

Drug Shortages

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DISCLOSURE

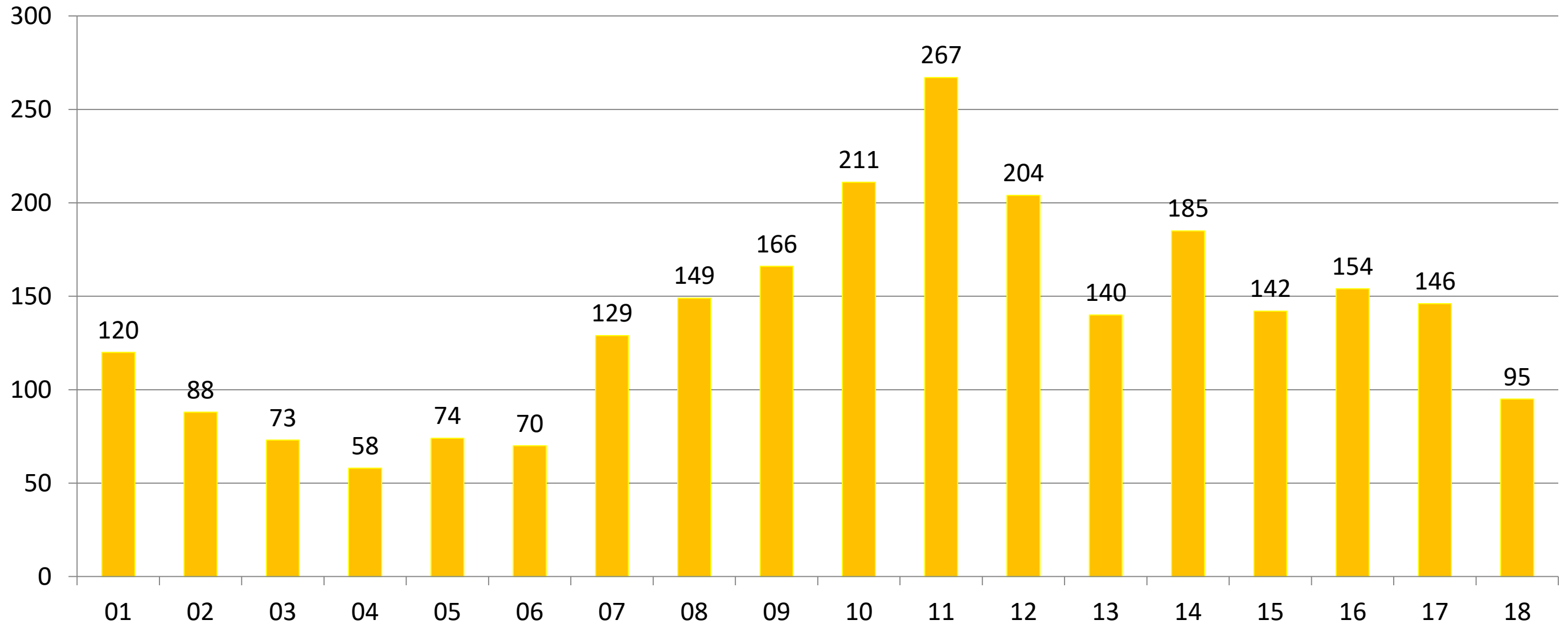
- This presentation represents my own opinions
- University of Utah Drug Information Service has a contract with Vizient (a GPO) to provide drug shortage information. The total amount is < 5% of total budget.
- University of Utah Health is a Vizient member

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

National Drug Shortages

New Shortages by Year - January 2001 to June 30, 2018



Note: Each column represents the number of new shortages identified during that year.

