October 21 Freight Initiatives Committee Agenda

- Roll Call of Members
- Approval of Minutes
- Update on NJTPA Freight Division Activities
- Presentations: The Pharmaceutical & Food and Beverage Industries and Supply Chains – Managing through the Pandemic and Pivoting for the Future
- Two-Minute Reports on Freight Activities from Committee Members
- Next Meeting: December 14, 2020
 TPA Adjournment

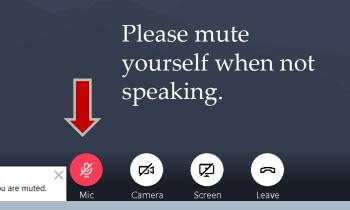
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NJTPA Freight Division Update

 September 10 Truck Parking Workshop

View and read the summary at: https://njtpa.org/Newsroom/NJTPA-News/NJPTA-Update-Blog/2020/September/Workshop-Calls-for-Expanding-Truck-Parking-Needed.aspx



- Anne Strauss-Wieder, Moderator
- Panel Members:
 - Darrin Roth, American Trucking Association
 - Thomas Weakley, Owner-Operator Independent Drivers Association
 - Lisa Mullings, National Association of Truck Stop Operators
 - Ellen Voie, Women In Trucking
 - Stefano Pascucci, JFKIA truck stop operator





NJTPA Freight Division Update

- Council on Port Performance
- 2020 Port Economic Impact Report



View and read the report at: <u>https://njtpa.org/NJTPA/media/Documents/Planning/Regional-</u> <u>Programs/Freight/2020 NYSA Economic Impact.pdf</u>



NJTPA Freight Division Update

- Third Quarter 2020 Industrial Real Estate Numbers
 - 851 million SF in NJTPA region, with 3 million in new starts
- Pandemic Transportation and Supply Chain Implications
- Freight Concept Development Program



Learn more at **www.njtpa.org/freight**



October 21 Freight Initiatives Committee Presentations

- The Pharmaceutical Industry, Ronald T.
 Piervincenzi, Ph.D.,
 Chief Executive
 Officer, United States
 Pharmacopeia
- Food and Beverage Industry, Linda
 Doherty, President & CEO, New Jersey
 Food Council

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Strengthening pharmaceutical supply chains: USP insights to drive transparency

Ronald T. Piervincenzi, Ph.D. Chief Executive Officer, USP

Freight Initiatives Committee Meeting October 21, 2020



Agenda



▶ Who is USP?

- Challenges surfaced due to the COVID-19 pandemic
 - Pharmaceutical supply chain resilience
 - Development, manufacturing, and distribution of COVID-19 vaccines and treatments



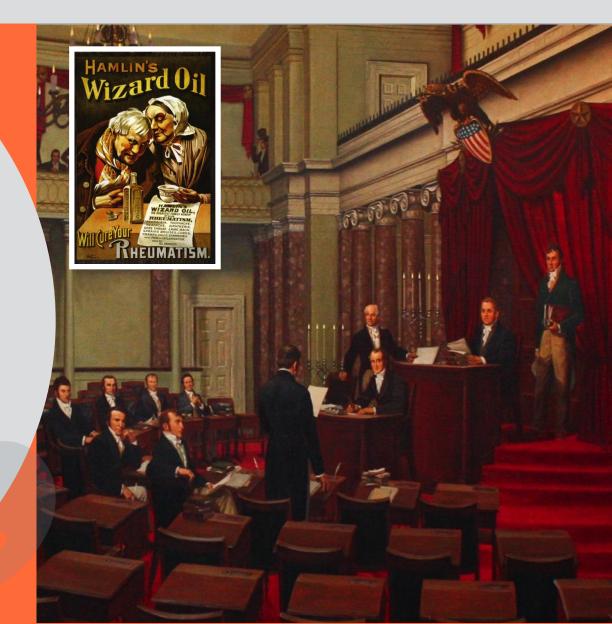


Who is USP?

