From Strategy to Action: Understanding Medical Product Shortages During the COVID-19 Pandemic and Future Events

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Dr. Heather Agler is a Senior Science Health Advisor in the U.S. Food and Drug Administration (FDA) Center for Devices Radiological Health (CDRH). Dr. Agler develops collaborations between medical device developers in government agencies (i.e., Department of Defense [DoD], Biomedical Advanced Research and Development Authority [BARDA]) and the CDRH review divisions to reduce the regulatory hurdles that often accompany bringing new, high-risk / high-benefit, medical countermeasure technology to market. At the beginning of COVID-19, Dr. Agler worked on ways to make ventilators accessible and on the emergency use authorization process. She continues to work on critical supply chain issues to ensure access to needed medical devices. Previously, she worked in the areas of Digital Health and was a lead reviewer in the Office of Device Evaluation reviewing interventional cardiology devices. Dr. Agler was a Christine Mirzayan Fellow at the National Academies. She has a B.S. degree in chemical engineering from the University of South Carolina and a Ph.D. degree in biomedical engineering from the Johns Hopkins School of Medicine.

Disclosures

- Dr. Heather Agler has no relevant financial or non-financial relationships to disclose relating to the content of this activity.
- The views expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of the Food and Drug Administration, nor the U.S. Government.
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Learning Objectives

At the conclusion of this activity, participants will be able to:

1. Explain the Center for Devices and Radiological Health's (CDRHs) role in emergency preparedness and response.
2. Describe how CDRH collaborates with the Department of Defense (DoD) and other agencies to develop new medical countermeasures.
3. Discuss CDRHs role in the COVID-19 pandemic response, including mitigation of shortages.
4. Illustrate how CDRHs new Resilient Supply Chain Program is building resilience in the medical device supply chain.

Agenda

- Food and Drug Administration (FDA) and our role in emergency preparedness and response
- The All-Hazards Readiness and Response's (ARC) role in the Center for Devices and Radiological Health
- COVID-19 Response and Shortages
- Creation of the Resilient Supply Chain
- Q&A

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- Q&A

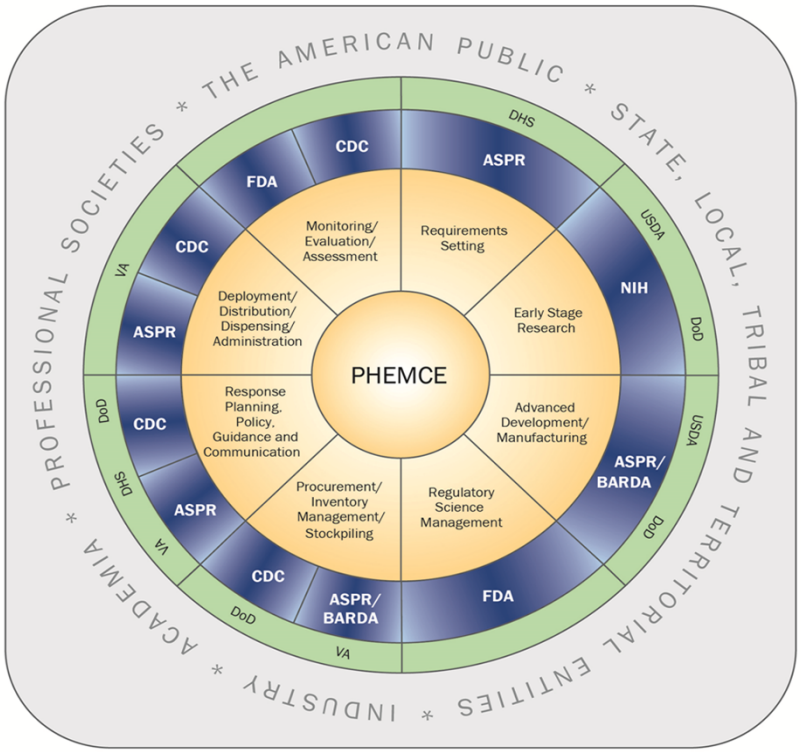
Center for Food Safety & Applied Nutrition | Center for Drug Evaluation & Research | Center for Biologics Evaluation & Research | Center for Tobacco Products | **Center for Devices & Radiological Health (CDRH)** | Center for Veterinary Medicine | National Center for Toxicological Research

(FDA.gov, n.d.)

Center for Devices and Radiological Health (CDRH)

- Responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices and in-vitro diagnostics (IVD) for sale in the United States.
- Regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Public Health Emergency Medical Countermeasure Enterprise (PHEMCE)



Key

- PHEMCE Mission Components
- HHS PHEMCE Agencies
- Non-HHS PHEMCE Agencies
- Non-Federal Stakeholders

Acronyms

PHEMCE: Public Health Emergency Medical Countermeasures Enterprise
DHS: Department of Homeland Security
DoD: Department of Defense
USDA: U.S. Department of Agriculture
VA: Department of Veterans Affairs
HHS: Department of Health and Human Services
ASPR: Assistant Secretary for Preparedness and Response
BARDA: Biomedical Advanced Research & Development Authority
CDC: Centers for Disease Control and Prevention
FDA: Food and Drug Administration
NIH: National Institutes of Health

(int.nyt.com, 2016)

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

- PHEMCE coordinates Federal efforts to enhance chemical, biological, radiological and nuclear threats (CBRN) and emerging infectious diseases (EID) preparedness from a medical countermeasure (MCM) perspective.

- PHEMCE is led by the Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) and includes three primary HHS internal agency partners: the Centers for Disease Control and Prevention (CDC), FDA, and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA)

Office of Counterterrorism and Emerging Threats (OCET)

- Policy and planning matters concerning global health security, counterterrorism and emerging threats.
- Serves as the FDA focal point for the HHS PHEMCE and DoD MCM programs to **support the warfighter.**
- Coordinates FDA's MCM Initiative (MCMi) to facilitate the development of safe and effective MCMs against CBRN and emerging threats, such as pandemic influenza.
- Develops and coordinates implementation of FDA policies and procedures to facilitate the availability of MCMs, including appropriate mechanisms, such as Emergency Use Authorization (EUA).

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CDRH's All-Hazards Readiness, Response, and Cybersecurity (ARC)

Create a culture of preparedness that allows the American people to have ready access to safe and effective medical devices during steady-state and response to any natural, accidental, or intentional public health or cybersecurity emergency.