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National Drug Shortages – Active Shortages by Quarter



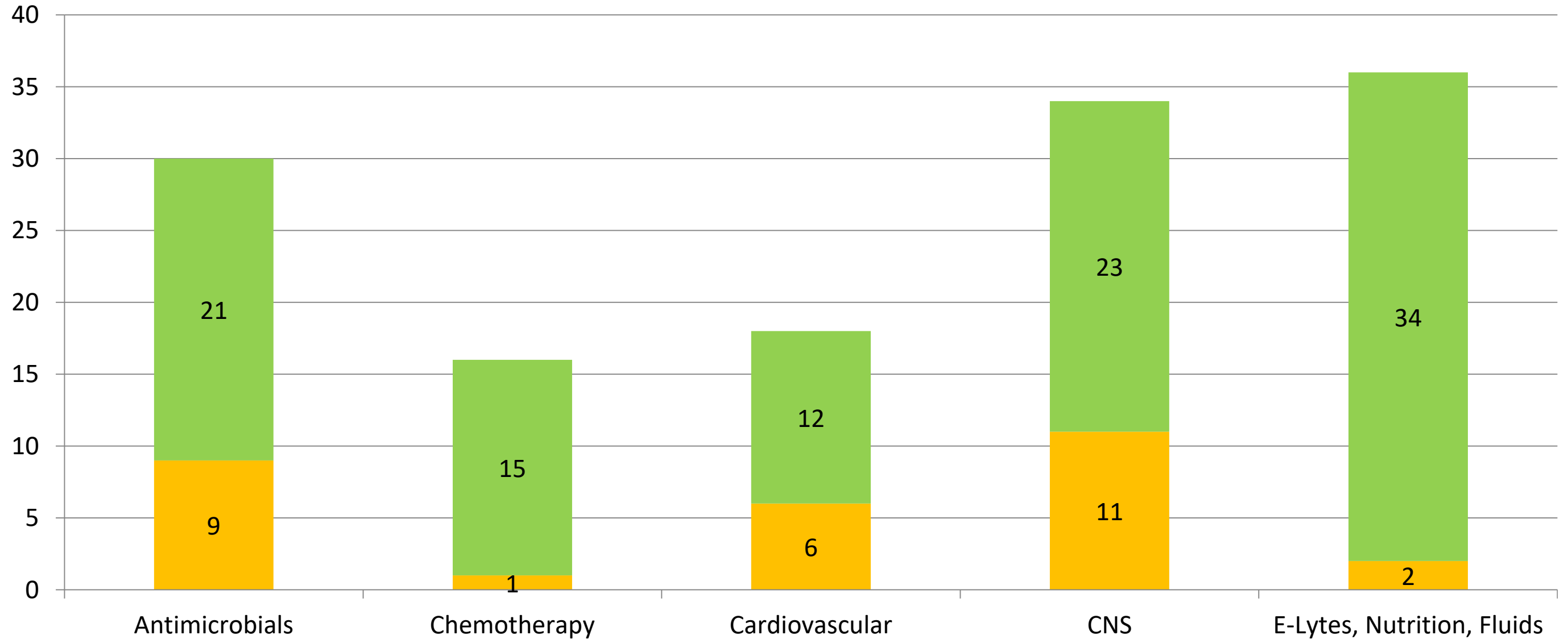
Note: Each point represents the number of active shortages at the end of each quarter.

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Active Shortages - Top 5 Drug Classes

Active Shortages June 30, 2018



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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.

<https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/managing-drug-product-shortages.ashx>

<https://www.ashp.org/Drug-Shortages/Shortage-Resources/Roundtable-Report>

<http://www.nejm.org/doi/full/10.1056/NEJMp1800347>

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

<http://fortune.com/longform/pfizer-drug-problem-fortune-500/>

- Fixes are taking a long time, no capacity to make up difference <https://aspe.hhs.gov/report/economic-analysis-causes-drug-shortages>

