QUALITY MATTERS FOR HOSPITALS AND PATIENTS

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UNIVERSITY OF UTAH HEALTH

QUALITY MANAGEMENT MATURITY WORKSHOP - MAY 25, 2022

DISCLAIMER

- Erin Fox is not presenting on behalf of University of Utah or FDA.
- University of Utah is a member of a group purchasing organization, Vizient. No funds are paid directly to Erin Fox.

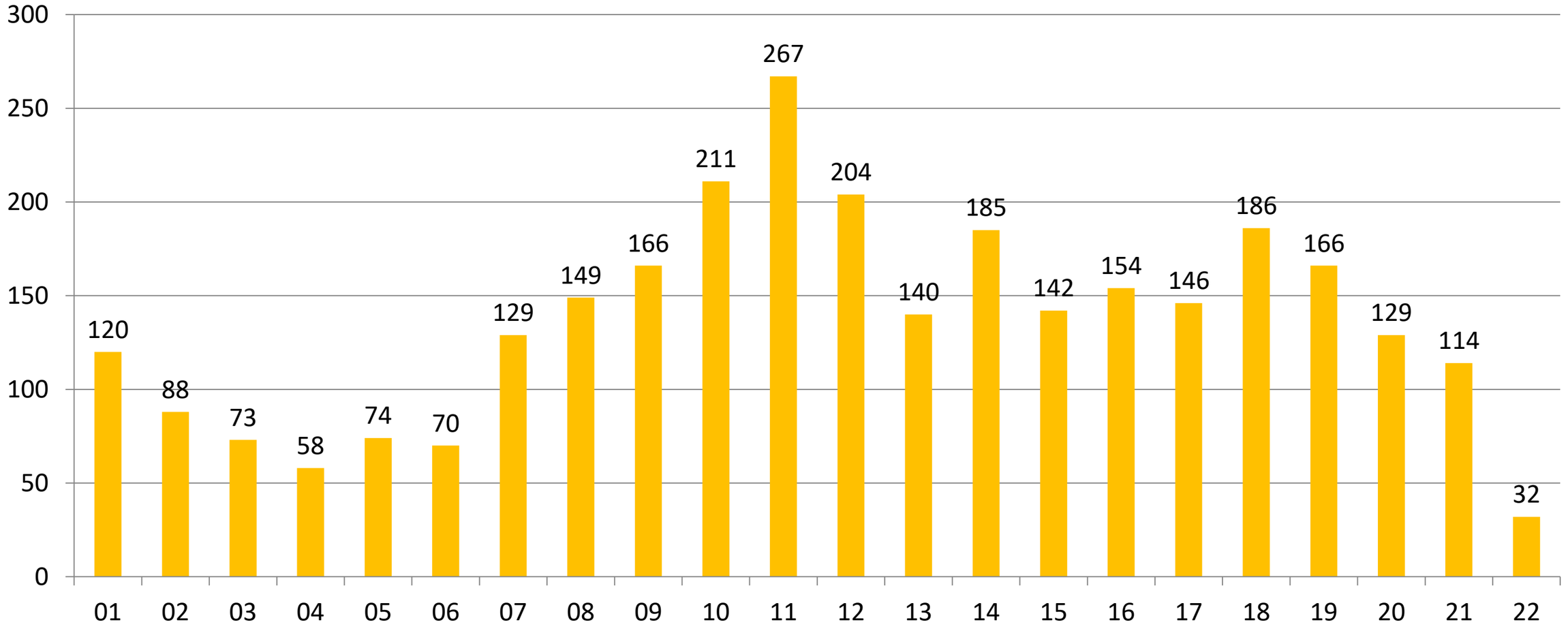
OVERVIEW

- Describe the state of drug shortages and impact on patient care
- Summarize the recent report from NASEM – "Security of America's Medical Product Supply Chain"
- Explain the real-world utility of quality ratings

SHORTAGES AND UNIVERSITY OF UTAH

- National drug shortage information since 2001 – www.ashp.org/shortages
- Investigate voluntary reports
- Share information with FDA
- Alternatives and safety recommendations

