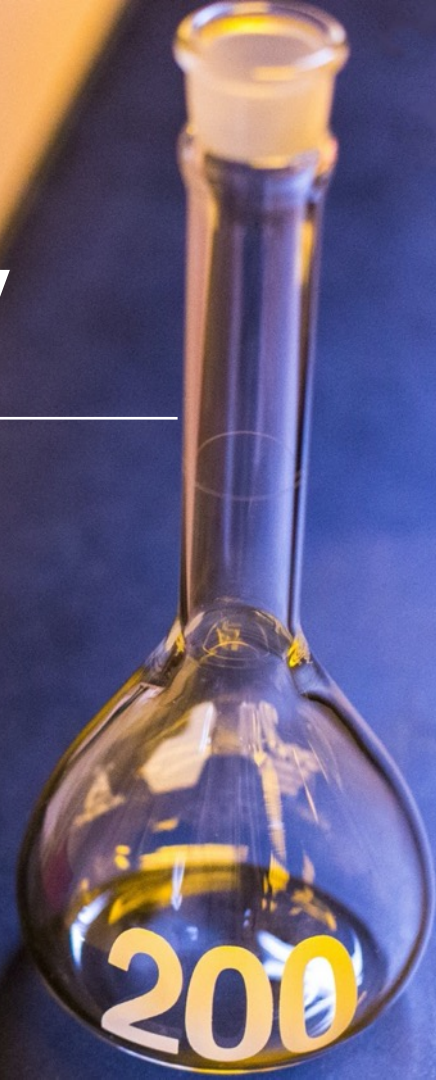


Strengthening the U.S. medicines supply chain: Analytics to bring transparency and drive solutions

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Overview

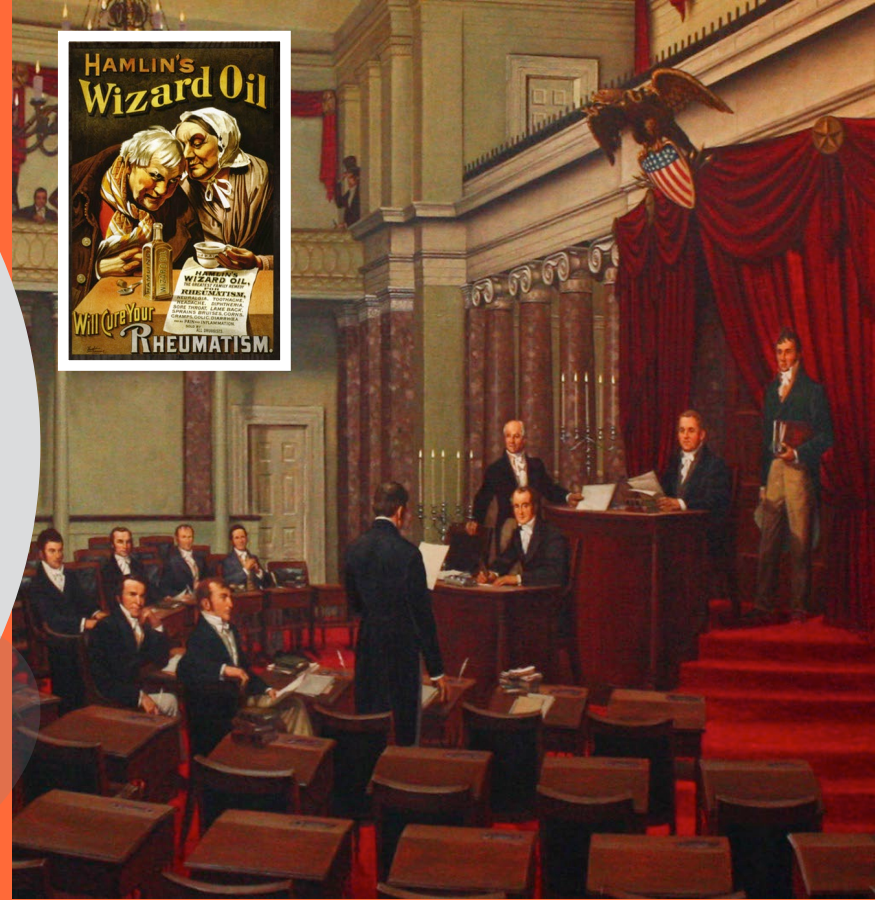
- ▶ Who is USP?
- ▶ Insights on supply chain vulnerabilities
- ▶ Strengthening the medicine supply chain



1 Who is USP?

USP Mission

To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.



