, FDA, Center for Drug Evaluation and Research

- ASPR Healthcare and Public Health Sector Supply Chain Preparedness and Response: Laura Kwinn Wolf, Ph.D., Branch Chief, Critical Infrastructure Protection, ASPR, Office of Emergency Management
Shortages of Small-volume IV Solutions

AHA urges FDA and Congress to Act to Address Critical Drug Shortages

- Existing shortages of small-volume IV solutions
  - Made worse due to impact of Hurricane Maria on Puerto Rico’s drug manufacturing plants
- These shortages are quickly becoming a crisis and looming threat to the public’s health
- The AHA is urging FDA and Congress to take immediate action to expedite the resolution of these shortages

FDA Updates on Drug Shortages

CAPT Valerie Jensen RPh.
FDA Updates on Drug Shortages

- FDA's Drug Shortage Process and Effects of Notification
- Current shortages – hurricane update
- New initiatives at FDA and future of shortages – what’s still needed
FDA Drug Shortage Staff (DSS)

**Drug Shortage Staff:** The program office that is designated by FDA to oversee and facilitate the resolution of all drug shortage situations.

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

Manufacturers Report on Potential Impact to Supply

At the time of any change in manufacturing that may lead to a reduction in supply of a product*, e.g.:
- Plans for upgrade or remediation
- Manufacturing issues at CMO
- API batch failures
- Media fill failure

*Note, product refers to a specific strength, dosage form, and route of administration

**Best Practices**

“We have placed the following product(s) on hold pending an investigation. Due to the investigation being in progress and the completion date being not estimated at this time, we wanted to inform Drug Shortage of this potential for a supply interruption.”
Requirements to Industry For Early Notifications Under Section 506C of the FD&C Act (2012)

Manufacturers are required to notify the FDA of “a change in production that is reasonably likely to lead to a reduction in the supply” of a covered drug in the United States

- “At least 6 months in advance of…but in no case later than 5 business days after the…interruption in manufacturing occurs”
- Not limited to medically necessary products
- Regardless of market share, or number of companies marketing, or wholesaler volumes

FDA Drug Shortage Staff – Toolbox

If there is a critical shortage concern, then DSS can:

- Request expedited FDA review and inspection of all pending applications to prevent shortage or to assist with demand, as well as facilitate pre-submission advice
- Contact all manufacturers for status of supply, extent and timing for manufacturing capacity or constraints
- Inquire on allocation plans or emergency reserves
- Assist with import requests for ongoing marketed supply
- Coordinate with manufacturers in their efforts to address root cause or to minimize shutdowns or delays
- Prioritize drugs of critical patient need
- Coordinate on risk mitigation measures
- Facilitate consideration for regulatory discretion

Manufacturers coordinate with DSS in order to prevent, mitigate, and resolve potential and existing drug shortages
Impact of Early Notifications to the FDA

- Ongoing dialogue/work with industry – high numbers of prevented shortages continue (115 in 2016)
- New shortages have decreased, however there have been ongoing shortages that have been difficult to resolve.

FDA Drug Shortage Staff – Key Communications
Hurricane Impact

- Hurricane Maria affected multiple manufacturers in Puerto Rico – FDA working closely with the firms to mitigate shortage impact
- Baxter has experienced shortages related to Hurricane Maria and currently IV fluids (dextrose and saline) in multiple sized bags as well as amino acids are critical as well as several others - imports being initiated from 6 different Baxter sites, and FDA expediting review of applications for new suppliers, and working with other manufacturers to help resolve these shortages.

IV Fluids Shortage

- Began in 2014 – increased demand and tight capacity
- FDA expedited review of 2 new manufacturers Fresenius Kabi and Laboratorios Grifols
- B. Braun reported slowing of production in fall 2017 from their approved facility. Currently importing from a German facility.
- Baxter PR site impacted by Hurricane Maria – now back in production and imports continuing from 4 Baxter sites
- FDA will continue to monitor supplies and continue imports as long as they are needed to meet patient needs.
Opportunities and Challenges to Assist with Shortages

FDA will work closely with manufacturers to address problems
• We can advise, assist, and expedite, but the manufacturer must fix the problem

What we CAN require:
• Notification by manufacturers (FDASIA)
• Supply disruptions
• Delays
• Discontinuations
• Notification of manufacturing changes

What we CANNOT require:
• A company to make a drug
• A company to make more of a drug
• How much and to whom the drug is distributed

FDA Drug Shortage and Other Initiatives

• Establish the FDA Drug Shortage Assistance Award
• Drug Competition and Action Plan announced in June 2017 by Commissioner Scott Gottlieb
What’s still needed?