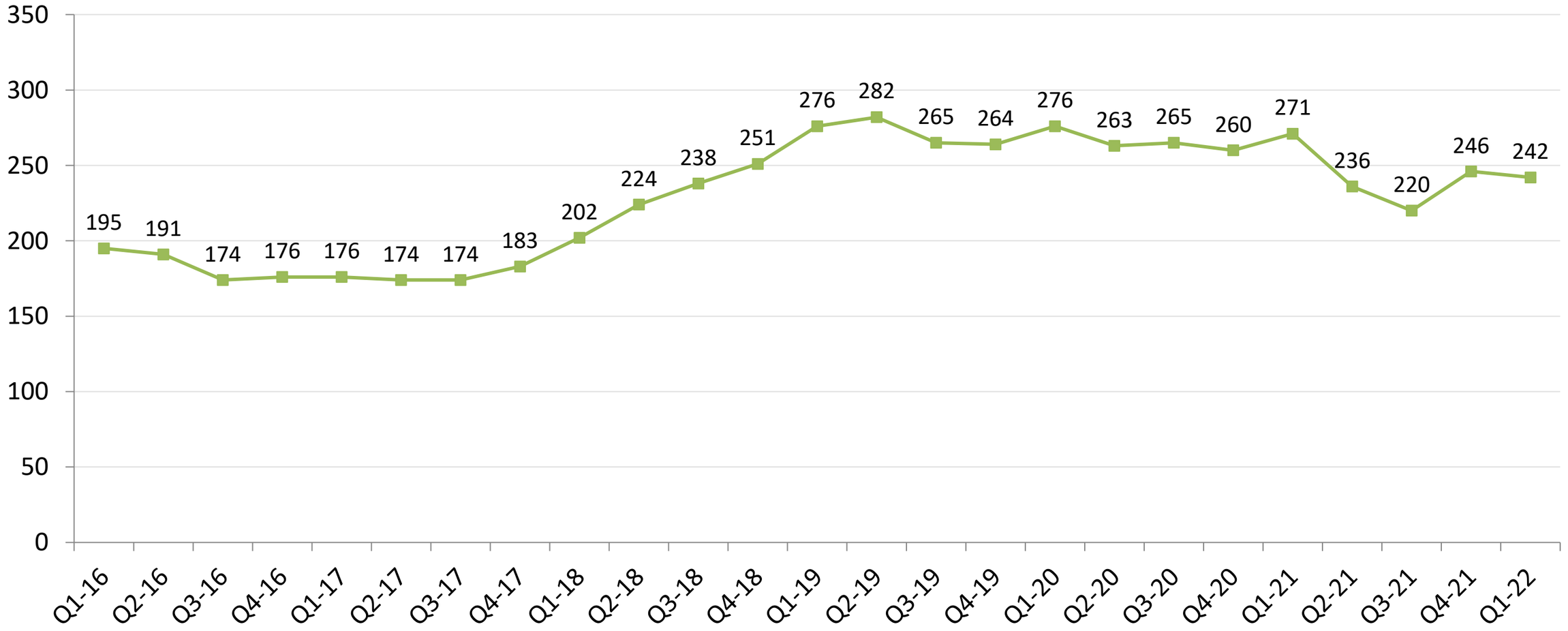
NATIONAL DRUG SHORTAGES - NEW SHORTAGES BY YEAR JANUARY 2001 TO MARCH 31, 2022



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

University of Utah Drug Information Service

NATIONAL DRUG SHORTAGES – ACTIVE SHORTAGES BY QUARTER – 5 YEAR TREND



Note: Each point represents the number of active shortages at the end of each quarter.
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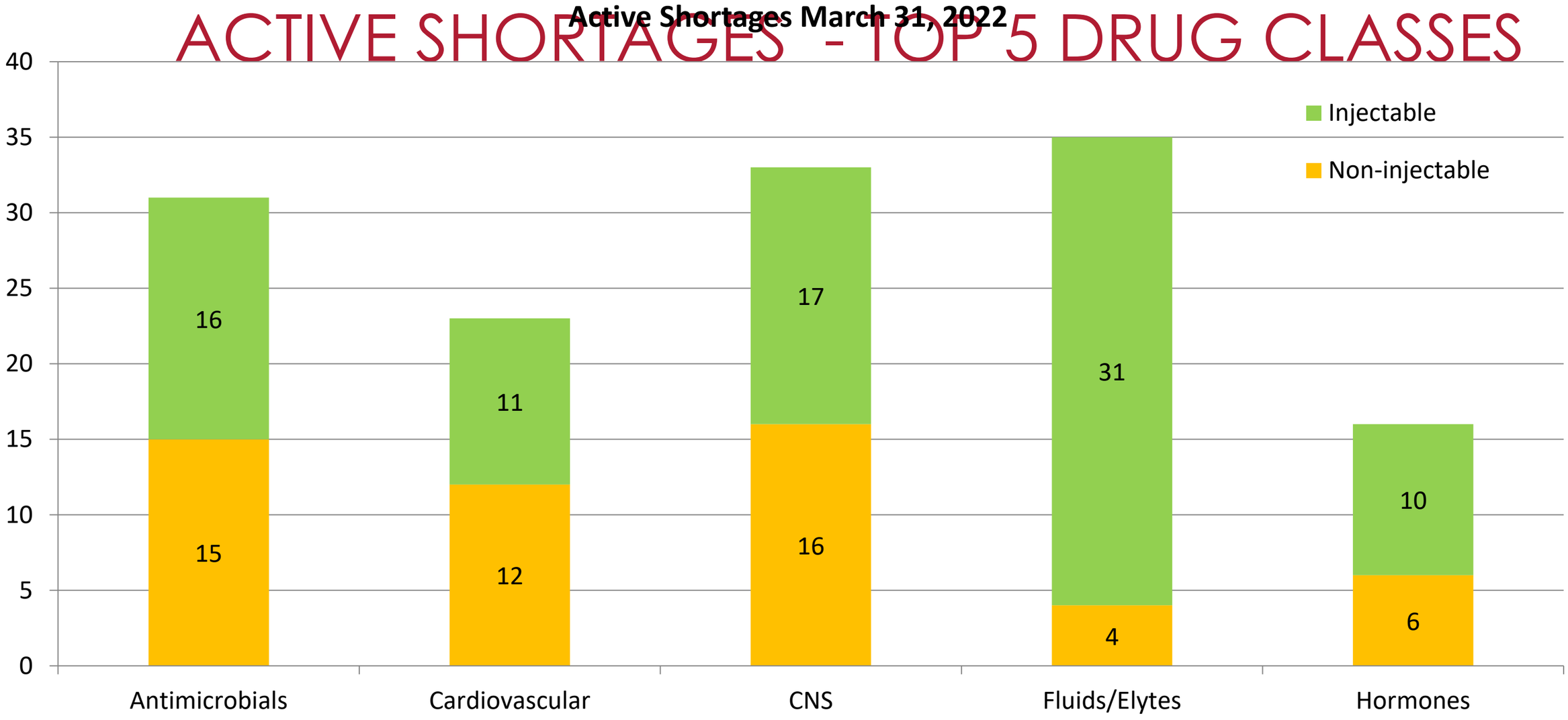
ACTIVE SHORTAGES - TOP 5 DRUG CLASSES



Green = injectable, yellow = non-injectable

University of Utah Drug Information Service

WHY?

- Most shortages are generic, injectable
  - Inexpensive
  - Market does not recognize or reward quality
  - Regulatory hurdles to entry