USP Standards provide quality benchmarks across the supply chain

- ▶ Standards for medicines, excipients, and APIs, Dietary Supplements, and Food ingredients in our compendia
 - 350 General Chapters
 - 4,900 product-specific monographs
 - 3,500 physical reference standards
 - 1,200 standards for dietary supplements
- ▶ Healthcare Quality & Safety Standards, include compounding, naming, labeling, safety, and Medicare Model Guidelines

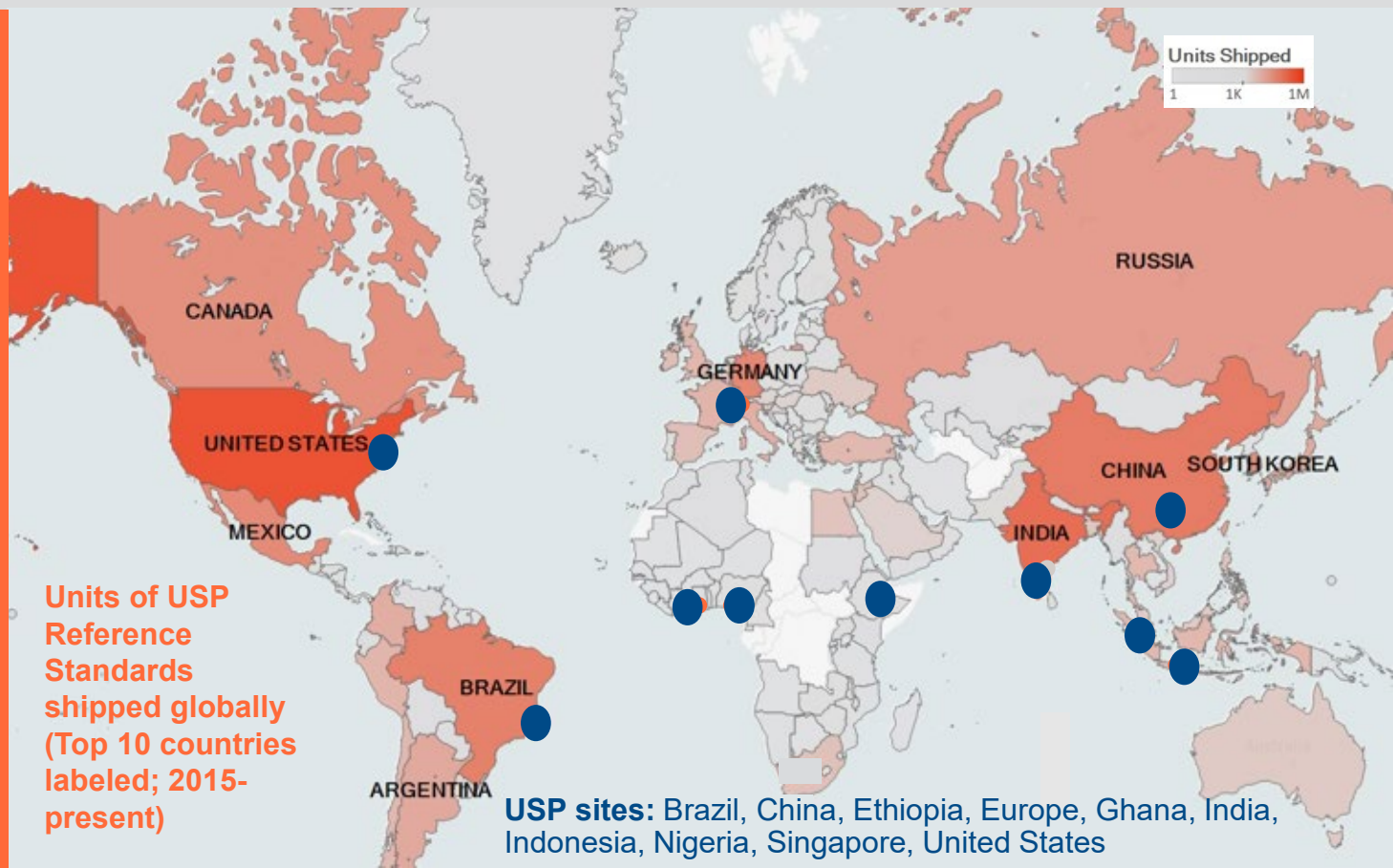


Standards usage drives our global staff presence

~80% of medicine API manufacturers are located outside the United States¹

USP Reference Standards were shipped to over 22,000 entities in FY19

¹ FDA <https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance>



2 Insights on supply chain vulnerabilities

COVID-19 has surfaced long-standing vulnerabilities in the medicine supply chain

Health Experts Concerned Coronavirus Could Lead to Drug Shortages.

– ***Specialty Pharmacy Times Online***

Coronavirus raises fears of U.S. drug supply disruptions

– ***The Washington Post***

Coronavirus Outbreak Will Lead To More Drug Shortages In The U.S., Including Antibiotics

– ***Forbes***

Coronavirus strains fragile pharmaceutical supply chain

– ***USISCC***

Coronavirus strains fragile pharmaceutical supply chain

– ***Modern Healthcare Online***