- Companies need to have a Drug Shortage Plan in place – build better inventories of finished product and raw materials and components, have a plan for when things fail.
- Redundancy in manufacturing and suppliers – encouraging industry to have “warm” lines and components and supplies at the ready for critical drugs.
- Better notifications - some firms still do not provide more than the minimum amount of information and provide it at the last possible minute.
- More capacity, additional manufacturers making critical drugs.

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THANK YOU!
References


Federal Register Final Rule, 80 FR 38915 (July 8, 2015), Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products. https://federalregister.gov/a/2015-16659. See also 21 CFR 310.306, 314.81, and 600.82.


Healthcare and Public Health Sector Supply Chain Preparedness and Response

Laura K. Wolf, Ph.D.
Healthcare and Public Health Sector Critical Infrastructure Partnership

- By providing a venue for public and private sector partners to collaborate, we
  - Promote risk management activities;
  - Share threat information;
  - Socialize best practices; and
  - Develop useful tools and policies;

...to mitigate impacts of disasters and enhance resilience of the entire health care system to minimize disruptions in care for all Americans

Resilient People. Healthy Communities. A Nation Prepared.
Healthcare and Public Health Sector Critical Infrastructure Partnership

2017-2018 Priorities
• Supply Chain
• Cybersecurity
• Risk Assessment
• Response/Exercises

Partnering to respond to evolving threats

Public Sector
FDA
VA
DoD
CDC
ASTHO
NACCHO

Private Sector
American Hospital Association
American Society of Health-System Pharmacists
Healthcare Distribution Management Association

Coordinating Groups
PHEMCE
Global Supply Network for Pandemic Preparedness and Response
All-Hazards Consortium

Resilient People. Healthy Communities. A Nation Prepared.
Role in Response

- CIP supports national ESF-8 response
  - Sits in HHS Secretary’s Operations Center
  - Sector-wide calls daily during events
  - Coordination with trade association partners
  - Outreach to affected organizations
  - Coordinated messaging across sector
  - Partner reach has expanded into the hundreds of thousands
- Coordinating with FEMA to support private sector

HHS/FEMA support to Puerto Rico

- CIP considers all healthcare industry and public health in response efforts, not just hospitals, and advocates for support
  - DHS/FEMA generally does not provide assistance for for-profit companies
  - For-profit companies are critical to Puerto Rico’s recovery and to national healthcare

- Partnered with FDA to prioritize available resources for manufacturing
- Ongoing challenges
  - Power restoration
  - Medical gas availability
Supply Chain Preparedness Activities

- Support to supply chain resilience more broadly
  - Working with government partners to identify additional authorities that can support FDA Drug Shortage Program efforts to
    - Prepare for;
    - Prevent; and
    - Respond to shortages
- American Society for Health-System Pharmacists and Association of State and Territorial Health Systems
  - Recommendations
- Private sector partners- engaging with industry to provide tools to better help them prepare for disasters

ASPR’s TRACIE

- ASPR TRACIE: asprtracie.hhs.gov
  - Technical Resources, Assistance Center, and Information Exchange
  - Wide variety of information resources
  - Drug Shortages page
    - https://asprtracie.hhs.gov/technical-resources/53/pharmacy/47#drug-shortages
Partnership Engagement

- Weekly Highlights Newsletter
- Innovation Seminar Series
- Bi-annual Public-Private Partnership Meetings
- Response Coordination
- Phe.gov (ASPR) twitter, facebook
- ASPR blog posts
- Response/incident communications
- Pilot: Podcast

Questions?

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