- Prepare and respond to emergencies
- Mitigate shortages of essential devices during emergencies
- Promote the development of new medical countermeasure devices
- Lead and advance the cybersecurity posture of the healthcare ecosystem

All-Hazards Readiness, Response and Cybersecurity (ARC) Program

ARC's work focuses on three main areas:

- Innovation Program – Supports the development of new innovative medical countermeasure devices and new innovative devices to support the warfighter
- Cybersecurity Program - To lead and collaboratively advance the security posture of the healthcare and public health (HPH) medical device ecosystem
- Emergency Preparedness/Operations and Response - To prepare and respond to emergencies and outbreaks via a framework that supports timely CDRH efforts to prevent and mitigate patient harm

All-Hazards Readiness, Response and Cybersecurity (ARC) Innovation Program

Supports the development of new innovative medical countermeasure devices and new innovative devices to support the warfighter

- **MCM Devices**: A medical device used in the detection, prevention, and management of a CBRNE, emerging infectious disease, or natural disaster event.

- Work with our federal partners including the DoD, BARDA, CDC, and others to get new medical countermeasure devices cleared and approved.
  - Outreach
  - Education
  - Collaboration

- **Our goal**: Shorten time it takes to develop safe & effective MCM devices so they are available when needed.

ARC Innovation Program

- Stay in contact with DoD and BARDA, and other PHEMCE partners on a regular basis and answer their medical device regulatory questions.
- Speak at DoD, BARDA, and other PHEMCE partner events to discuss programs available for new innovative medical devices and to help them navigate pre-market pathways.
- Work with pre-market review Divisions to educate them on the special needs and special use environments that often accompany MCM medical devices.
- Continue to run a working group that gathers CDRH subject matter experts to respond to DoD, BARDA, and other PHEMCE related questions and requests.

Types of Interactions: Medical Device Manufacturers

- Work with small medical device companies that are developing needed medical devices for the warfighter.
  - Often have no prior experience with FDA and need help with understanding our processes and regulations.
  - Provide strategic help by educating companies on the various pathways available. (ex. Breakthrough Devices Program, HDE, De Novo…)
  - Provide information on the various resources FDA has available on our website.

Provide a POC to ask questions!!

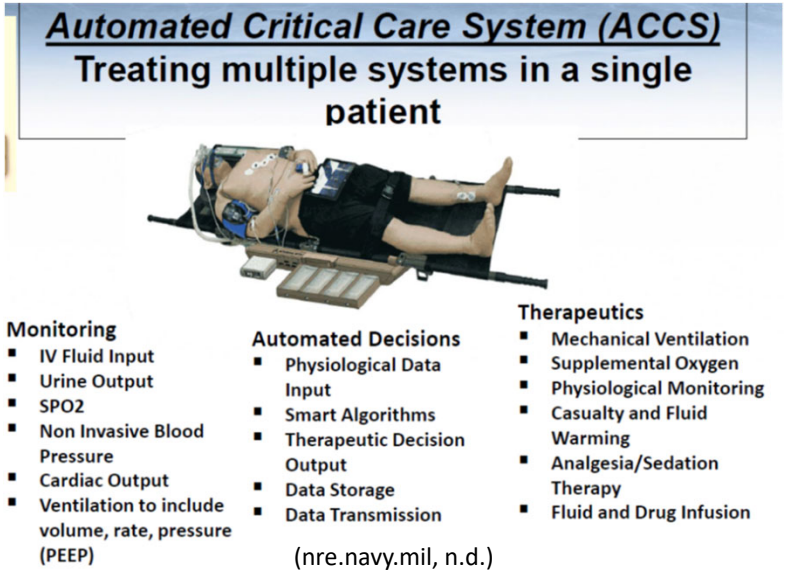
Collaborations with DoD

- Defense Advanced Research Projects Agency (DARPA)
  - Sepsis, Traumatic Brain Injury (TBI), Prosthetics, Wound Stasis System,
- Office for Naval Research (ONR)
  - Automated / Autonomous Critical Care
- ARMY/Medical Research and Development Command (MRDC)
  - TBI, closed-loop control technologies, wearables
- Air Force
  - Closed-loop control ventilation
- DTRA (Defense Threat Reduction Agency)
- Special Operations Command (SOCOM)

(medpagetoday.com, n.d.)

Types of Interactions: Military Contacts

- Regular interactions with the Army, Navy, and Air Force on their medical device development needs.
- Example: ONR's Automated Critical Care System (ACCS)
  - Unique complex device devised of a system of closed loop systems.
  - Established internal group that fields difficult questions on a closed loop systems, unique use environment, etc… Educate internal reviewers on some of the special use environment considerations.



(nre.navy.mil, n.d.)

Types of Interactions: BARDA

- Regular interactions with BARDA to discuss their product portfolio.
- BARDA manages the devices that are in the Strategic National Stockpile. They also fund development of needed MCM devices.
- Example: Shelf-life extension of devices in the Strategic National Stockpile (SNS)
  - Work with OCET to understand the regulations and how they apply for a given situation
  - Work with BARDA to develop an achievable plan to provide testing that will extend the device's shelf-life

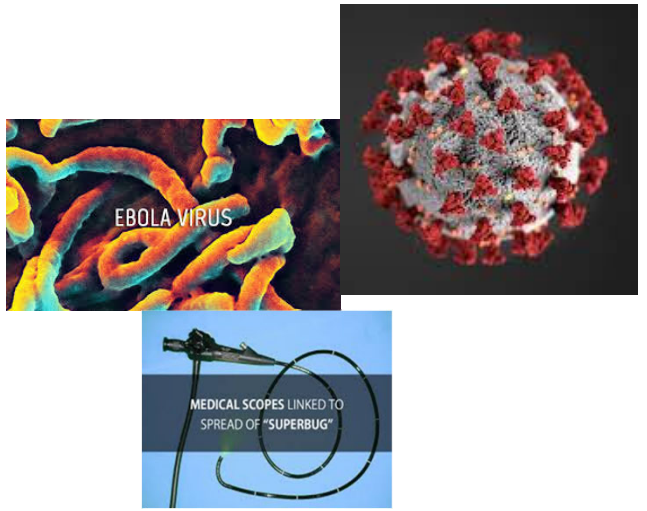
(aspr.hhs.gov, n.d.)

