“You Don’t Have...What?”
Drug Shortage in the Hospital Setting

Rob Wills, Pharm.D., BCPS
Sr Clinical Manager of Pharmacy
St. Luke’s Boise & Meridian Medical Centers
March 2016

Objectives
• Identify at least two potential causes of drug shortages.
• Discuss at least two potential strategies to manage drug shortages in the hospital setting.
• Identify two resources that can notify them of current medication shortages.

Disclosures
• Nothing to disclose

Drug Shortages Forcing Hard Decisions on Rationing Treatments
Such shortages are the new normal in American medicine. But the rationing that results has been largely hidden from patients and the public.

“We essentially did military-style triage,”

• Dr. Fitzsimons restricts the limited supply to patients at the highest risk of bleeding complications.


http://www.gettyimages.com
ER drug shortages for life-saving medications on the rise

Monday, January 25, 2016 | By Zack Budryk

- Drug shortages in hospital emergency departments have worsened, increasing more than 400 percent since 2008, according to a study published in Academic Emergency Medicine.
- Nearly 1,800 drug shortages were reported between 2001 and 2014.
- More than half of the shortages involved lifesaving drugs.
- More than 1 in 3 involved drugs used in emergency rooms.
- The drugs most at risk for a shortage:
  - Infectious diseases
  - Poisoning
  - Severe pain
  - Although shortages dropped between 2002 and 2007, they spiked 435 percent from 2008 to 2014.

Table 1: Comorbidities of Drugs on Shortage used in Emergency Medicine and High-acute Varsity Non-High-acuity Drugs Januaries 2001-March 2016

<table>
<thead>
<tr>
<th>Drug Category</th>
<th>Number of Shortages</th>
<th>High-acute</th>
<th>Low-acute</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious disease</td>
<td>1,342</td>
<td>960</td>
<td>938</td>
<td>3,248</td>
</tr>
<tr>
<td>Poisoning</td>
<td>1,076</td>
<td>752</td>
<td>757</td>
<td>1,588</td>
</tr>
<tr>
<td>Severe pain</td>
<td>1,000</td>
<td>625</td>
<td>612</td>
<td>1,237</td>
</tr>
<tr>
<td>Total</td>
<td>3,428</td>
<td>2,337</td>
<td>2,207</td>
<td>7,972</td>
</tr>
</tbody>
</table>

Antibiotics

- Cefazolin
- Cefotetan
- Zosyn
- Meropenem
- Vancomycin
- Unasyn

Oncology

- Drug Shortage Occurs
  - First seek different formulation
    - Concerns over potential errors in dosing and admin
    - Different concentrations
    - Different packaging
    - Different storage requirements, etc.
  - Then seek alternative med
    - Possibly older line of therapy
    - Increase adverse events
    - Drug interactions
    - Decreased efficacy
    - Worst case scenario
      - There are no alternatives
      - Result is to triage patients to determine who gets meds


Young & Old

- “Two kids in front of you, you only have enough for one. How do you choose?”
  - DR. YORAM UNGURU

Large & Small

- Obese patients, who researchers found needed up to three times the amount of an antibiotic before surgery than average-size patients, were given only the standard dose at the Cleveland hospital until a shortage subsided.
Why are we talking about this?

1. Drug product shortages can adversely affect drug therapy
2. Compromise or delay medical procedures
3. And can result in medication errors
4. Affects bottom line – budgeting med costs
5. And...can cause spontaneous yelling by pharmacists, pharmacy buyers, clinical managers
6. And...can cause hypertension and hair loss in managers
7. And...

What do these numbers mean?

- The rate of new shortages has decreased
- Long-term active and ongoing shortages are resolving
- Shortages of basics like antibiotics, cardiovascular drugs, electrolytes, and diagnostic dyes still impact large numbers of clinicians and patients

http://www.gao.gov/products/GAO-14-194

Why are we talking about this?

1. Drug product shortages can adversely affect drug therapy
2. Compromise or delay medical procedures
3. And can result in medication errors
4. Affects bottom line – budgeting med costs
5. And...can cause spontaneous yelling by pharmacists, pharmacy buyers, clinical managers
6. And...can cause hypertension and hair loss in managers
7. And...

Slowing Progress

Drug shortage slows clinical trials
US researchers faced with cancer-drug shortfall struggle to keep trials on track.