USP Mission



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



More than 9,000 USP Standards provide quality benchmarks across the supply chain





Documentary standards

Provides information and methods needed to assess quality

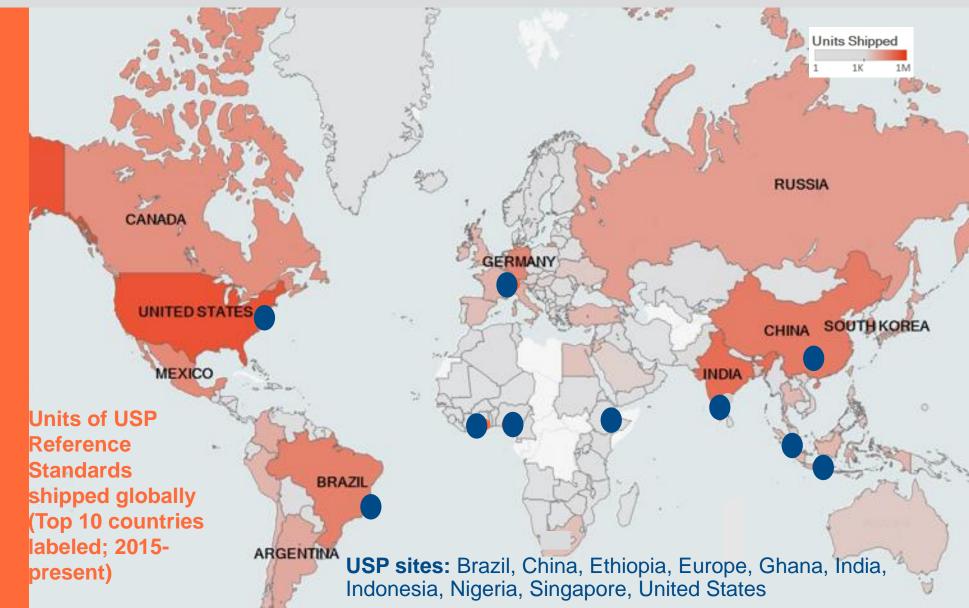
Reference standards

A benchmark against which to compare tested material



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

USP Staff are located across more than **10** global sites



USP's work to address challenges surfaced by the COVID-19 pandemic







Pharmaceutical supply chain resilience: vulnerabilities and solutions

There are many participants in the modern pharmaceutical supply chain...driving complexity



Ingredient Suppliers

- Pharmaceuticals typically contain active ingredient(s) or API and excipient(s)
- The starting materials for producing these are also often outsourced

harmaceutical

Pharmaceutical Manufacturers

Contract manufacturing orgs (CMOs) are often turned to for their specific expertise, so the manufacturer and labeler might be different entities

Wholesalers or Distributors

- There may be several intermediaries and procurement channels (publiclyfunded, privatelyfunded, donorfunded)
- Buying groups or warehouses

Providers

- This could include hospitals, online, mail order, community or retail
- pharmacies, etc.
- Physician or veterinary offices can also administer or supply medicine



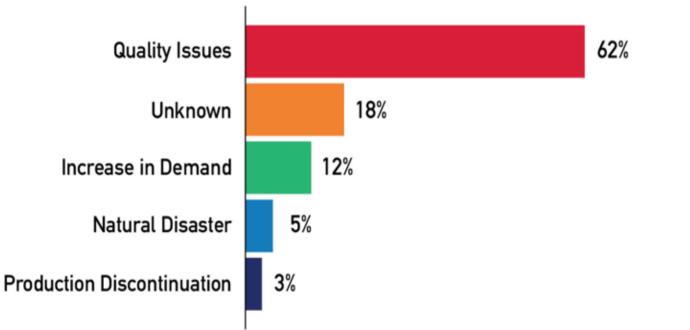
- Patients
- Ultimately, patients trust that a medicine is of high quality because they cannot perform tests to ensure quality themselves

Downstream

Drug shortages overwhelmingly have quality issues as root cause



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



The European Association of Hospital Pharmacists (EAHP) reported that 43.7% of shortages were related to quality issues.