China's 'choke hold' on drug supply fuels fears of U.S. disruptions, shortages

– ***The Washington Post***

Coronavirus spurs fears of drug shortages as outbreak disrupts the medicine supply chain.

– ***USA Today Online***

U.S. Pharmacopeial Convention Statement on India Export Restrictions of 26 Finished Drug Products, Active Pharmaceutical Ingredients

– ***Targeted News Service***

Coronavirus strains fragile pharmaceutical supply chain

– ***Modern Healthcare Online***

U.S. Pharmacopeia (USP) Offers Support for Developers of COVID-19 Antiviral Drugs and Vaccines.

– ***KOTV-TV Online***

10 Quirky Questions About Coronavirus Answered

– ***Best Health Online***

How Coronavirus Could Threaten America's Prescription Drug Supply.

– ***U.S. News & World Report***

Commentary: Biggest Threat of Coronavirus Could Be to Medicine Supply

– ***WTOP-FM Online***

Drug shortage experts: What consumers need to know during the coronavirus pandemic.

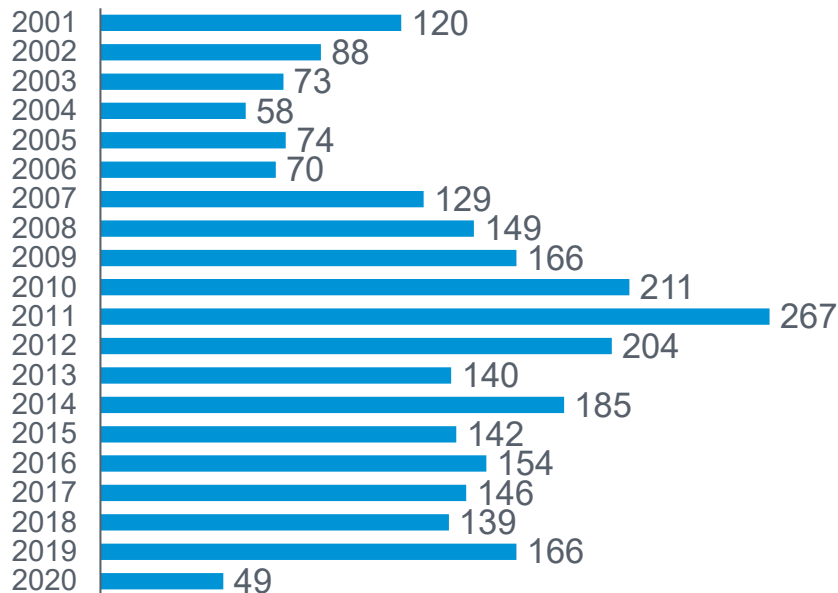
– ***CNBC Online***

Virus Likely Curtailed China Drug Output, Raising Shortage Fears.

– ***Bloomberg***

Drug shortages have been a long-standing problem in the US

Number of new U.S. drug shortages identified each year (Jan 1, 2001-Mar 31, 2020)



Source: ASHP (2020)

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.