A shortage of chemotherapy drugs such as doxorubicin is causing problems for clinical trials.

Who gets it?

- Some institutions prioritize based on age; others do not.
- Marc Earl, a Cleveland Clinic pharmacist, said children were not favored over adults during chemotherapy shortages.

Playing the shortage game

- "We do play the pediatric card for sure," said Alix Dabb, a pharmacy specialist in pediatric oncology at Johns Hopkins Hospital.

Pharmacist Gatekeeper

Chris Snyder, a pharmacist at the Cleveland Clinic, tracks a list of shortages that included more than 75 drugs the first week of January.

Learning Assessment Questions

1. Which of the following are potential causes of drug shortages?
   a) Voluntary recall
   b) Change in guidelines that cause an unexpected increased demand
   c) Raw & Bulk material unavailability
   d) Industry consolidations
   e) Both a and c are potential causes
   f) All of the above are potential causes of drug shortages

Answer: F. All of the above
Contributing Factors

- Can be a result of one or multiple factors in a supply chain
- Supply Chain includes
  - sources of raw materials
  - manufacturers
  - regulators
  - wholesalers or distributors
  - Natural disasters
  - prime vendors
  - group purchasing organizations
  - And end-user health care systems

Raw & Bulk Material Issues

- Unavailability of raw and bulk material
- Suboptimal quality of raw materials
- Raw material shortage can result from a number of factors
  - including a sole source manufacturer that ceases operation,
  - suboptimal quality of the raw material
  - wars that disrupts importation
  - In 2010, nearly half of drug shortages resulted from quality issues of raw materials
  - including impurities
  - microbial contamination
  - chemical instability
  - 80% of the raw materials come from foreign markets
  - The market for Chinese active pharmaceutical ingredients (APIs) was reduced by nearly 50% in 2010,
  - Heparin contamination in 2008
  - Especially problematic when a major or sole-source supplier ceases production
    - Downstream effects of all the producers of finished products

Manufacturing Difficulties and Regulatory Issues

Contributing factors may include:
- Old or antiquated manufacturing equipment
- Shift of resources by the manufacturer from maintenance of equipment and facilities to research and development
- Loss of experts or those experienced enough to maintain GMPs as a result of company mergers or retirements
- cGMP-related problems with subcontractors who supply products to multiple pharmaceutical manufacturers
- And limited FDA resources for timely inspections of manufacturing sites.
### Manufacturing Difficulties and Regulatory Issues

- FDA and compliance with GMPs
- Lengthy process to get out of compliance
- Some manufacturers decide just to close shop
- FDA wants to help the public...protect the public...so
- FDA actions are evaluated by FDA's Center for Drug Evaluation and Research (CDER) drug shortage coordinator
  - Want to determine if the action might create a drug shortage
  - If corrective action involves a medically necessary product
    - FDA will help the manufacturer get back up and running
    - OR permit a foreign manufacturer to supply product

### Change in Product

- In formulation
  - MDIs to Powder to...Elipta and Respimat, oh my!
  - Another is the transition from albuterol metered-dose inhalers (MDIs) containing chlorofluorocarbons to MDIs containing hydrofluoroalkanes in 2006

- In Manufacturer
  - Yes, Hospira/Pfizer we are looking at you!
    - The great merger of Pfizer and Hospira has seen product availability issues.
  - Others?

### Recalls

- Generally occur due to a lapse or issue with manufacturing
- Usually affect specific lots but could be of significant scale
- Particularly significant for sole sourced products
- Or if this manufacturer’s product really dominates the market
  - Switching to alternatives can work but typically their production is not on the scale to fulfill the need
- Can cause ethical problem if the recalled product is all we have

### Manufacturer's Product Decisions and Economics

- Decisions based on a variety of factors
  - Availability of generic products
  - Market size
  - Patent expiration
  - Drug-approval status
  - Regulatory compliance requirements
  - Anticipated clinical demand
  - Management of new products
    - Stopping or reducing production for new or other agents
    - Manufacturer decides to stop permanently
    - Hits hard for sole sourced items
  - FDA application process

### Industry Consolidations

- Mergers
  - Yes, Hospira/Pfizer we are still watching
  - Teva and Allergan
  - Mylan (Merk & Abbot)
  - Pharma companies believe that acquisitions are really the only way to see continued growth in revenues
    - Cheaper than creating a blockbuster medication!
  - Moving plant operations to another facility
  - Waiting on a new facility to come online