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

Sources: FDA. "Drug Shortages: Root Causes and Potential Solutions." Oct. 2019 Source: FIP. "Report of the International Summit on Medicines Shortage June 2013

15 © 2019 USP New vulnerabilities are driven by greater complexity of the upstream supply chain



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 it's too late

A sustained supply of quality medicines relies on stakeholders 2000 balancing cost, quality and supply chain resilience



USP has published a white paper identifying key actions to secure a more resilient supply chain



- Foster more, not less, supply chain diversity
- Invest in more manufacturing capacity for critical medicines (e.g., continuous manufacturing)
- Enable more transparency and data sharing
- Conduct crisis contingency planning and action
- Strengthen regulatory systems and quality assurance globally

https://www.usp.org/sites/default/files/usp/document/our-impact/covid-19/global-policy-supplychain.pdf



Investing in manufacturing capacity: Continuous Manufacturing could strengthen the supply chain

Batch vs. Continuous Manufacturing — 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
- Bigger physical footprint and environmental impact
- Regulatory clarity
- Ample trained workforce
- Greater variability in quality



Continuous Manufacturing

- Widely used outside of the pharmaceutical industry
- Subject of significant investment in China, India, UK, and Europe
- Reduces capital investment, risk, physical footprint and environmental impact
- Achieves better quality control, scale-up, and costefficiency of production to shorten supply chains (critical in context of COVID-19)
- Lacks sufficient trained workforce





Driving transparency in the supply chain: Generating proactive insights through the USP-Pharmaceutical Supply Chain Center



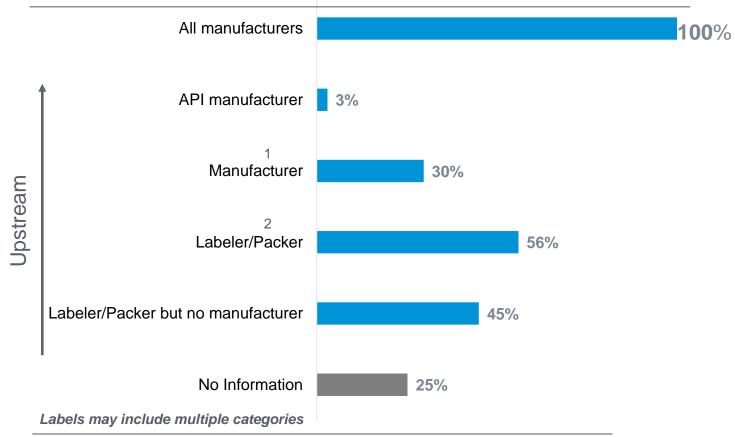
- We created the USP Medicine Supply Map as an early warning system to identify, characterize and quantify risk in the upstream pharmaceutical supply chain
- Data model links across 10+ datasets and dozens of data elements, including USP's proprietary insights
- "In-the-field" data gathering, including through USP's subject matter expert network
- More than 1 million medicines globally included
- Graph-based data model is capable of tracking quality issues up the supply chain



Early insights: there is a need for greater upstream supply chain transparency



Information listed on U.S. approved human prescription drug labels (N=40,178)



Source: USP analysis of DailyMed

1 Includes 'Analysis', 'FDF Manufacturer', 'Manufacturer', Particle size reduction', "Positron Emission Tomography Drug Production', 'Recovery', 'Sterilize', 'Transfill' 2 'Label, Relabel, Pack, Repack'' While approval information is known, we don't know how many are manufacturing the medicine/API

- All labels specify ANDA filer, an entity responsible for the drug's quality. However, manufacturing is often done by a different entity than the filer
- While manufacturers are required and do report suppliers to U.S. FDA, also sharing supply chain information publicly could help providers proactively safeguard patient health. (e.g., when a safety issue is identified with an API manufacturer, providers will have on-hand information about impacted brands)



Development, manufacturing, and distribution of COVID-19 vaccines and treatments

Agile approach to support COVID-19 vaccines and treatments





Improve access to innovative vaccines through reductions in development times and increased scalability, launching the *Trust Accelerated* program with free technical assistance

2

Provide a safeguard against poor quality vaccines, ensuring public trust and safety USP standards are publicly available tools that vaccine manufacturers can use to help answer questions such as:



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Ingredients

How can I be sure my ingredients are appropriate for my vaccine process? Are they pure? Is there a consistent supply from a reliable supplier?