Emergency Preparedness/Operations

- Emergency - an unforeseen occurrence or a combination of circumstances that poses a significant risk to public health and that involves the safety, efficacy, and security of human and veterinary medicines, biological products, medical devices, our Nation's food supply, cosmetics, products that emit radiation, and tobacco products that call for immediate actions by FDA staff

- The ARC program is involved when there are emerging public health issues involving medical devices that require a coordinated response from CDRH.
  - Triage and manage incidents
  - Coordinate interactions with internal and external stakeholders
  - Evaluate and synthesize data associated with the incident
  - Coordinate cross-cutting response for CDRH
  - Brief FDA and CDRH leadership

- Examples:
  - COVID-19 Response
  - Ebola response
  - Heater-cooler devices
  - Duodenoscopes



(cdc.gov, n.d.)
(cidrap.umn.edu, 2021
(topdoctors.co.uk, 2017)

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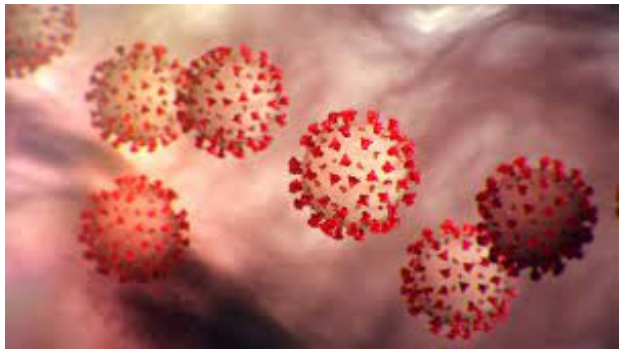
COVID-19 Response

- Serve as the CDRH representative for the Agency level Incident Management Group (IMG)
- Managed non-IVD EUAs at the beginning the PHE
- Managed policies related to Personal protective equipment (PPE)
- Predict, manage, and mitigate shortages
- Creation of the Resilient Supply Chain Program



(hsph.harvard.edu, 2020)

Collaboration with the DoD was Key During the COVID-19 Response

- Relationships with federal partners such as DHA, MRDC, Joint Program Executive Office (JPEO) Chem-Bio, and Air Force were already in place.
- FDA was already aware of devices that the DoD was developing that might be used in the COVID-19 response.
- Based on the device development work done before the pandemic, along with conversation with our federal partners including DoD during the pandemic, FDA quickly had an understanding of the technologies available that could help facilitate the availability of critical devices using
  - EUAs
  - Enforcement policies

(who.int/health-topics/coronavirus, n.d.)

Background

Impact of COVID-19 on the medical device supply chain

The COVID-19 pandemic created cascading disruptions in the medical device supply chain producing shortages in a wide range of critical medical devices

- Personal Protective Equipment (PPE) (N95s, surgical gloves, gowns)
- Respiratory devices (ventilators, filters, breathing circuits)
- Blood collection tubes
- COVID testing kits


Lack of adequate medical supplies can result in harm to patients

(news.mit.edu, n.d.)
(bd.com, n.d.)
(statnews.com, n.d.)
(brainandlife.org, n.d.)

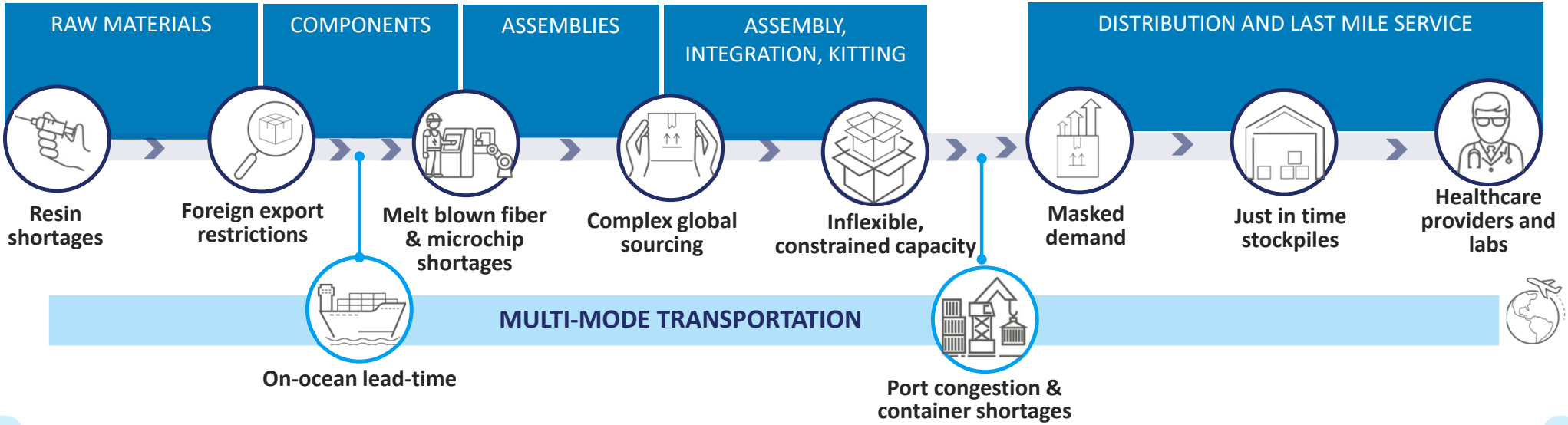
Background

Medical devices are critical during the pandemic

- When the right devices are not available, it affects individual patients and effects the ability of the country to respond to the pandemic.
  - Proactive vs. Reactive – Want to prevent shortages so that it never affects a patient's health
  - Pandemic strained the supply chain – just-in-time manufacturing could not keep up with the demand
  - Major challenges during the pandemic:
    - Raw material shortages
    - Component shortages
    - Shipping overseas/port congestion
    - Transportation inside the U.S.
    - Worker shortages

(who.int/health-topics/coronavirus, n.d.)

Complexity of Medical Device Supply Chain



Source: US Food & Drug Administration

Challenges Predicting Shortages

Limited data available for tracking and predicting shortage

Current FDA databases

- Registration and listing information is not always up to date
- No information on production volumes
- Databases are not connected

Difficult-to-Find Medical Device Data

- Information is distributed among various data sources
- Medical devices are diverse in terms of technology, raw materials, distribution, etc.
- Different types of data may have varying degrees of importance based on the device type

Challenges Predicting Shortages

Creating a shortages program within the Center for Devices and Radiological Health (CDRH/FDA)

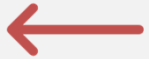
Limited Regulatory Authorities

- FDA had no shortage authorities for devices before 2020
- Now manufacturers need to notify FDA of a disruption in manufacturing or inability to keep up with demand during a public health emergency (506J of the FD&C Act)
- Most information needed is provided voluntarily by manufacturers

FDA's Center for Devices and Radiological Health (CDRH) was building a shortages program during the response to the pandemic