Clinical Pharmacology & Therapeutics

Review | Full Access

The Drug Shortage Era: A Scoping Review of the Literature 2001–2019

Emily L. Tucker, Yizhou Cao, Erin R. Fox, Burgunda V. Sweet

https://doi.org/10.1002/cpt.1934

- Most shortages are due to quality issues

Report | Drug Shortages: Root Causes and Potential Solutions

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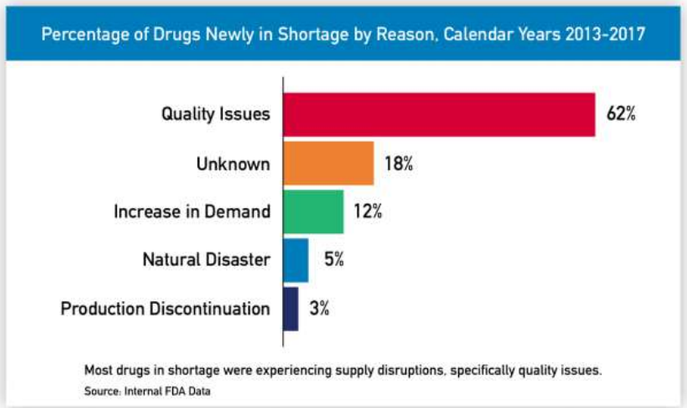


https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions

QUALITY ISSUES CAN HARM PATIENTS

Vincristine – 2019

- Teva (3% market share) discontinued July 2019
- Pfizer (97% market) quality control issue – needed to investigate
- No "safety stock," no back up plan, just a halt with poor communication