Containers

Will the items used, such as syringes, make it easy for the patient to get the vaccine? Do they leak? Does the container react with the vaccine and change its quality?

Sterility

Is the vaccine sterile? For multi-dose vials, is the antimicrobial agent effective?

4 Labeling

Does the label clearly and accurately indicate the name, dose and how it should be administered?

Packaging and distribution

Is the vaccine packaged correctly to avoid damage and temperature fluctuations during storage and shipping?

* List not exhaustive

usp.org/trust-accelerated

Stay Connected

@RonPiervincenzi | www.usp.org | @USPharmacopeia



NEW JERSEY FOOD COUNCIL

Linda M. Doherty President & CEO

NEW

JERSEY

FOOD

COUNCIL

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It's good that grocery stores have sense of humor.



New Jersey Food Council Mission Statement

THE NEW JERSEY FOOD COUNCIL IS AN ALLIANCE of food retailers and their supplier partners united to provide vision and leadership to advance the interests of its members.

IN SUPPORT OF THIS MISSION, WE ARE COMMITTED TO:

CONTINUING AND MAINTAINING the Food Council's reputation for excellence and integrity;

SERVING AS AN ADVOCATE on both legislative and regulatory issues on behalf of our retail members and the mutual interests of their supplier partners;

DISSEMINATING ACCURATE AND TIMELY INFORMATION in order to educate and inform government, our members and the public;

DEVELOPING STRATEGIC ALLIANCES to further our mission and achieve our short and long term goals;

and Enhancing the image of the food industry.



2020 Board of Directors



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Wels

Markets





KraftHeinz

Company



Pepsi Beverage

Company



Goya Foods

Markets





Rafael Cuellar Cuellar, LLC/ ShopRite of Passaic



Whole Foods Market



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Beverages

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James Ostling Bimbo

Bakeries USA



Joseph E Pagano Inserra Supermarkets



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PRESIDENT & CEO Linda M. Doherty New Jersey Food Council

Platinum Sponsors

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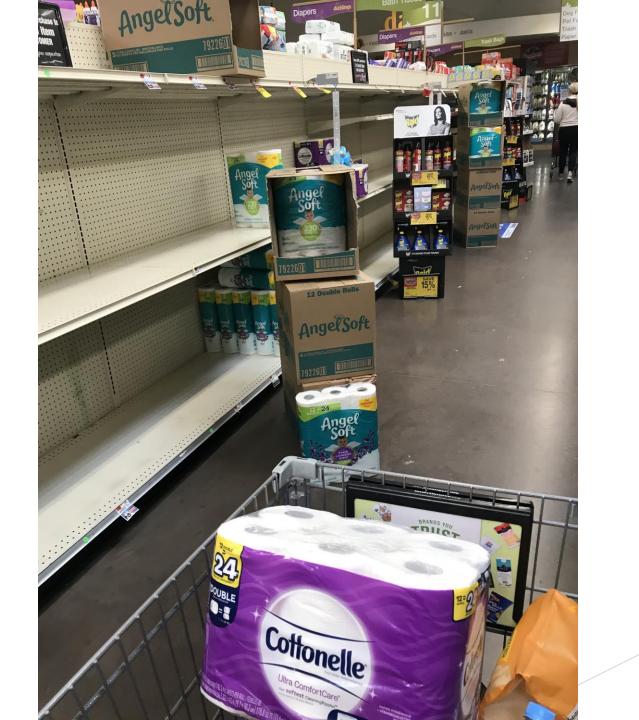
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- ShopRite of Hunterdon County
- Somerset Stores









STATE COVID RESPONSE:

FOOD SUPPLY CHAIN WORKING GROUP

NJ Food Council

Community Food Bank of New Jersey Conrail Governor's Office NJ Department of Agriculture NJ Department of Health NJ Department of Human Services NJ Department of Labor NJ Economic Development Authority NJ Transportation Planning Authority NJ State Police Office of Homeland Security & Preparedness Port Authority of New York and New Jersey

FACT: THERE IS ENOUGH FOOD

Our food supply is strong.
 <u>THERE IS NO SHORTAGE OF PRODUCT.</u>

Any empty shelves are the result of increase demand from customers, not a lack of inventory.

• <u>PLEASE DO NOT STOCKPILE</u>. Purchase what you need but leave something for your neighbor.

• We are working around the clock to stock our shelves and sanitize our stores to keep you and our employees in good health.

FACE COVERING REQUIRED!

WE WILL NOT ALLOW YOU IN THE BUILDING WITHOUT FACE COVERING. THIS IS AN EXECUTIVE ORDER OF THE STATE OF NEW JERSEY.

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It's perfectly clear: We care about your well-being.

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READER RANKINGS EVENTS V LATEST HEADLINES DIGITAL EDITIONS EXECUTIVE MOVES

EDUCATION ENERGY FOOD & HOSPITALITY GOVERNMENT HEALTH CARE LAW MANUFACTURING MONEY REA

OPINION: Building the plane while flying it

The grocery and food distribution businesses moved quickly to meet the COVID-19 challenge

By: Linda Doherty

June 29, 2020 12:01 am



DEPOSIT PHOTOS

First and foremost, I hope as you read this column you and your family are healthy and safe. The first six months of 2020 have been an extraordinary time and one that will be remembered by generations to come. As we look back to mid-March, the emergence of the COVID-19 global pandemic changed the world with the blink of an eye. The grocery and food distribution industries were designated as essential businesses and overnight our New Jersey food retailers and suppliers had the overwhelming responsibility to feed 9 million disconcerted

Observations ★ Insights ★ Trends

- Workforce
- Food Retailer
- Supply Chain
- Shopper
- Growth of e-Commerce
- Opportunities
- Holiday Shopping Behavior



NJFC HOLIDAY SAFE SHOPPING TIPS

As shoppers navigate state restrictions, our favorite holidays are fast approaching! We are providing the best practical guidelines to keep shoppers and grocery store workers safe during the holidays in lieu of COVID-19. Please use these helpful Safe Shopping Tips to shop with ease during this holiday season

1. Limit going to the grocery store only when it is essential and focus on buying what you need.

COVID-19 has upended our daily lives and the usual grocery store trips need to be planned. As you shop the holidays, <u>plan ahead</u>. There is no need to stockpile items. Buying enough for your holiday celebration is advisable. If everybody maintains normal shopping patterns, the food supply will replenish and remain stable.

2. Shoppers must wear face masks.

As shoppers know, it is a NJ mandate by Governor Phil Murphy that all customers wear face masks to enter a retail location. It is the law.

3. Reduce store crowding by shopping alone.

Especially during the holidays, some of us enjoy going to the grocery store with our spouse or families, but to keep everyone safe, shop alone if you can. By reducing capacity, it is easier to maintain less crowded aisles and safe social distancing between customers.

Full list of tips can be found on www.njfoodcouncil.com



Monmouth County COVID-19 Lawn Sign



DISPOSE OF MASKS AND GLOVES PROPERLY



THEY BELONG IN THE GARBAGE CAN NOT IN RECYCLING NOT ON THE GROUND



Resources

- Grocery Dive e-Newsletter
- FMI.org/foodprices
- The Shelby Report
- Food Trade News
- Progressive Grocer
- Winsight Grocery Business
- Supermarket News

Contact

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NJ Food Council 429 Riverview Plaza Trenton, NJ 08611

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- Presentations on Analyzing and Visualizing Critical Supply Chains
- Two-Minute Reports on Freight Activities from Committee Members
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Thank you. Stay healthy and safe.

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