

Drug Shortage Update Current Status & Significant Trends

Erin R. Fox, PharmD

Manager, Drug Information Service University
of Utah Hospitals & Clinics

Associate Professor (Adjunct),

Department of Pharmacotherapy, University
of Utah College of Pharmacy



Disclosure Statement

- I currently direct the University of Utah Drug Information Service. The University of Utah Drug Information Service receives a portion of the funding for our drug shortage work from Novation, LLC.



Shortages and University of Utah Drug Information Service

- UU DIS provides drug shortage content to Novation and ASHP
- Public website at www.ashp.org/shortage
 - Partners since 2001
 - Receive voluntary reports submitted to ASHP and Novation
 - Collaboration is key - FDA, ASHP, Novation, UU DIS



Shortage Report Process



- Generates email to UUDIS, ASHP, Novation and FDA



- Research availability at all manufacturers
- Share information

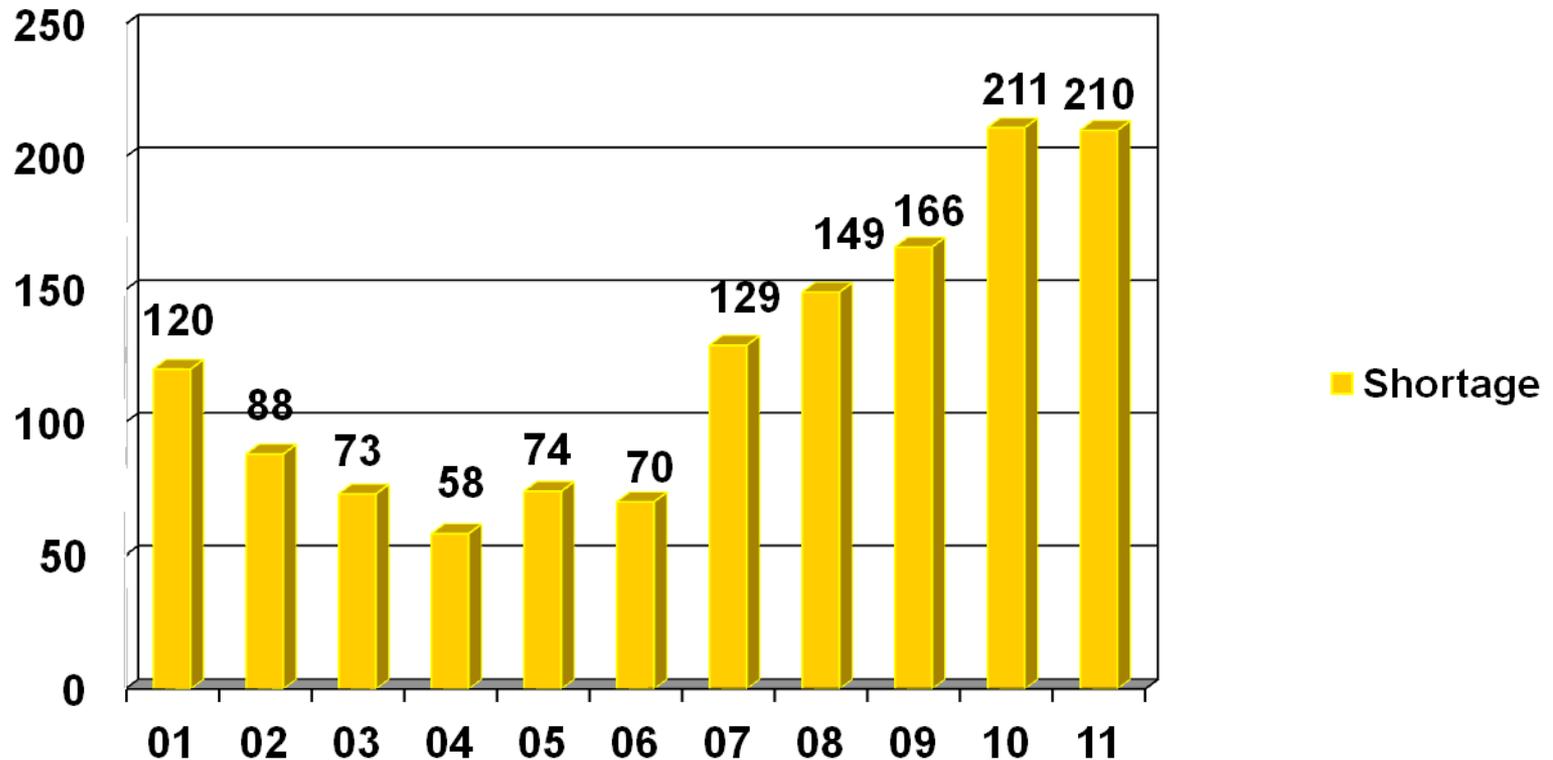


- Daily updates
- Alternatives when applicable



National Drug Shortages

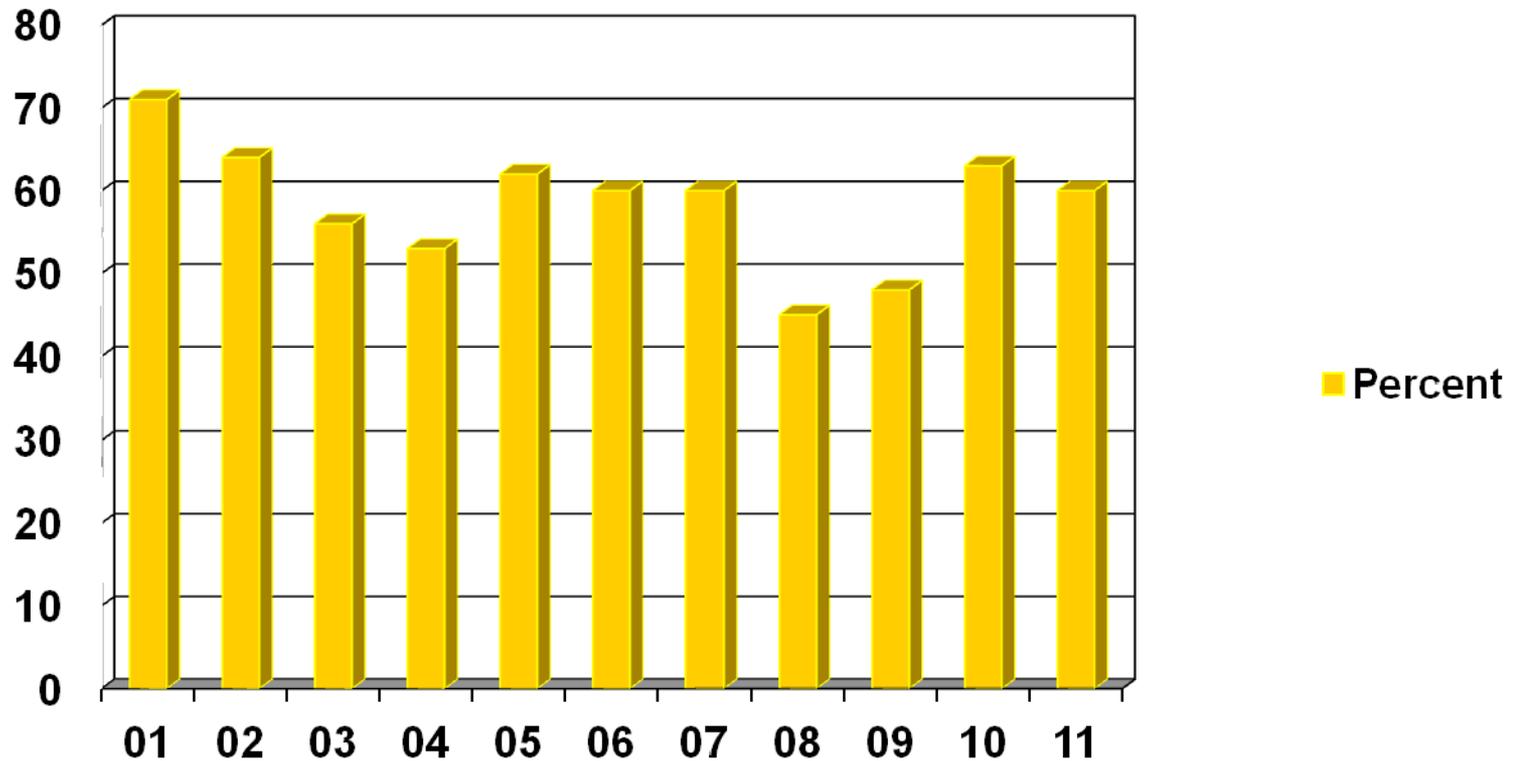
January 2001 to September 15, 2011



Each column represents the # of new shortages identified during that year
University of Utah Drug Information Service