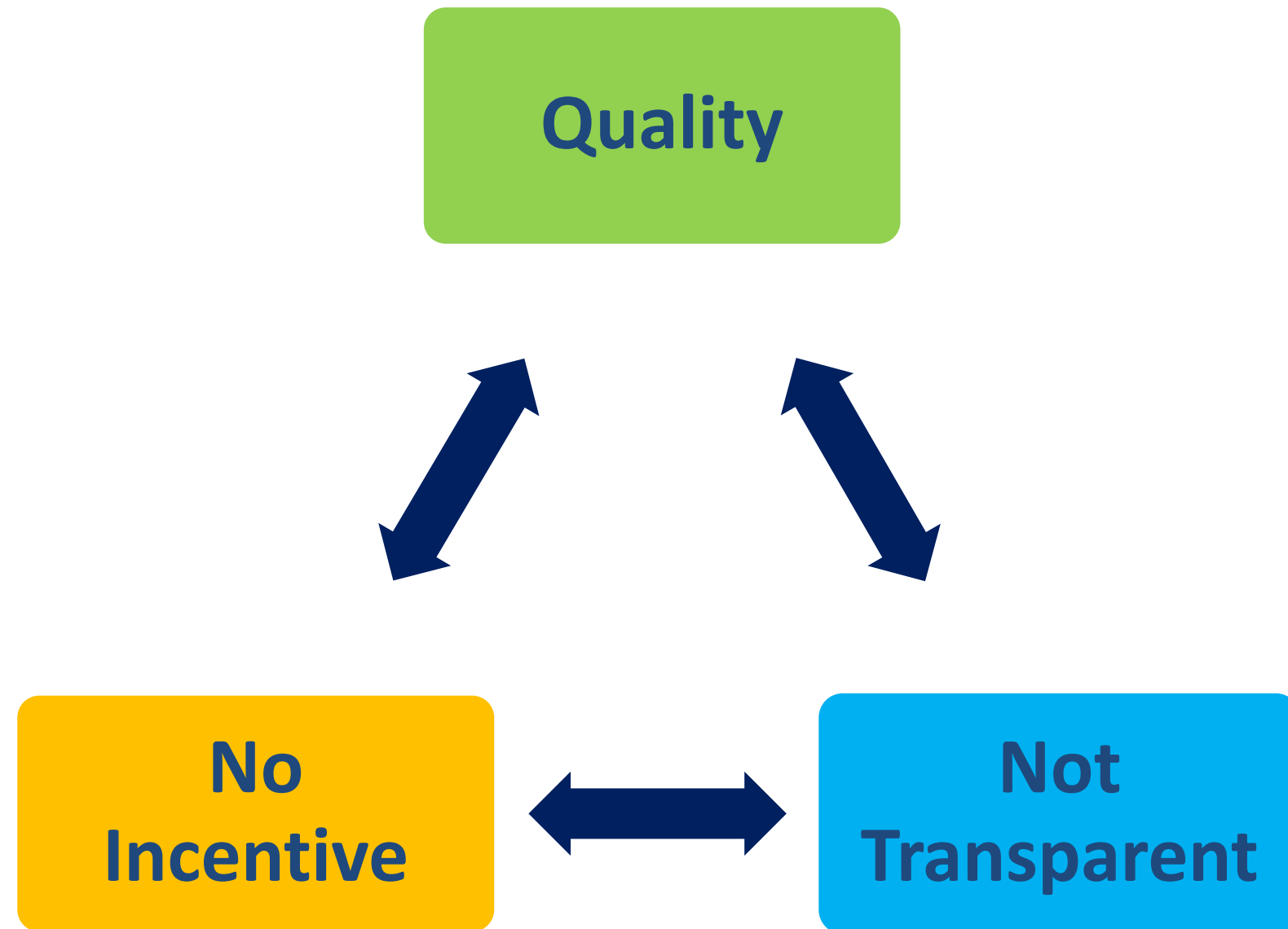
- Fluids shortage began with BBraun - warning letter outlines problems not fixed in 2013, 2014, 2015, 2016

<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?



Clin Pharmacol Ther. 2013;93:170–176
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

<https://www.blumenthal.senate.gov/imo/media/doc/Letter%20to%20FTC%20on%20Pfizer%20Drug%20Shortage.pdf>

ACTION?

- 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

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