The New York Times

Faced With a Drug Shortfall, Doctors Scramble to Treat Children With Cancer

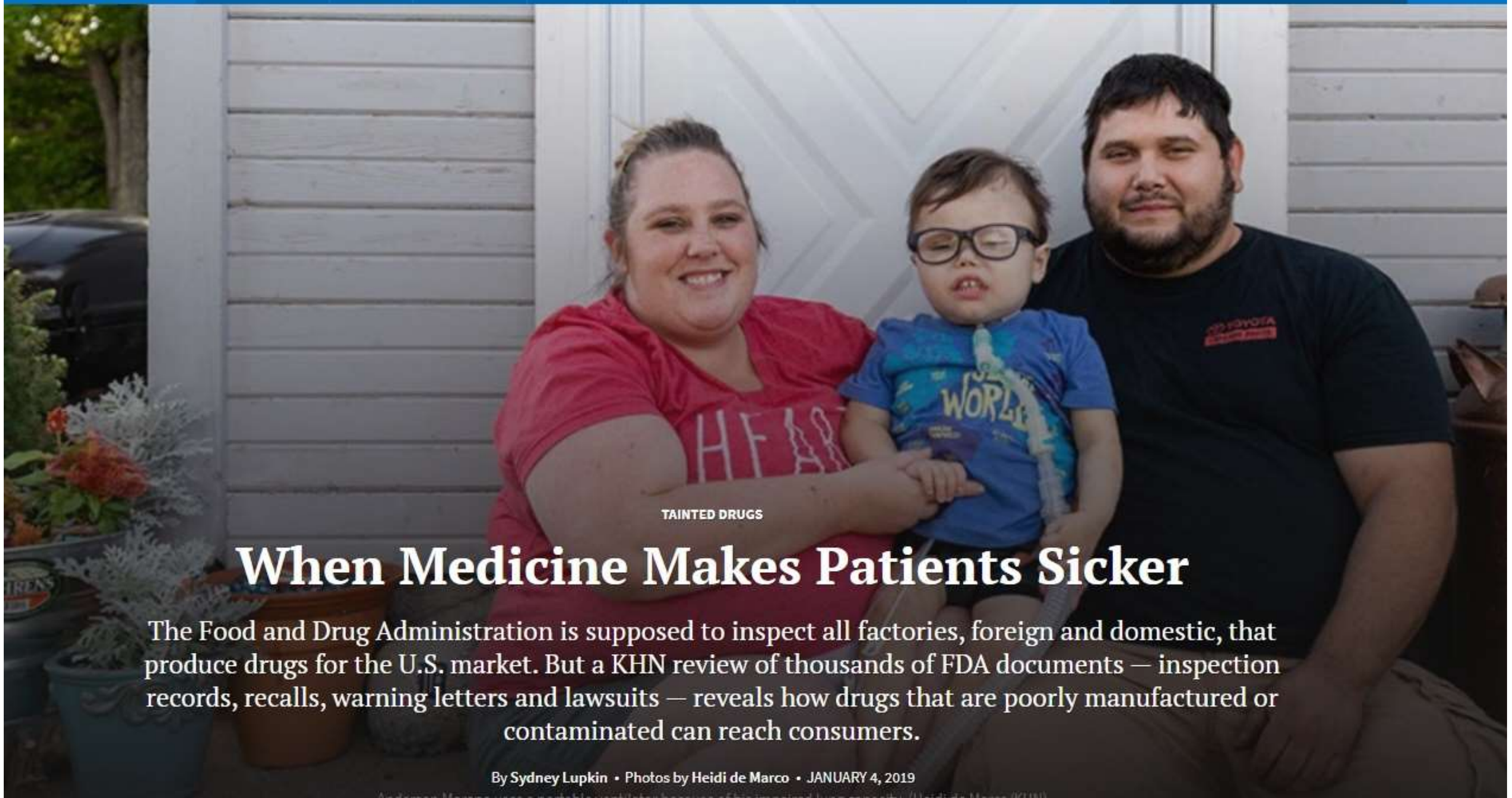
A critical chemotherapy medication is in short supply, and physicians say there is no appropriate substitute.

nature reviews clinical oncology

Comment | Published: 12 December 2019

Oncology drug shortages in the USA — business as usual

Erin R. Fox & Yoram Unguru



TAINTED DRUGS

When Medicine Makes Patients Sicker

The Food and Drug Administration is supposed to inspect all factories, foreign and domestic, that produce drugs for the U.S. market. But a KHN review of thousands of FDA documents — inspection records, recalls, warning letters and lawsuits — reveals how drugs that are poorly manufactured or contaminated can reach consumers.