Percent Parenteral Drug Shortages January 2001 to September 9, 2011



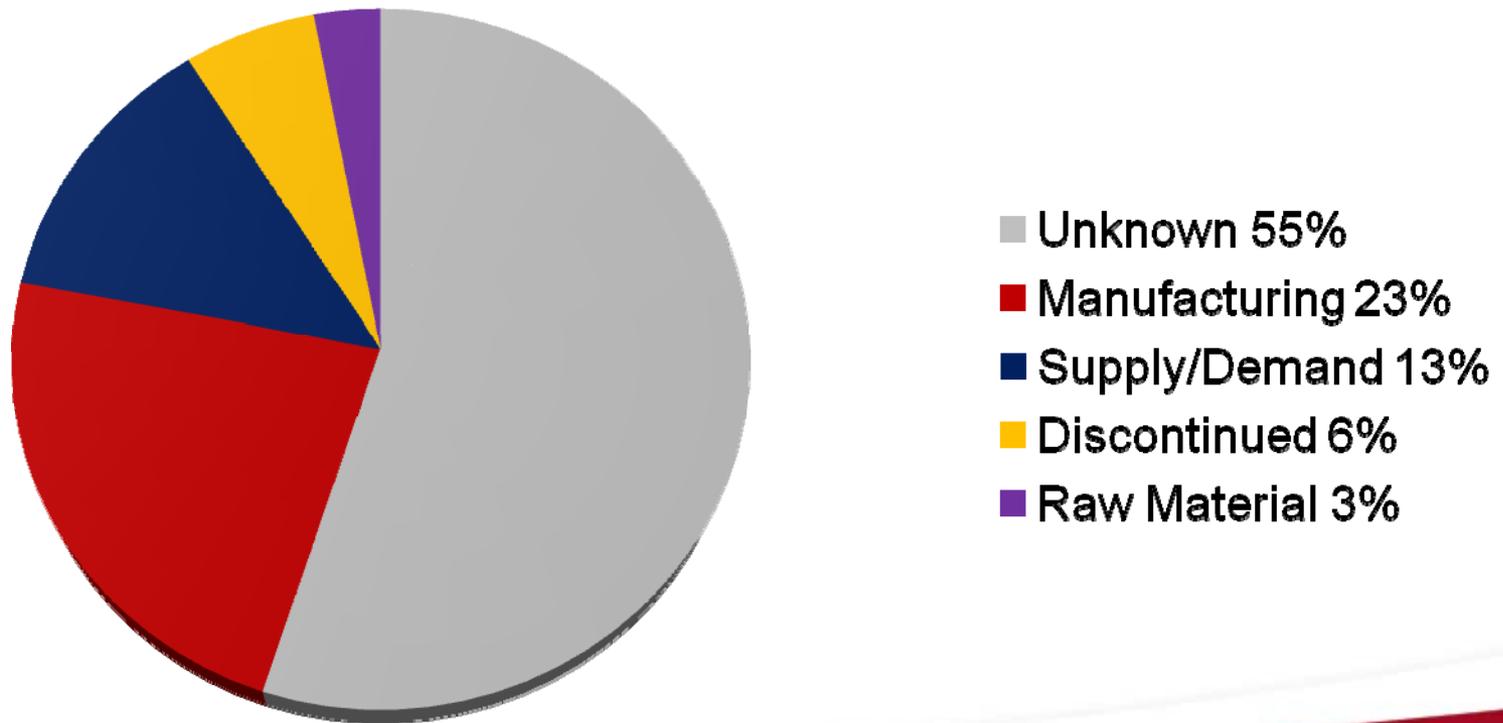
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Reasons for Shortages – 2011 (9/15/11)