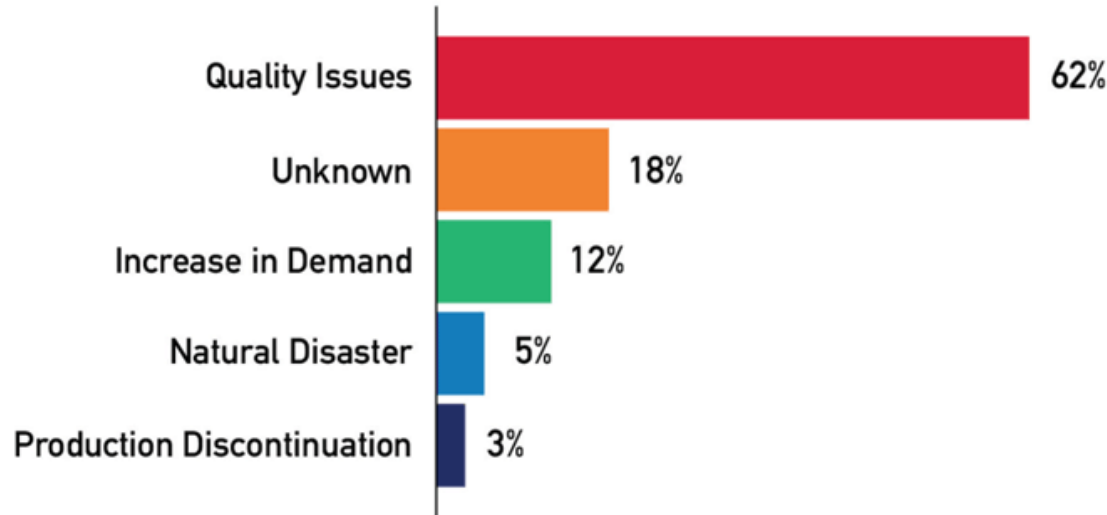
BECKER'S

HOSPITAL REVIEW

Researchers warn of an 'imminent risk' of global heparin shortage

Before COVID-19, a majority of drug shortages were caused by quality issues

Percentage of Drugs Newly in Shortage by Reason, Calendar Years 2013-2017



Most drugs in shortage were experiencing supply disruptions, specifically quality issues.

Sources: FDA. "Drug Shortages: Root Causes and Potential Solutions." Oct. 2019

Over time, the upstream pharmaceutical supply chain has become more vulnerable

Root causes

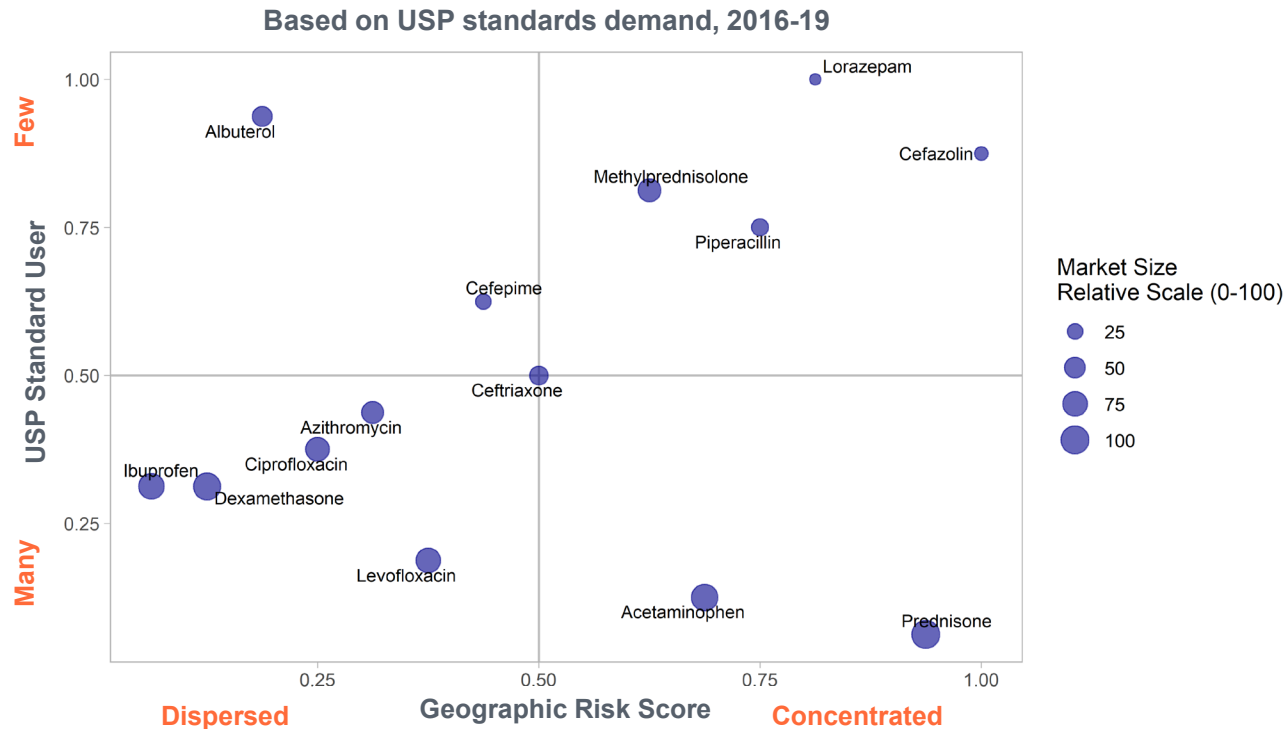
- ▶ Increased pressure on margins, particularly for generics
- ▶ Insufficient incentives for quality
- ▶ Regulatory and logistical hurdles that prevent agile responsiveness to market events