- Pulling together data and information was manual and strained resources
- Information was often incomplete
- Little information on raw materials and components

Novel approaches in the COVID-19 pandemic response



Novel Products

- Blood Purification Devices
- Decontamination Systems for N95s

Novel Manufacturers

- Auto, Airline Manufacturers Making PPE and Ventilators
- 3D Printing of Swabs and Ventilator Components

Novel Policies and Approaches

- Umbrella Emergency Use Authorizations
- Enforcement Policies

Assessing Supply Chain Weaknesses to Prevent Shortages

- Analyze supply data from various internal and external sources
- Outreach to >1,000 manufacturing sites across 12 countries to assess supply chain vulnerabilities
- Horizon scanning to assess demand for devices needed to respond to the public health emergency, including PPE, ventilators, diagnostic supplies, infusion pumps, non-contact infrared thermometers
- Establish a team working with the field to address import issues
- Outreach to component and raw material providers to predict downstream device availability concerns

Collecting Shortage Data and Identifying Critical Devices

- Created a group within CDRH to outreach to various groups and create a list of products critical to the care of COVID patients

- Collaborate with government agencies to share information
  - HHS worked with distributors and hospitals to collect data and create a database to track certain critical products

- Outreach to non-government groups to find new sources of data to further enhance information from internal databases
  - Group Purchasing Organizations (GPOs)
  - Distributors
  - Manufacturers
  - Professional societies

Creation of a Shortages Program

Notification of supply chain disruptions

- Section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C) Act requires manufacturers of certain medical devices to notify the FDA of an interruption or permanent discontinuance in manufacturing of such devices
- The FDA issued immediately in effect guidance to implement and clarify during the COVID-19 public health emergency
  - 506J Guidance: Who, When, What, How of Notification + Example
  - Web: List of Medical Device Types to Help Determine Section 506J Notification Obligations
- Manufacturer notifications contribute critical information to help the FDA assess, prevent, and mitigate shortages during the COVID-19 public health emergency

FDA/CDRH Approach to Addressing Shortages

Inputs

- Engagement & Outreach
- Horizon Scanning
- Supply Chain Illumination
- Supply / Demand Gap Analysis
- Shortage List Management
- Ongoing Collaborations
  - Partnering with CDC, BARDA, SNS, DoD, Assistant Secretary for Preparedness and Response (ASPR), Federal Emergency Management Agency (FEMA)
  - New and existing manufacturers
  - Distributors and End Users

CDRH Mitigation Actions

Outcomes

- Facilitated shortage mitigation
- Umbrella EUAs
- EUA Supplements
- IIEs
- Expedited 510Ks
- Policy updates
- Communications and guidance
- FAQs
- Letters to health care providers
- Facilitated webinars

Shortage Process/Mitigations Plan

Shortage Signal

- 506J Notifications
- Signal from GPOs or distributors
- Device Shortag Mailbox
- Other government agencies

Signal Triage

- Outreach to manufacturers, GPOs, distributors
- Alternatives available
- Market sho
- Effects unclear; need to monito
- Significant disruption?
- Brand specificity?

Shortage Assessment

- Outreach to manufacturers
- Production numbers/demand
- Get well date
- Identify pain points in the supply chain

Possible Mitigations

FDA Mitigations

1. Outreach to other manufacturers for increased production
2. Emergency Use Authorization to bring in new product
3. Enforcement discretion
4. Expedited review of submission for new product
5. Conservation strategies
6. Work with non-traditional manufacturers
7. Communications

Outside of FDA

1. DPA authority
2. Industrial-based expansion
3. Others

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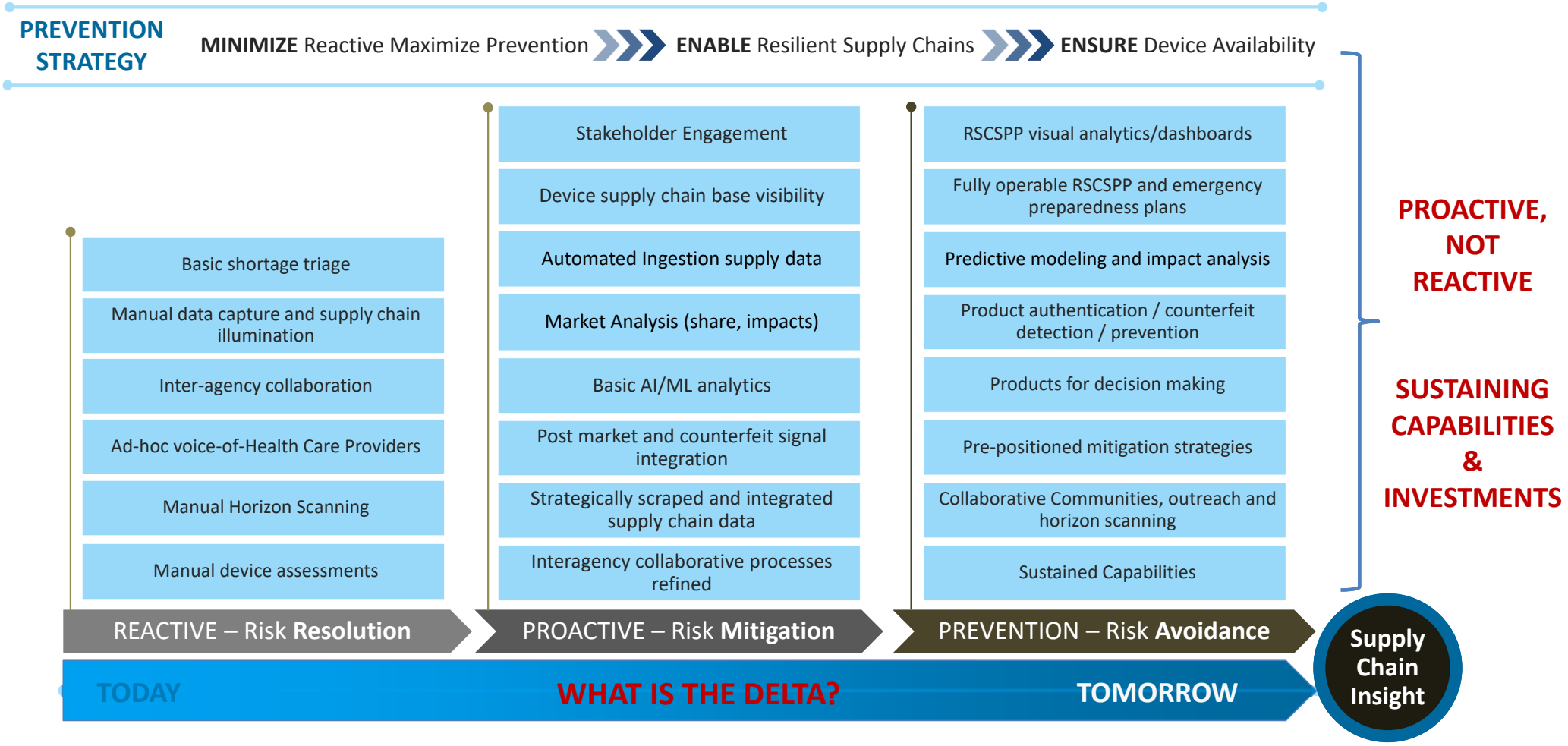
Roadmap to Resiliency