By Sydney Lupkin • Photos by Heidi de Marco • JANUARY 4, 2019

FDA advises health care professionals and patients not to use any liquid drug products manufactured by PharmaTech and distributed by Rugby Laboratories and possibly other companies

CDC lab testing detects product contamination, links products to patient infections

[8/8/2017] FDA is advising health care professionals and patients not to use any liquid product manufactured by

FDA announces Leader Brand, Major Pharmaceuticals, and Rugby Laboratories recall of all liquid products manufactured by PharmaTech due to *B. cepacia* contamination risk

Update [8/10/2017] FDA is announcing a voluntary recall of all liquid products manufactured by PharmaTech, and distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories, due to possible *Burkholderia cepacia*

FDA advises health care professionals and patients of Centurion Labs' voluntary recall of Ninjacof and Ninjacof A due to potential contamination with *B. cepacia*

Update [8/25/2017] FDA is advising patients to immediately stop using recalled lots of Ninjacof (Lot# 200N1601)

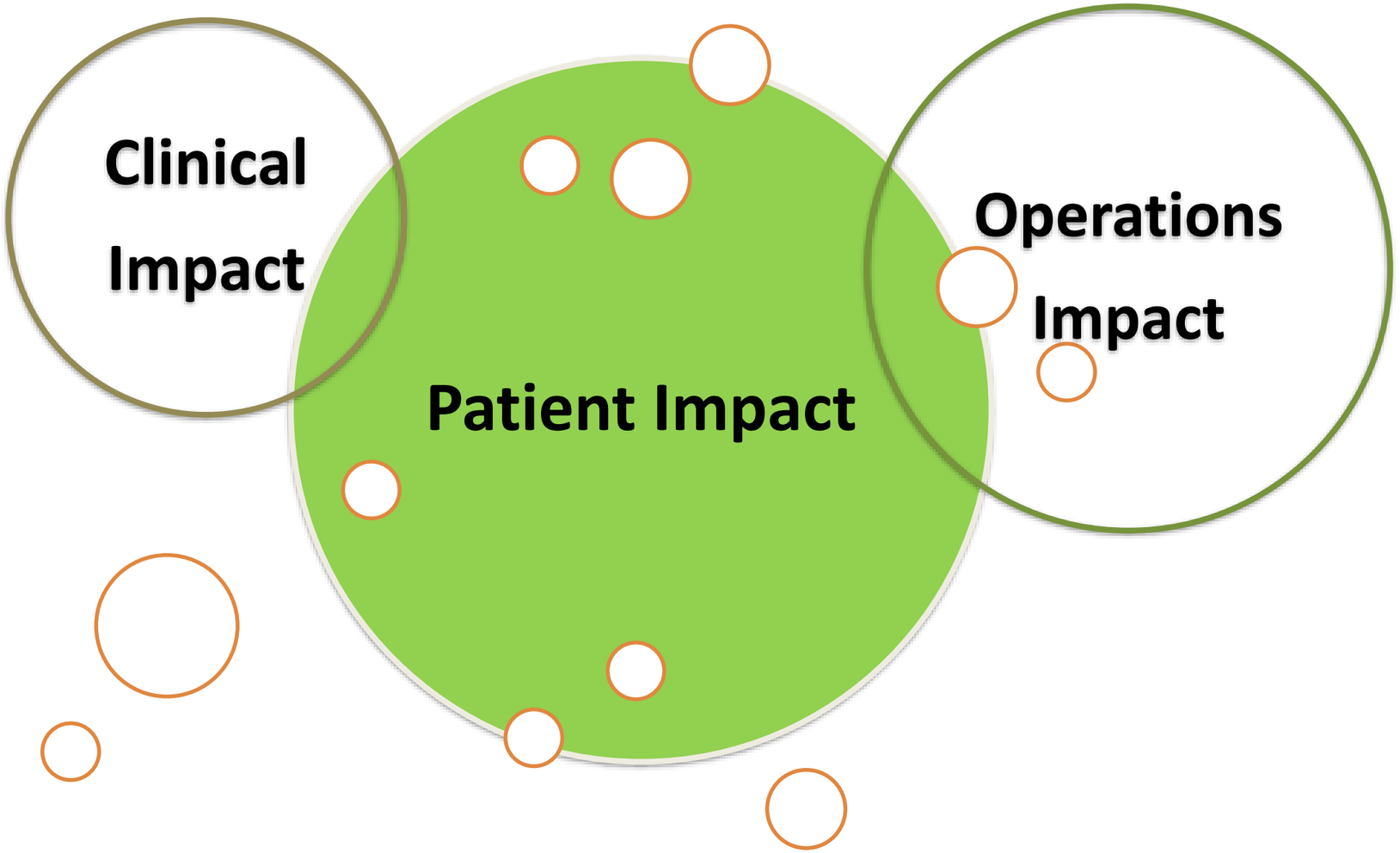
FDA advises health care professionals and patients of Mid Valley Pharmaceutical voluntary recall of Doctor Manzanilla Cough & Cold and Doctor Manzanilla Allergy & Decongestant Relief Syrup due to potential contamination with *B. cepacia*