Leading to....

- ▶ “Just-in-time” manufacturing with little redundancy to absorb demand or supply shocks
- ▶ Increased outsourcing of ingredients and even final product manufacturing
- ▶ Lack of transparency limiting the ability of stakeholders to take mitigative action before its too late

To address these challenges, USP is building a **Pharmaceutical Supply Chain Center**, leveraging internal + public/ proprietary data to map the upstream supply chain and predict vulnerabilities to help stakeholders take mitigative action

Drivers of potential supply-side vulnerabilities for COVID-19 therapies



3 Strengthening the medicine supply chain

USP has identified key actions to secure a more resilient supply chain

- ▶ Foster more, not less, supply chain diversity
- ▶ Strengthen manufacturing capacity, including through the adoption of new technologies
- ▶ Enable more transparency and data sharing
- ▶ Conduct crisis contingency planning and action
- ▶ Strengthen regulatory systems and quality assurance



Advanced/Continuous Manufacturing (ACM) could strengthen the supply chain

Batch vs. ACM — Providing the tools to strengthen the supply chain

Batch Manufacturing

- ▶ With 6 exceptions, none of which are generics, every medicine approved in the US uses batch manufacturing
- ▶ Known but higher capital and operating costs that scale with volume
- ▶ Regulatory clarity
- ▶ Ample trained workforce
- ▶ Greater variability in quality
- ▶ Labor and time intensive
- ▶ Bigger physical footprint and environmental impact

ACM

- ▶ Widely used outside of the pharmaceutical industry
- ▶ Subject of significant investment in China, India, UK, and Europe
- ▶ Enhances flexibility in the production quantity and utilization of manufacturing lines
- ▶ Reduces capital investment, risk, physical footprint and environmental impact
- ▶ Achieves better quality control, scale-up, and cost-efficiency of production
- ▶ Shortens supply chains: critical in context of COVID-19 and beyond
- ▶ Regulatory approach still being matured
- ▶ Lacks sufficient trained workforce
- ▶ Accelerates therapy development for orphan diseases and emerging therapies, thereby supporting goals of the Cures Act

It is critical for the U.S. Government to invest in facilitating ACM adoption for medicine production

USP is helping address barriers that have prevented the generics industry from adopting ACM

Barriers

ROI uncertainty

Time needed for manufacturers transitioning to ACM

Regulatory uncertainty

Lack of trained workforce

Lack of awareness and knowledge of advanced manufacturing

USP's work to address these barriers

Convened stakeholder meetings and expert panels

Published a roadmap article for ACM adoption (Nov. 2018)

Updating/developing new standards

Participating in ICH guideline development (Q13)

Demonstrating BM-ACM equivalence using a Gx drug example

R&D: Material Properties testing, Real time release, etc.

Advocating for ACM adoption

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