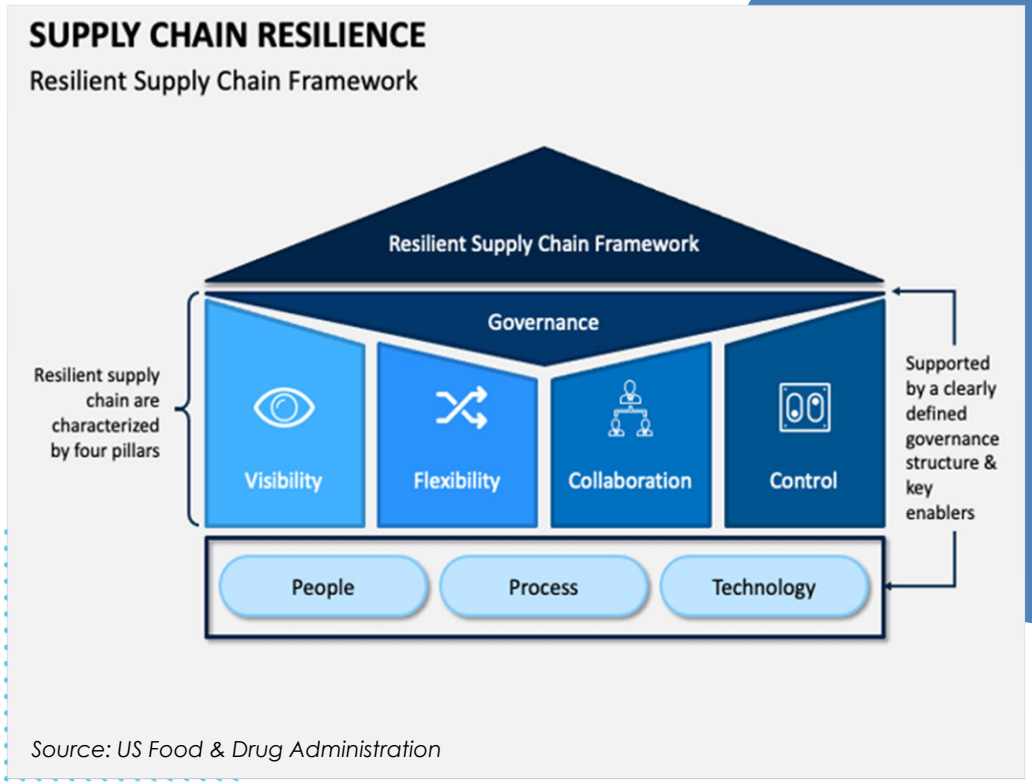


Source: US Food & Drug Administration

Resilient Supply Chain Program

Permanent, proactive program that reduces foreign dependence on medical devices and their components by ensuring availability of safe and quality medical devices for patients, health care providers, and other members of the American public in all settings

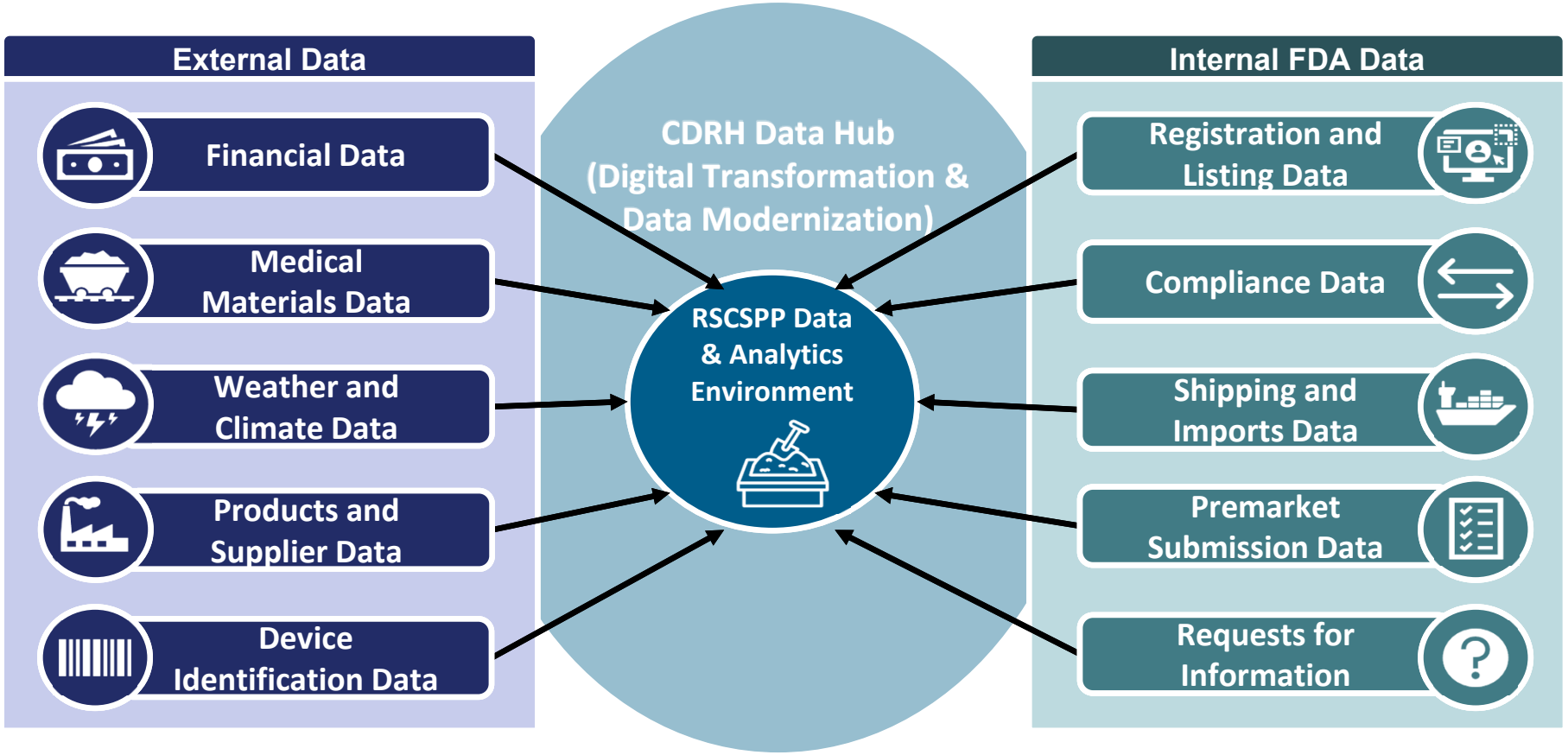
- **Enhancing Resilience** in the medical device supply chain by developing approaches to identify risk, anticipate and prevent potential supply chain disruptions, and inform response and mitigation actions
- **Supply Chain Monitoring** that will leverage advanced analytics and predictive modeling with real-time and integrated multi-sectoral data to enable proactive identification of potential supply chain disruptions
- **Triaging** signals and alerts of medical device shortages and potential supply chain disruptions to **Support Mitigation** plans and priorities and captures observations to improve resilience and response actions
- **Research & Innovation** to investigate and communicate best practices in supply chain sourcing, distributing, and monitoring, and communications