Update [9/1/2017] FDA is advising patients to immediately stop using recalled lots of Doctor Manzanilla Cough &

WHAT HAPPENS WHEN A SHORTAGE OCCURS?

- Pharmacy treats as emergency
  - How much do we have?
  - How long will it last?
  - Can we make it last longer?
  - What else can we buy?
- Clinicians work together
  - Develop management plans
  - Identify alternatives
  - Prioritize patients (ration care)

COMPLEX PROBLEM SOLVING



IMPLEMENT A PLAN TO MITIGATE HARM

- Challenges
  - Automation requires the use of the **same** product **all** of the time
  - Electronic health record changes (time)
  - Clinically equivalent products are not always seen by technology as equal
  - Staffing

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IMPROVING RESILIENCY

POLL QUESTION

- Is on-shoring the answer for drug shortages?
  a. Yes
  b. No
  c. Maybe

POLL QUESTION

- Most shortages of injectable generic products have occurred due to quality problems at factories inside the United States….

CARES ACT

116TH CONGRESS
2D SESSION

S. 3548

To provide emergency assistance and health care response for individuals, families, and businesses affected by the 2020 coronavirus pandemic.

- ✓ Shortage reasons, expected duration, allow public reporting
- ✓ Sources of APIs, use of CMOs
- ✓ Establish contingency plans during a disruption
- ✓ Incentives to produce drugs in shortage or at risk of shortage
- ✓ HHS / DHS conduct a risk assessment of national security threats related to manufacturing, distribution of critical drugs, APIs, associated medical devices

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Full report available at:
https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain

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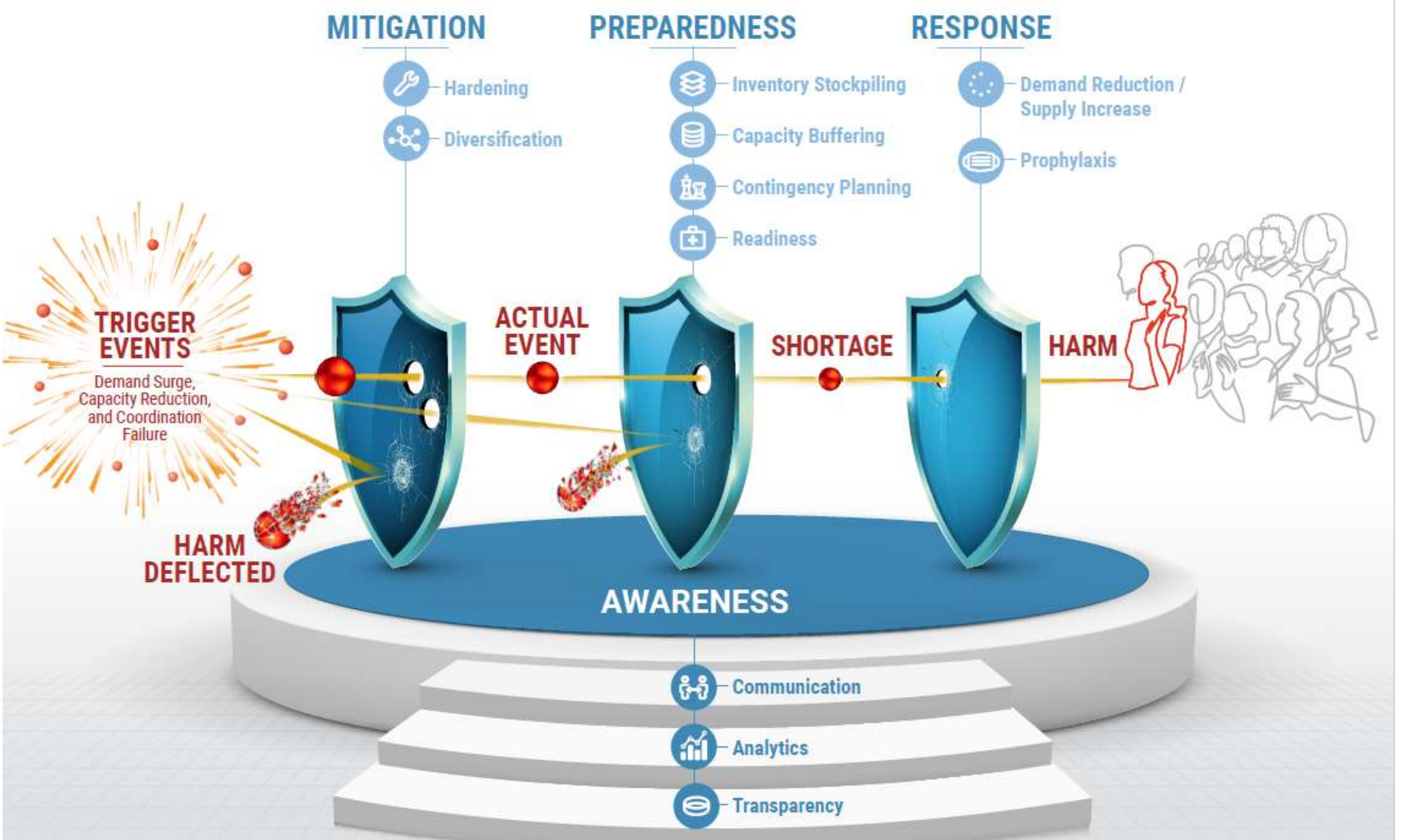
MITIGATION
Hardening
Diversification
PREPAREDNESS
Inventory Stockpiling
Capacity Buffering
Contingency Planning
Readiness
RESPONSE
Demand Reduction / Supply Increase
Prophylaxis
TRIGGER EVENTS
Demand Surge, Capacity Reduction, and Coordination Failure
ACTUAL EVENT
SHORTAGE
HARM
HARM DEFLECTED
AWARENESS
Communication
Analytics
Transparency

AWARENESS

Transparency

- The FDA should take steps to make **sourcing** and **quality** information **publicly available** for all medical products approved or cleared for sale in the U.S.

- The FDA, in cooperation with other government agencies, should establish a **publicly accessible database** for the supply chain information acquired for medical products.

MITIGATION

Resilience contracting

- Health systems should promote a more resilient market for medical products by **deliberately incorporating quality and reliability**, in addition to price, in their **contracting**, **purchasing**, and **inventory** decisions.
- When quality ratings for medical products are available, accreditation organizations for **health systems should use the ratings** of the products sourced by health systems in their evaluations and ratings, as well as the frequency of shortages experienced at a health system that negatively affected patient care.

PREPAREDNESS

Stockpiling, Capacity Buffering, Readiness

- ASPR should take steps to develop strategies to **modernize and optimize inventory management** to respond to medical product shortages at the national and regional levels.
- ASPR and the FDA should take steps to cultivate **capacity buffering** for supply chain critical medical products where such capacity is a **cost-effective complement to stockpiling** and as **protection** against long lasting supply disruptions or demand surges.

RESPONSE

Last mile solutions

- Ensure those most at need can receive product
- Formalize resource-sharing and allocation strategies.

Global supply chains require actions across borders

- Major exporters of medical products, including the United States, should negotiate a **plurilateral treaty** under the World Trade Organization that prohibits export bans or other interventions on key components of global medical product supply chains. Any country that violates the terms of this agreement should be subject to sanctions by other signatories of the agreement.