### Distribution & Allocations

- Manufacturers bypass the typically wholesaler pathway and often allow for allocations
  - Reduces hoarding by wholesalers and systems
  - Problems arise when allocation is not available
    - Promises, promises
  - Specialty distribution
  - Can cause delays
  - Maybe not seen as often since this is usually with newer brand name meds that haven’t seen the shortages as of late like generic products
Inventory Practices

- **The Lean Journey OR ‘Just In Time’ inventory**
  - Next day delivery from wholesalers
  - Allowed hospitals to keep inventory levels down
  - Increases risk if shortage occurs it can affect a Hospital or Health System very rapidly
  - Reduces the cost of inventory on hand and optimizes cash flow
  - Occurs not just with hospitals but with all points in the supply chain
  - Distributors
  - Manufacturers
  - Stockpiling following rumors of shortages
  - Rural hospitals
  - Can’t borrow from neighbors
  - More isolated from alternative supply

Risk involved if all hospitals in an area use the same distributor

- **Some shortages are wholesaler specific**
  - Contracts
  - GPOs
  - etc.

Natural Disasters

- Blocking Supply Routes
  - Salt Lake snowed in
  - Ice
  - Bad weather in other parts of country where product is located
  - Damage to manufacturing facility
  - Tornadoes
  - Hurricanes, etc
  - 1998 – Hurricane George caused damage to manufacturing plants in Puerto Rico
  - 2005 – Areas affected by Hurricanes Katrina and Rita found themselves in acute need of more medications without the ability to obtain them

Low Margin...for error

- Majority of drugs experiencing shortage from 2001 – 2014 were injectable drugs
  - Generic sterile injectable drugs
  - WHY?
  - Low reimbursement rates from Medicare Part B
  - Initiated in the Medicare Modernization Act of 2003
  - Commonly referred to as “ASP [average sales price] plus 6%”
  - Caps Medicare reimbursement to hospital outpatient clinics and individual physicians at 6% over the average sales price of the drug.
  - Since generic sterile injectables are already priced very low, the profit margin remains low
  - Plus 6-month lag between manufacturers’ submission of ASP data and when changes in sales prices are reflected in reimbursement
  - It is difficult for manufacturers to raise their prices more than 6% in any 6-month period. Even though this reimbursement policy
  - Doesn’t directly apply to the inpatient setting but indirectly affects supply overall!

Low Revenue → Little Investment

- The constant drive to lower costs leaves little room for investment in manufacturing facilities
  - Many manufacturers have dropped out of the market
  - Number of manufacturers becoming very small
  - Added Factor = Lack of “Capacity”
  - Another line or facility would not be available to manufacture the same product if active lines or facilities were deemed inoperable
  - Shortages concentrated in drugs where the volume of sales and drug prices were declining in years preceding the shortage
  - Suggests that manufacturers may be diverting resources to more profitable product lines

Demand & Practice Changes

- Occurs when a new indication is approved for an existing drug product
  - When usage patterns change in response to new therapeutic guidelines
  - When a substantial disease outbreak occurs
  - Or when unpredictable factors influence demand
  - Examples:
  - When the CDC recommended annual influenza vaccination for children age 6-59 months in 2006
  - Only one product had FDA-approved labeling for use in children 6-23 months old
  - HD Flu Vaccine
  - Shortages may be prolonged if there is significant lag time due to availability of raw materials

Demand & Practice Changes

- **Longitudinal Trends in U.S. Drug Shortages for Medications Used in Emergency Departments (2001-2010)**
Drug Shortages &
Increasing Labor Costs

• To manage drug shortages
  • All hands on deck – significant use of resources
  • A survey conducted by the University of Michigan and the American Society of Health-System Pharmacists (ASHP) indicated that drug shortages create cumulative estimated labor costs of approximately $216 million annually for hospitals nationwide
  • Not just to identify alternatives
    • All steps needed to add/change to alternative product
      - Adding to pharmacy database
      - Ordering in new product
      - Setting up smart pump library
      - Cost info
      - Safety processes
      - Nurse education
      - Pharmacy education
      - Prescriber education

A survey conducted by the University of Michigan and the American Society of Health-System Pharmacists (ASHP) indicated that drug shortages create cumulative estimated labor costs of approximately $216 million annually for hospitals nationwide.