Source: US Food & Drug Administration

Supply Chain Resilience PowerPoint Template - PPT Slides | SketchBubble

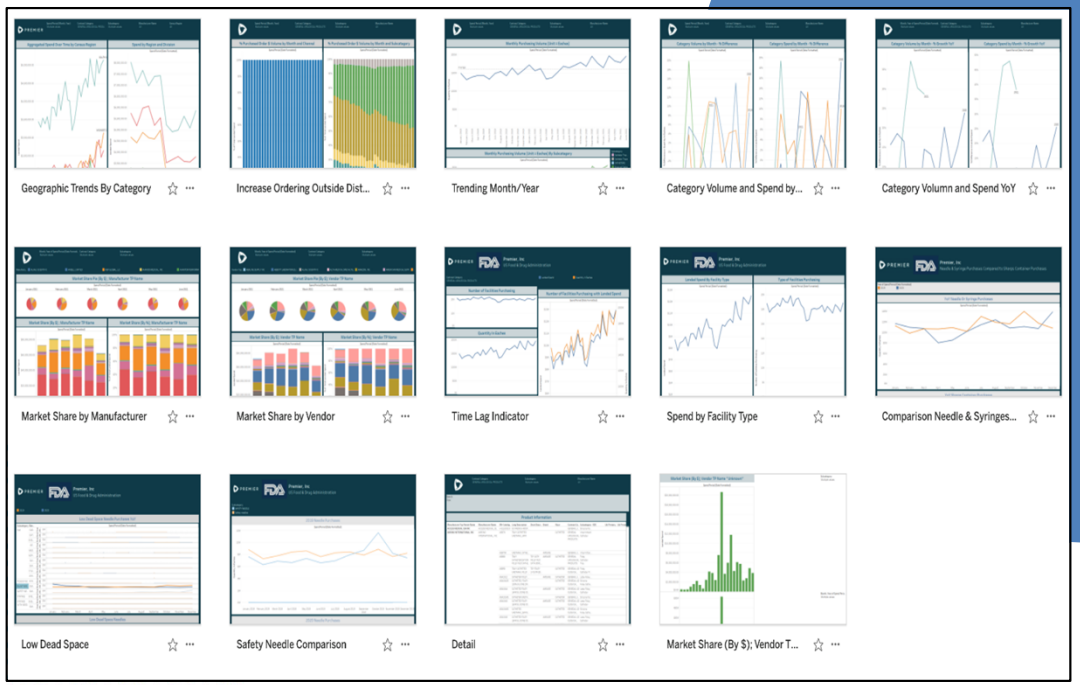
A Multi-source Dataset for Supply Chain Data Science



Source: US Food & Drug Administration

Self-service data analytics & visualization

- Data source vendor hosted advanced self-service analytics tools
- Analysts could get to work right away, directly on the data, with no technical setup
- Easily create their own dashboards, data visualizations
- Premier data stewards provided explanation and validation of data understanding