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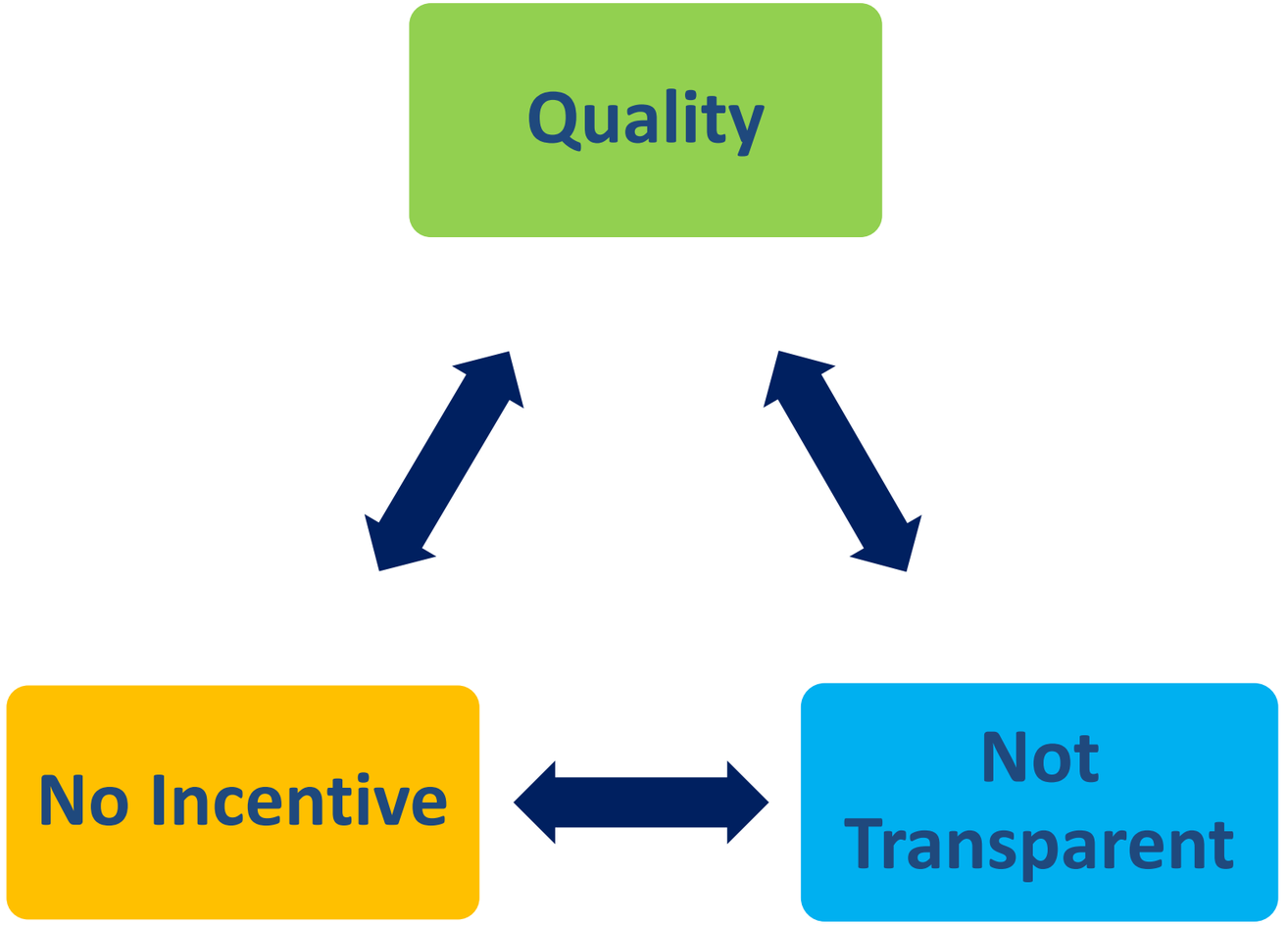
UTILITY OF A QUALITY RATINGS SYSTEM

CURRENT STATE

- Hospitals assume all products available on the market are equal
- No data available beyond FDA approval to note quality or reliability
- Suppliers **do not** reveal companies producing, site of manufacture, API source to single health systems
- Name on product may not be manufacturer (CMO)
- Price is only differentiation point

CAN TRANSPARENCY INCENTIVIZE QUALITY?



Clin Pharmacol Ther. 2013;93:170–176
Mayo Clinic Proc.2014.89(3):361-373

WITH QUALITY RATINGS

- Health systems must change mindset
  - Quality and reliability will cost more
  - Don't pay more without quality ratings / supply assurance
  - Costs of shortages outweigh management strategies (time, labor, patient impact)
  - Cottage industry of band-aids cannot provide real help

FINAL THOUGHTS

- FDA sees clear differences between products, but those are not communicated to purchasers or clinicians
- Quality ratings could allow health systems to reward companies that improve quality
- Quality issues are key reason for shortages. Incentivizing quality aims at this root cause

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QUESTIONS?

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