The Ripple Effects

• Compounding
• Gray Markets
• Labor Costs
• Patient Care

Compounding pharmacies have also pursued the production of drugs that are in short supply

Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards

Sources of raw materials used by compounding pharmacies have been questioned

And apparent lapses in quality control have resulted in serious patient injury, including death.
Gray Market Supply.gov

- Most drugs enter the gray market through pharmacies.
- These pharmacies usually buy drugs from legitimate Authorized Distributors of Record (ADR), including AmerisourceBergen, Cardinal Health, McKesson, and H.D. Smith.
- While some buyers are "fake pharmacies," others appear to be legitimate purchasers, such as Walgreens Infusion Services and a Medicine Shoppe franchisee.
- Multiple secondary wholesalers handle gray market products, adding huge mark-ups along the supply chain.

Learning Assessment Questions

3. True or False: In 2012 the president signed an executive order requiring manufacturers to notify the FDA of impending production disruptions in certain prescription medications.
   a) True
   b) False

   Answer: True

FDAISIA

- FDA Safety & Innovation Act (July 2012)
  1. Manufacturers must give 6 month advance notice of temporary or permanent product discontinuations/shortages for all drugs and biologics
  2. Approves user fees for generic drugs
  3. Also gave FDA authority to expedite review of products and new drug applications
  4. Requires the FDA to notify DEA of controlled substance shortages and request the DEA to increase quotas
  5. Allows for the repackaging of drugs in short supply for use within the same health system without having to register as a manufacturer

Gov Steps In...

- The justification for FDAISIA
- FDA’s bold moves to mitigate shortages
  - Determine if other manufacturers are willing and able to increase production
  - Expedite inspections and reviews of submissions
  - Exercise temporary enforcement discretion for new sources of medically necessary drugs
  - Work with the manufacturer to ensure adequate investigation into the root cause of the shortage
  - Review possible risk mitigation measures for remaining inventory
Track & Trace Legislation

- H.R. 3204, the Drug Quality and Security Act, was approved by a voice vote without amendments following House passage in late September 2013.
- H.R. 3204 will immediately go into effect in 2015.
- The legislation sets a number of important deadlines for manufacturers.
- By Jan. 1, 2015, all finished forms of prescription drugs must include a lot-level transaction history that documents each step a product takes from manufacturer to final sale. Manufacturers face the same deadline for establishing a system to quarantine, investigate and validate via the history record a product suspected of being counterfeit, adulterated or stolen.
- The legislation sets a number of important deadlines for manufacturers.
- Ten years after enactment, manufacturers must develop an electronic traceability system that history that documents each step a product takes from manufacturer to final sale.
- By January 1, 2015, dispensers (primarily pharmacies) must establish systems to obtain critical supplies of prescription drugs and use them to track and trace information.
- The legislation sets a number of important deadlines for manufacturers.
- All of the above
- F. All of the above

Supply Chain

Managing Shortages

Learning Assessment Questions

2. Which of the following are potential strategies for managing drug shortages?

a) Auto substitution to equivalent or alternative agent
b) Partnering with outside health-systems to obtain critical supplies
c) Implementing conservation strategies for select patient groups in critical need of the medication
d) Developing strong communication pathways to connect with prescribers and other healthcare team members regarding the shortage and the alternatives
e) Both B & C are correct
f) All of the above

January 1st, 2015

- By January 1, 2015, dispensers (primarily pharmacies) must establish systems for verification and handling of suspect or illegitimate product
- The verification requirements include quarantine and investigation of suspect product to determine if it is illegitimate, and notification of FDA and immediate trading partners if illegitimate product is found.
- Also by January 1, 2015, dispensers must confirm that trading partners (manufacturers, repackers, wholesale distributors, dispensers, and third-party logistics providers) are authorized, as defined by the Food, Drug & Cosmetic Act. FDA suggests checking with trading partners directly to confirm they are authorized, or checking the agency’s drug establishment registration database or the respective state authority to confirm licensure.
- By July 1, 2015, dispensers must be able to provide lot-level product tracing information—namely, transaction information, history, and statement—for 6 years. Such information may be requested by FDA or an appropriate state regulatory authority. (By January 1, 2015, manufacturers, repackers, and wholesale distributors must provide lot-level product tracing information.) FDA published a related draft guidance in November 2014.