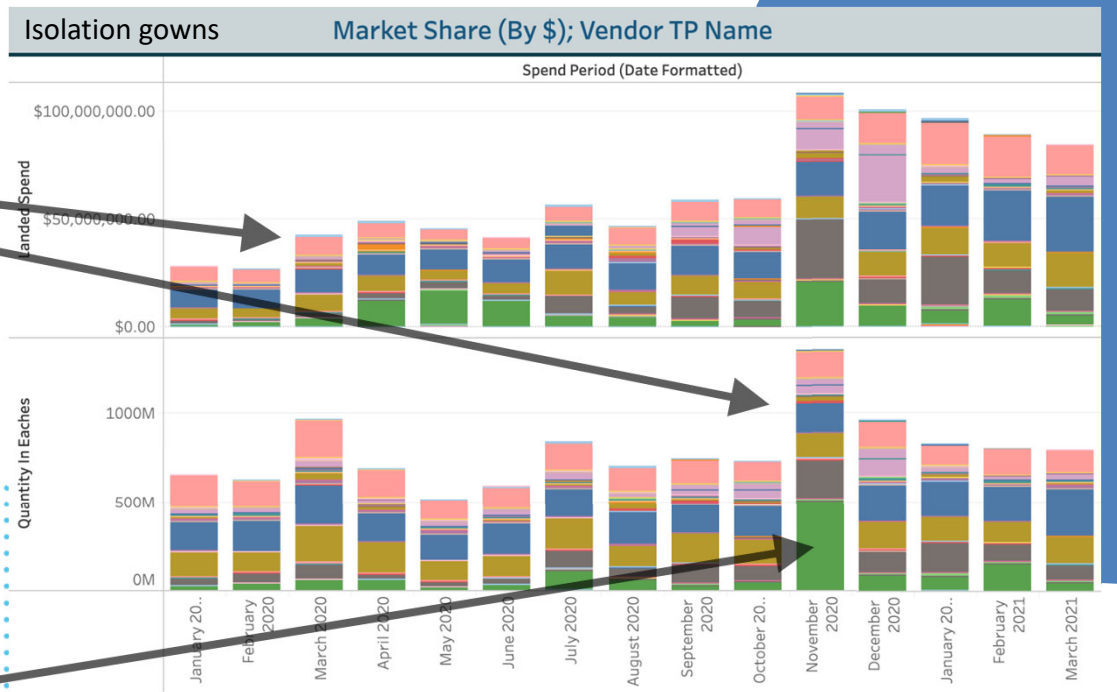


Source: US Food & Drug Administration

Signals of shortage

Large increase in total quantity ordered

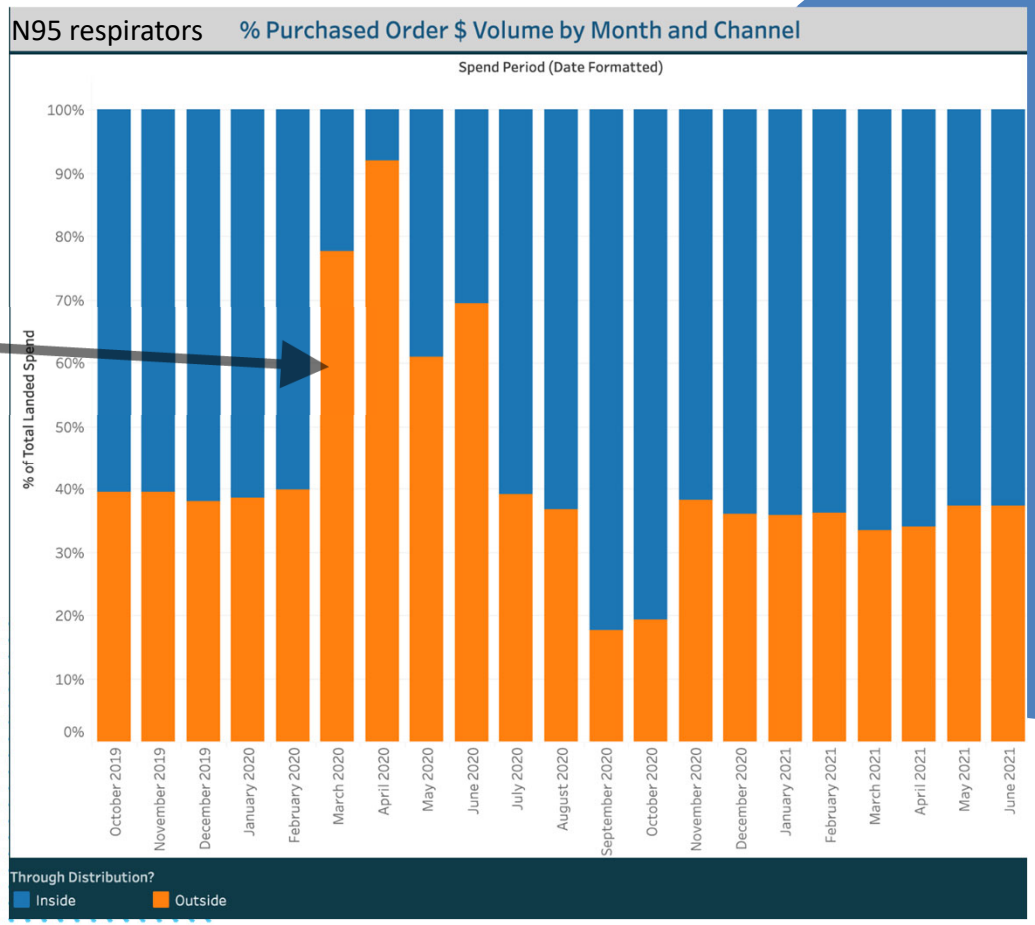
Hospitals seeking alternative suppliers: Increase in orders from unknown suppliers (green)



Source: US Food & Drug Administration

Signals of shortage

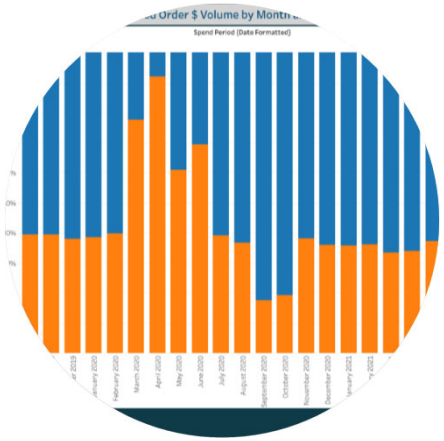
- Increase in orders from outside distributors