**Reason Determined by University of Utah Drug
Information During Shortage Investigation**

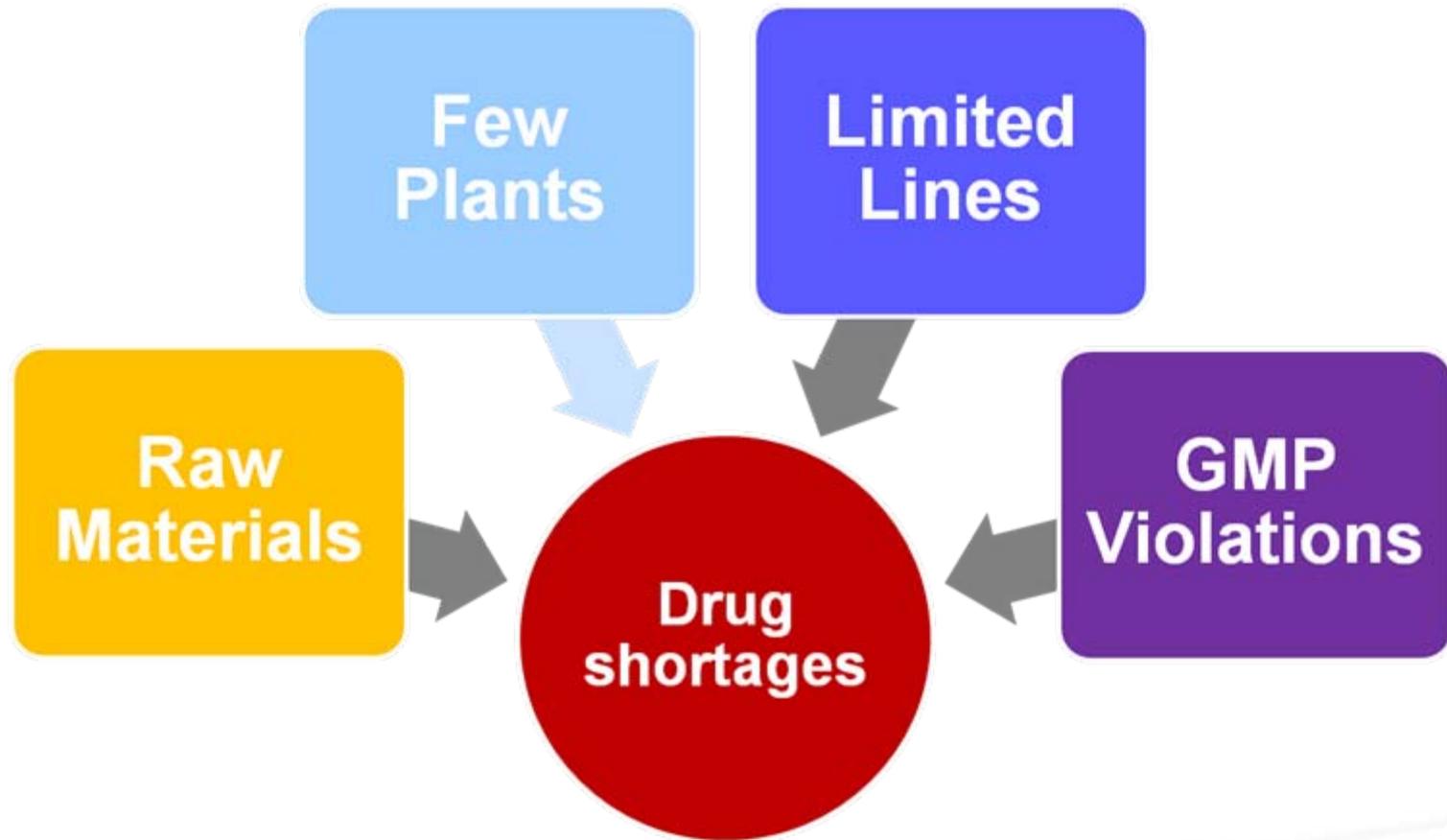


Business Decisions

- Consolidation
- Free market– single source items
- Business decisions
 - Profitability
 - Costs - GMP improvement / violation
 - Annual quotas (production halts)
 - Vacations