Phased Approach

Answer: F. All of the above
Phased Approach

- Drug Shortage Identification
  - 9/10th of the battle
  - Knowledge is key

WARNING “Drug Shortage Identified”

- WHAT’S YOUR SYSTEM?
  - Pharmacy buyers
  - Wholesaler alert
  - Backorders
  - Drug Reps
    - Hospira, Baxter
  - GPO
    - VHA, HealthTrust
  - ASHP
    - University of Utah
  - List serves
    - Lipids

Therapeutic Assessment

- AKA Clinical Assessment
- Typically done by a pharmacist
- Identify primary patient population affected
- Identify therapeutic alternatives
- What’s the impact?
  - Critical med
  - Are there alternatives?

Clinical Assessment

- Time to Panic?
- What if alternative is gone?
- In many cases the first 24 to 48 hours are crucial
- Caution – don’t become too trigger happy

Operational Assessment

- Validate details of shortage
- Determine stock on hand
- Determine supply from predetermined alternative sources
- Determine purchase history and/or current usage at sites
- Estimate time to impact on health system
- Determine supply of alternative drug products

Utilization & Where?

- Utilized in Key area
- Utilized by certain Group
- One physician?
- Procedural?
Critical drug shortage: Olanzapine injection

November 21, 2014

Definition
Olanzapine injection 20 mg/mL is a racemic raclopride with an estimated release date in early December 2014.

Background
Olanzapine injection is an intramuscular antipsychotic that is indicated for the treatment of acute psychosis and agitation in patients with schizophrenia or bipolar mania. It is also often utilized in the inpatient setting of acute agitation.

Assessment
A shortage of olanzapine injection may be temporarily available prior to its release date. There are currently two alternative short-acting intramuscular antipsychotics available for use in patients with acute agitation: aripiprazole and ziprasidone. These agents are not long-acting typical antipsychotics but are not recommended for the treatment of acute agitation due to its severe adverse effect profile. Additionally, haloperidol injection is a typical antipsychotic available for the management of acute agitation and psychosis. The table below provides dosing information and additional considerations.

Recommendations

<table>
<thead>
<tr>
<th>Alternative Agent</th>
<th>Therapeutic Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aripiprazole</td>
<td>Short-acting atypical antipsychotic</td>
</tr>
<tr>
<td>Ziprasidone</td>
<td>Short-acting atypical antipsychotic</td>
</tr>
<tr>
<td>Haloperidol</td>
<td>Short-acting typical antipsychotic</td>
</tr>
</tbody>
</table>

During the short-term shortage, it is strongly recommended that olanzapine injection is reserved for use in patients with acute agitation or patients with schizophrenia or bipolar disorder. During the shortage period, if a short-acting antipsychotic is warranted, prescribers should select an alternative agent (i.e., aripiprazole or ziprasidone) with caution, given the associated risk to benefit ratio. 

<table>
<thead>
<tr>
<th>NDC</th>
<th>Description</th>
<th>Next Release</th>
<th>Total Qty</th>
<th>Qty On Hand</th>
<th>Days On Hand</th>
<th>Expected Run Out Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5037</td>
<td>CEFAZOL DUPLEX INJ 2GM BRAU x 24 MFR Allocating</td>
<td>2400</td>
<td>1000</td>
<td>1272</td>
<td>13</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>4204</td>
<td>CEFOTETAN DEXT INJ 2GM BRAU x 24 MFR Allocation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>798</td>
<td>EPINEPH 1MG/10ML SYR IMS X 10 MFR Allocation</td>
<td>115</td>
<td>40</td>
<td>85</td>
<td>10</td>
<td>22</td>
<td></td>
</tr>
<tr>
<td>720</td>
<td>POT CHLOR 15% (2MEQ/ML) 250ML BULK BOTTLE B Braun</td>
<td>41</td>
<td>14</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>320</td>
<td>POTASSIUM CL 2 MEQ/ML VIAL 20 ml Late Feb</td>
<td>300</td>
<td>100</td>
<td>150</td>
<td>10</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>1539</td>
<td>SODIUM CHLORIDE 4 MEQ/ML 30ML Vial x 25</td>
<td>308</td>
<td>125</td>
<td>22</td>
<td>12</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>219</td>
<td>SOLU-MEDROL A-O-V 125MG 2ML</td>
<td>675</td>
<td>100</td>
<td>75</td>
<td>4</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>218</td>
<td>SOLU-MEDROL A-O-V 40MG 1ML x 25</td>
<td>238</td>
<td>140</td>
<td>150</td>
<td>18</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>2492</td>
<td>ZOSYN (PIPER/TAZ) INJ ADV 4.5G HW 10</td>
<td>1,940</td>
<td>500</td>
<td>200</td>
<td>8</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>2484</td>
<td>ZOSYN (PIPERACIL-TAZOBACT) VL 4.5GM x 10</td>
<td>1,940</td>
<td>500</td>
<td>200</td>
<td>8</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>
ASHP Guidance for Purchasing Drug Products in Short Supply