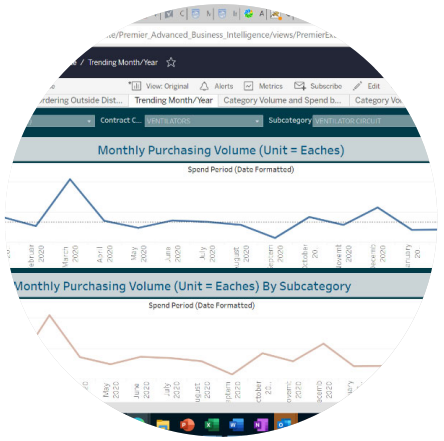


Source: US Food & Drug Administration

Using Multiple Data Sets for Monitoring and Predicting Shortages

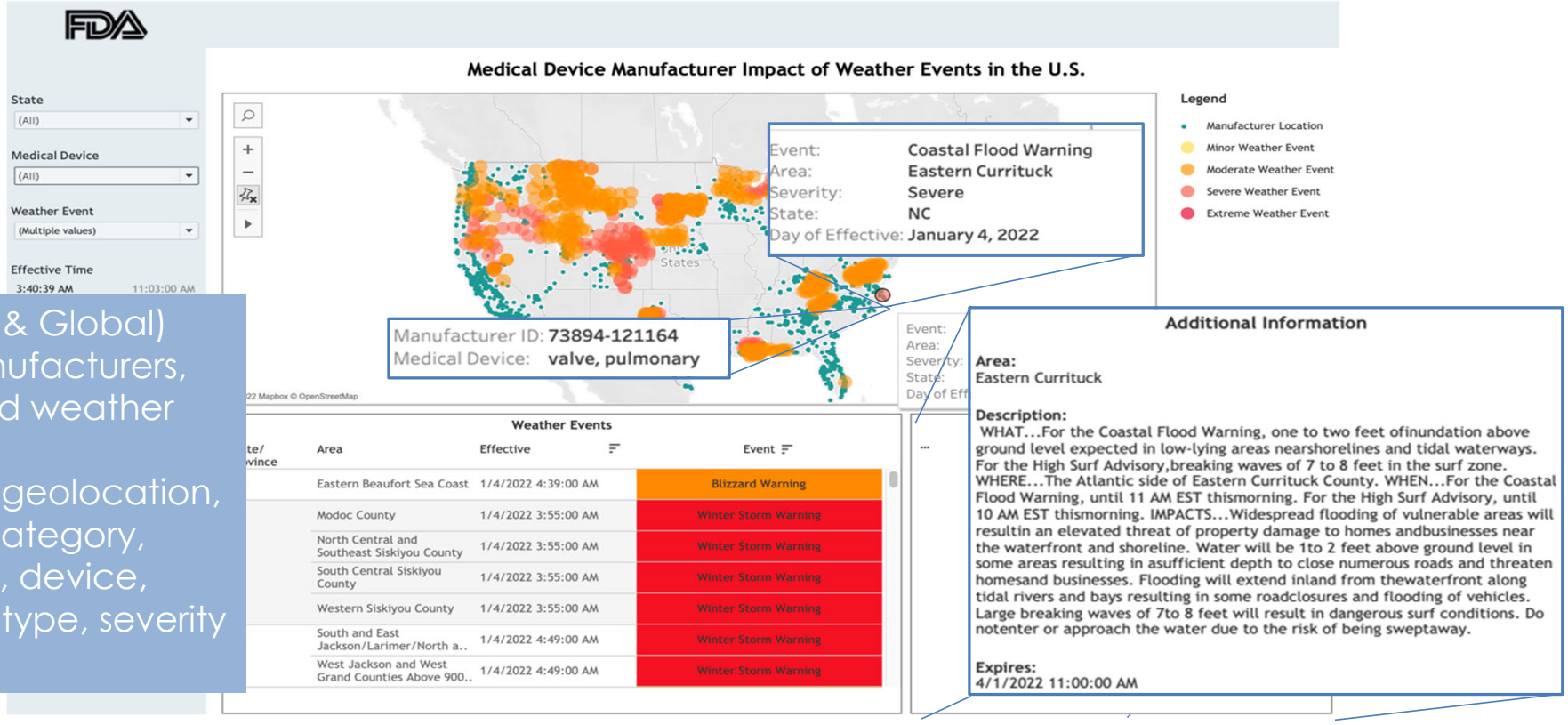
- Market share data for a given device type
- Trends in purchasing outside distribution
- Manufacturing locations and import data
- Estimate of fill rates based on invoice and purchase order (PO)
- Spend data/Monthly purchase volume
- Facility trending and forecasting





Example
Preliminary Visualization: Weather Events

- Map (US & Global) with manufacturers, ports, and weather events
- Filters by geolocation, device category, procode, device, weather type, severity



Source: US Food & Drug Administration

Preliminary Visualization: Risk Scorecard

User filters by procode and/or risk level

Select Device Procode:	MSH		Select Risk:	All
Risk Category	Upstream Risk	Manufacturing Risk	Downstream Risk	Category Risk Composite
Financial Risk	**1** *T1/T2 suppliers*	**23** *Finished Product*	**11** *Hospital data*	**12**
Manufacturer Diversification / Market Share Risk	**10** *T1/T2 Suppliers*	**11** *Finished Product Manufacturers*	**8** *Dispensation point demand*	**10**
Geographic Risk	**40** *Component/Sub-assemblies*	**75**	**15** *Relates to transportation*	**43**
Transportation Risk	**25** *To Manufacturers*		**78** *To Hospitals*	**49**
Recall/Quality Risk	**1** *Component Recalls*	*FDA-level recalls*	**56** *Adverse events*	**24**
	50 */T2 Suppliers (SAM etc.)*	**50** *Finished Product*	**75** *Pilferage / Illegal substitution*	**58**
	5 *Refinery Labor etc.*	**10** *Plant/Warehouse labor*	**75** *Hospital staffing etc*	**30**
	5 *Raw materials*	**45** *Key sub-assemblies (ie semiconductors*	*s*	**22**
	55 *terial export regulations*	**90** *Customs Clearance Issues*	*?A etc.)*	**78**
			Total Composite Risk Score for Device:	**36**
				Scale: 0-100

Risks by category across end-to-end supply chain will be added over time

Composite scores, weighting by impact, likelihood, etc. are in roadmap

- Scorecard, built over time, to capture various aspects of risk to a product category or device
- Filter by procode, risk

Source: US Food & Drug Administration

Next Steps

- Automating integration of datasets
- Building out the Resilient Supply Chain Shortages Prevention Program
- Working with partners to develop better data visualization methods to quickly identify shortages

Key Takeaways

- Understand FDA's Center for Devices and Radiological Health's (CDRH) role in pandemic response and preventing shortage.
- Identify supply chain challenges and risk mitigation strategies for medical device shortages.
- Identify key data sources for detecting supply shortages and conducting demand planning.
- Identify challenges that impact shortage detection, demand planning, and forecasting.

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https://www.fda.gov/about-fda/cdrh-offices/office-strategic-partnerships-and-technology-innovation

Where to go for help

General Questions:

- FDA Medical Device website (www.fda.gov/medicalDevices/)
  - Guidance Documents
  - Public information on cleared or approved devices
  - Regulations
- Heather.Agler@fda.hhs.gov

Division of Industry and Consumer Education (DICE)

- If you have a question – Email: DICE@fda.hhs.gov
- Phone 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30pm EST)

Web Homepage:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Questions?

How to Obtain CE/CME Credits

To receive CE/CME credit, you must register by 0800 ET on 28 October 2022 to qualify for the receipt of CE/CME credit or certificate of attendance. You must complete the program posttest and evaluation before collecting your certificate. The posttest and evaluation will be available through 27 November 2022 at 2359 ET. Please complete the following steps to obtain CE/CME credit:

1. Go to URL: https://www.dhaj7-cepo.com/content/oct-2022-ccss
2. Search for your course using the Catalog, Calendar, or Find a course search tool.
3. Click on the REGISTER/TAKE COURSE tab.
   a. If you have previously used the CEPO CMS, click login.
   b. If you have not previously used the CEPO CMS click register to create a new account.
4. Follow the onscreen prompts to complete the post-activity assessments:
   a. Read the Accreditation Statement
   b. Complete the Evaluation
   c. Take the Posttest
5. After completing the posttest at 80% or above, your certificate will be available for print or download.
6. You can return to the site at any time in the future to print your certificate and transcripts at: https://www.dhaj7-cepo.com/
7. If you require further support, please contact us at: dha.ncr.j7.mbx.cepo-cms-support@health.mil