Manufacturing Problems

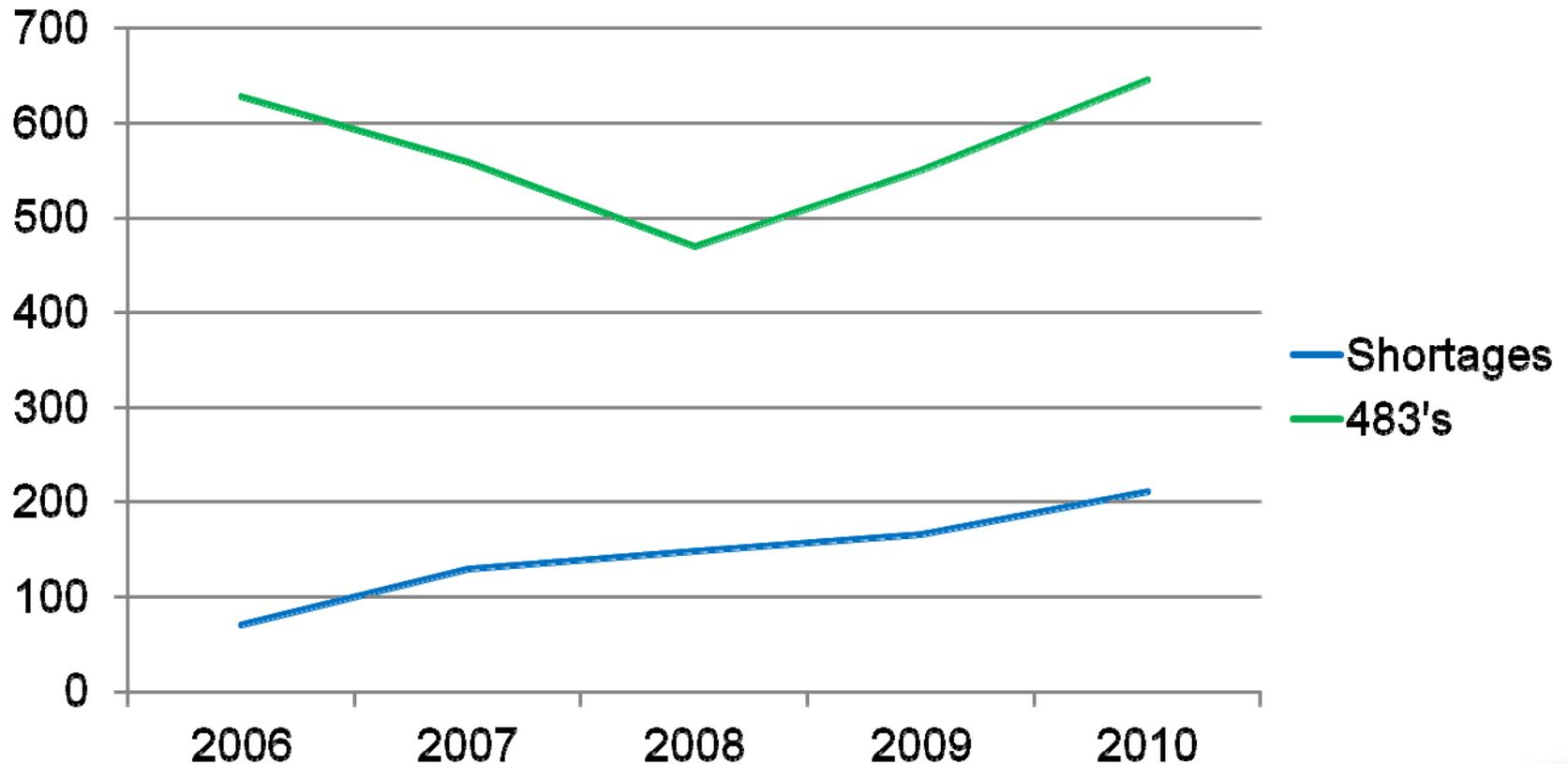


Trends in 483's

- Majority are issued for violations of:
 - Quality control – not following procedures / unwritten procedures
 - Standard operating procedures – not followed or documented
 - Discrepancies – failure to investigate
 - Absence of sound scientific controls
 - Manufacturing performance – lack of procedures to validate, monitor.