1. Each health system must determine its philosophy on purchasing drugs from
   • the gray market
   • compounding pharmacies and on compounding agents in-house
2. These decisions should be made before the pressure and emotion of a specific shortage occur.
3. Each option and its potential effect on patient risk should be evaluated.
4. Nontraditional drug product sources (e.g., secondary wholesalers) have extremely limited supplies, and the quality of these products may be questionable, as the provenance of the medication may be unknown.

A consequence of some drug shortages is that product becomes available from secondary sources at sometimes drastically different price levels.

ASHP recommends that health systems verify that a wholesaler is licensed to distribute products in their state prior to purchasing drug products from noncontracted wholesalers.

Information about each state licensing entity is available from
   • Health systems should also consider requesting pedigree or other tracking information before purchasing products in short supply.

Sample Drug Shortage Monograph

- Last updated
- Tested by manufacturer
- Additional information
- Reference text
- Other issued products

There's a drug shortage. I'm thinking of replacing your mesd with eight hours a day before & after meals!

http://infusionnurse.files.wordpress.com/2010/09/drugcartoon.jpg
Contracting the FDA (CDER) and ASHP Drug Shortage Websites: What are the differences?

<table>
<thead>
<tr>
<th>FDA</th>
<th>ASHP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Provides information obtained from manufacturers about current shortages, estimated duration, and determinations and provides information about ORs and other stakeholders’ roles in resolving and preventing shortages.</td>
</tr>
<tr>
<td><strong>Audience</strong></td>
<td>Healthcare professionals.</td>
</tr>
<tr>
<td><strong>Scope of shortage list</strong></td>
<td>All drugs are listed but are considered to be a national shortage by FDA. A shortage is considered to end on the period of time when the demand for the drug within the United States exceeds the supply of the drug. Note: A separate <strong>Drugs in Short Supply</strong> list is maintained by the Center for Drug Evaluation and Research (CDER).</td>
</tr>
<tr>
<td><strong>Source of shortage reports</strong></td>
<td>Manufacturers submit all reports on shortages and voluntarily provide updates. Reports are also entered from the FDA’s Drug Shortage Database through the Drug Shortage Reporting System (DSERS).</td>
</tr>
<tr>
<td><strong>Credit for inclusion on list</strong></td>
<td>Manufacturers cannot meet current market demand for the drug.</td>
</tr>
<tr>
<td><strong>Coping with/for national shortage</strong></td>
<td>FDA-licensed manufacturers are in production and able to meet demand.</td>
</tr>
<tr>
<td><strong>Reason for shortage</strong></td>
<td>Provided by manufacturers using reasons required by legislation.</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Updated daily, list of available products, modifications for patient care and safety, and shortage management strategies.</td>
</tr>
</tbody>
</table>

ASHP’s Drug Shortages Resource Center Overview

- Part of ASHP’s larger strategy to address drug shortages since 2001.
- **Purpose:** to collect and share timely, verified information about products in shortage with practitioners, administrators and regulators, and patients and caregivers.

**Shortage Lists**

Shortages are organized in lists for ease of use:

- **Current Shortages** – a product in shortage now
- **Drugs No Longer Available** – products discontinued in the U.S.
- **No Commercially Available Drug Preparations** – products in severe shortage
- **Resolved Shortages** – all products are back in stock (or discontinued)

**Drug Shortage Guidelines and Resources**

The Guidelines and Resources section collects guidelines, best practices, research, analysis, and tools to help practitioners understand and manage drug shortages.