DISCLOSURE

• This presentation represents my own opinions
• University of Utah Drug Information Service has a contract with Vizient (a GPO) to provide drug shortage information. The total amount is < 5% of total budget.
• University of Utah Health is a Vizient member
NATIONAL SHORTAGES AND UNIVERSITY OF UTAH DRUG INFORMATION SERVICE

• UUDIS provides drug shortage content to ASHP and Vizient

• Public website at www.ashp.org/shortages
  – Partners since 2001
  – Receive voluntary reports submitted via web
  – Collaboration is key to success
  – Frequent communication with FDA drug shortage team
Note: Each column represents the number of new shortages identified during that year.
University of Utah Drug Information Service
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National Drug Shortages –
Active Shortages by Quarter

Note: Each point represents the number of active shortages at the end of each quarter.
University of Utah Drug Information Service

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Active Shortages - Top 5 Drug Classes

Active Shortages June 30, 2018

University of Utah Drug Information Service Erin.Fox@hsc.utah.edu, @foxerinr
Green = injectable, yellow = non-injectable
WHAT DO THESE NUMBERS MEAN?

• The rate of new shortages is increasing and common shortages are severely impacting patient care and pharmacy operations
• Long-term active and ongoing shortages are not resolving
• The most basic products required for patient care are short: dextrose, hydromorphone, morphine, fentanyl, ketamine, ondansetron, saline, and sterile water.

WHAT’S MAKING IT WORSE?

• EHR, automation, smart pumps
  – All designed to require the use of the same product, all of the time

• Large amounts of product needed

• Uncertainty about syringes / stability
  – FDA says cannot store drug in syringes, yet syringe pumps are approved. 503b’s also store in syringes

• Uncertainty about compounding regulations

• Unapproved drugs (manage price hikes like shortages)

• Regulatory burden of USP 797, 800, DSCSA
QUALITY IS A PROBLEM

• Pfizer shortages are due to the same Hospira factories with warnings in 2011, 2012
  – Fixes are taking a long time, no capacity to make up difference

• Fluids shortage began with BBraun - warning letter outlines problems not fixed in 2013, 2014, 2015, 2016
  https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm560634.htm
LACK OF TRANSPARENCY IS A PROBLEM

- Contract manufacturing means we don’t always know who makes the product
- No requirement to disclose manufacturer (or location) in product label (or 483)
- No requirement to disclose source of API
- Why is the list of products made in a specific facility proprietary? No way to follow the quality data...
TRANSPARENCY TO INCENTIVIZE QUALITY?

Quality

No Incentive ↔ Not Transparent

Mayo Clinic Proc.2014.89(3):361-373
CHALLENGE: SOLE SOURCE /NEAR SOLE SOURCE PRODUCTS

• Single firm often produces 90% of total supply – common to have sole source raw materials
• What limits competition and new entrants?
  – Low use products
  – Manufacturing expense / ROI?
• Are FDA recommendations / public health considered during mergers?
• Are essential medications critical infrastructure?
• DEA quota system

ACTIONS?

• FDA / Interagency Drug Shortage Task Force
  https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613346.htm

• Summits / Workshops
  – National Academy of Sciences (disasters)
  – ASHP/AHA/AMA/ASA/ASCO/ISMP (national security)

• Advocacy
  • https://www.ashp.org/-/media/assets/advocacy-issues/docs/GRD-Letter-to-EC-on-SVP-Shortages
KEY POINTS

- Severe drug shortages are affecting patient care
- Renewed interest by key stakeholders, Federal Govt, may result in some changes
- Will be years for lasting results / stabilization
CONTACT

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