Shortages vs. 483s



University of Utah Drug Information Service,
Pink Sheet. June 6, 2011



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Manufacturer Recalls

- Challenging on their own
- Worsen or precipitate shortages (cytarabine)
- Create immediate emergencies, wiping out all stock (fosphenytoin, TMP/SMZ)



Fragile Supply Chain

- Consolidation = fewer suppliers
- Tighter inventories = less resiliency
- Variable distribution methods
- Increasing production to make up a 20% market share virtually impossible
- Global outsourcing of raw materials
 - More than 80% of the raw materials (API) for US drugs made abroad, factories rarely inspected.

www.fiercepharma.com, 6/28/11



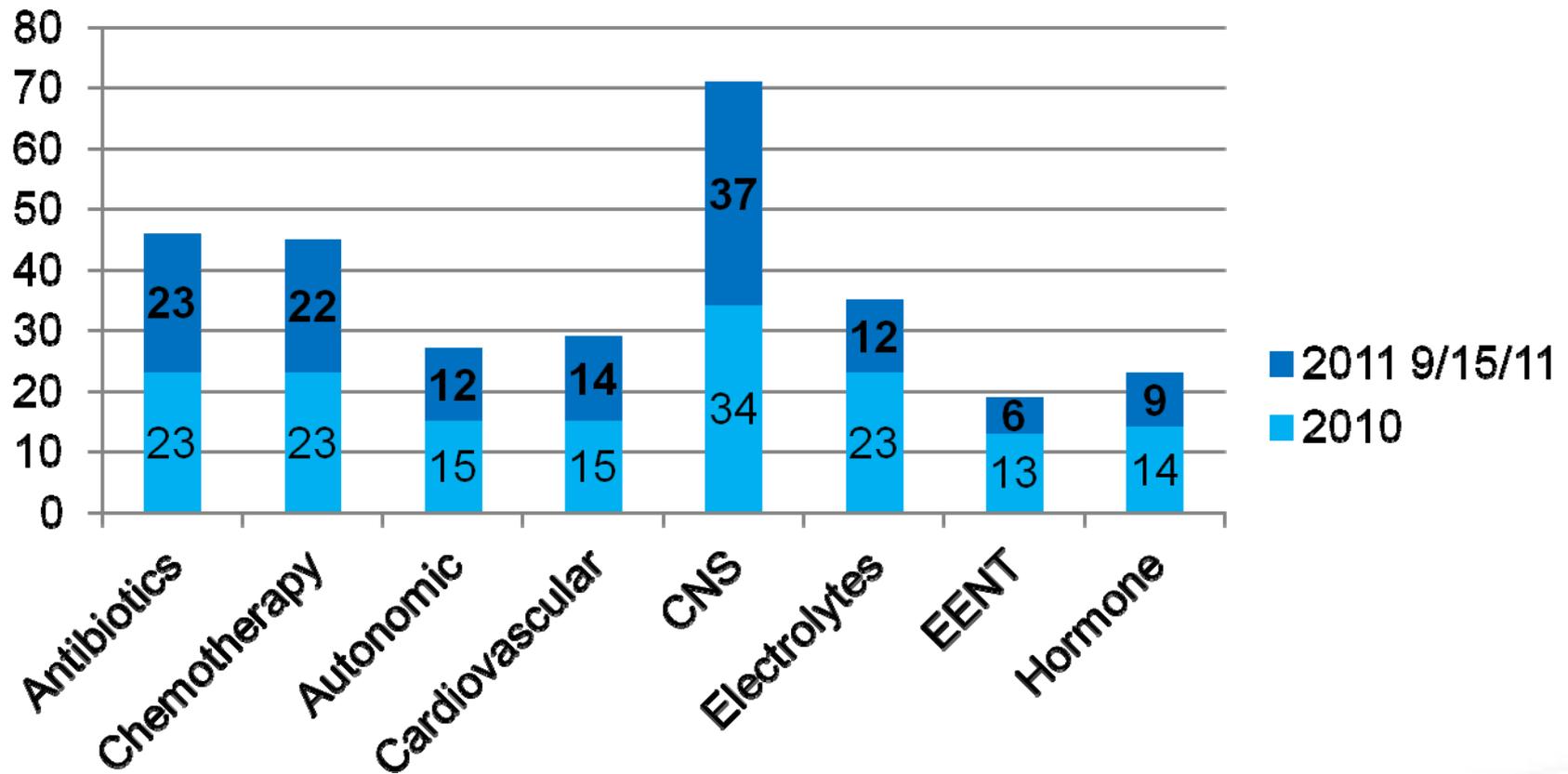
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2010, 2011 Critical Drug Shortages

- Clinical Impact
- No simple alternative –may not be optimal, may require treatment delays
 - Antineoplastics
 - Antimicrobials
 - Electrolytes



Shortages by Drug Class

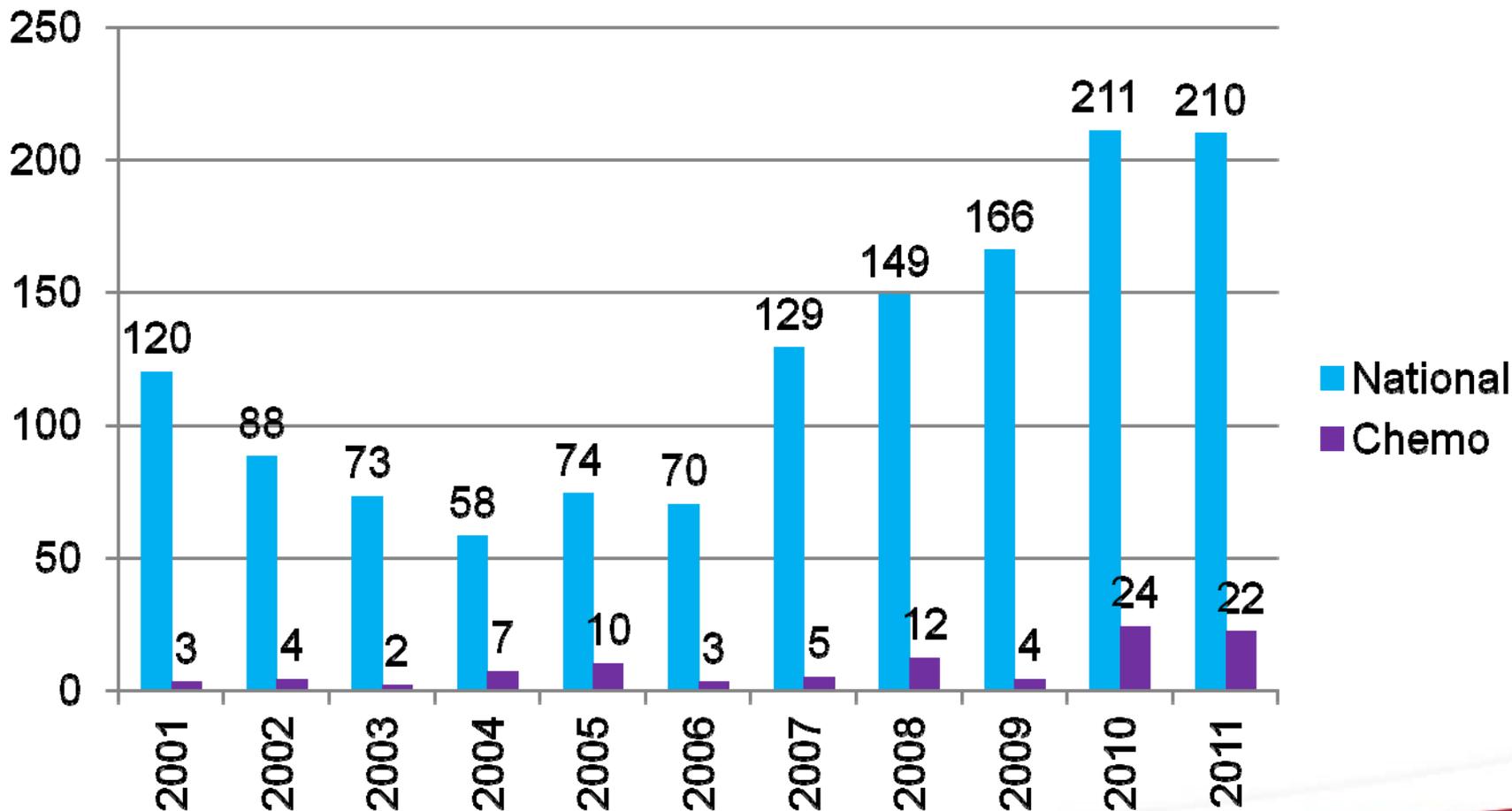


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National Shortages vs. Chemotherapy Shortages January 2001 to September 15, 2011



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Current Status

2010, 2011

- Manufacturing difficulties at the same time
- Extends to plants with good supply
- Prolonged and continued problems
- Patient Impact

Action and Solutions are needed

- Regulatory
- Manufacturing
- Wholesaler / distribution
- Purchasers

