



Mass General Brigham

# FDA Panel on Medical Device Supply Chain Resiliency and Shortages and the Proposed 506J Device List :

## Mass General Brigham's Perspective

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# Mass General Brigham

Mass General Brigham is a nonprofit organization committed to patient care, research, teaching, and service to the community. In addition, Mass General Brigham is one of the nation's leading biomedical research organizations with several Harvard Medical School teaching hospitals.

Mass General Brigham is an integrated academic health care system that connects a full continuum of care across a system of academic medical centers, community and specialty hospitals, a health insurance plan, physician networks, community health centers, home care, and long-term care services.

## **Patient care**

From routine care to the most complex cases, we offer comprehensive, full-circle clinical care to our patients, starting and ending at home.

## **Research and discovery**

Because we are built on a legacy of medical discovery, our researchers push the boundaries of knowledge and advance medicine in new and innovative ways.

## **Teaching**

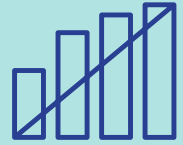
We have over 100 accredited physician residency and fellowship programs, and over 2,000 trainees preparing to be the healers of tomorrow.

## **Community**

We have five licensed and 15 affiliated community health centers. We have diverse community partnerships to support our local residents.



# Mass General Brigham At-a-Glance



**\$16 Billion**  
Total Operating  
Revenue



**\$2+ Billion**  
Over \$2.2 Billion in  
research activity  
with more than \$1  
Billion in direct  
DHHS funding



**Mass General  
Brigham System**

- 12 Acute and Specialty Hospitals
- 5 Harvard-affiliated Teaching Hospitals
- 28 Rehabilitation Locations
- 4 Ambulatory Surgery Centers
- 22 Urgent Care Centers
- 5 Community Health Centers

**Largest Private Employer  
in Massachusetts**



**~7,000**  
Physicians & Fellows  
**82,000**  
Employees



**2.5 Million**  
Unique Patients



# Supply Chain Shortages in Healthcare

- Premier Inc. comments that *“data indicate that shortages are largely shifting from multi-year, pervasive issues to an unpredictable revolving door of new products/categories every month.”*
- Healthcare systems commonly face many hurdles maintaining situational awareness and responding effectively during supply chain shortage events
  - Little advanced notice before shortages appear
  - Very little awareness of impacts on neighbor health systems
  - Opaque and variable timelines for resolution
  - Limited initial awareness of alternative products, strategies available in response



# Supply Chain Shortages are a Major Concern for Healthcare

What do you anticipate will be the overall largest operational and financial challenge for your organization in the next 12 months? Please rank.



- 45.81% Inflation and related effects on product costs
- 39.29% Ongoing supply disruptions, backorders and product shortages
- 46.02% Increased healthcare labor costs
- 39.82% Concerns of healthcare labor availability
- 7.08% Uncertainty in patient volumes
- 11.50% Inability to facilitate conversations due to staff limitations/bandwidth

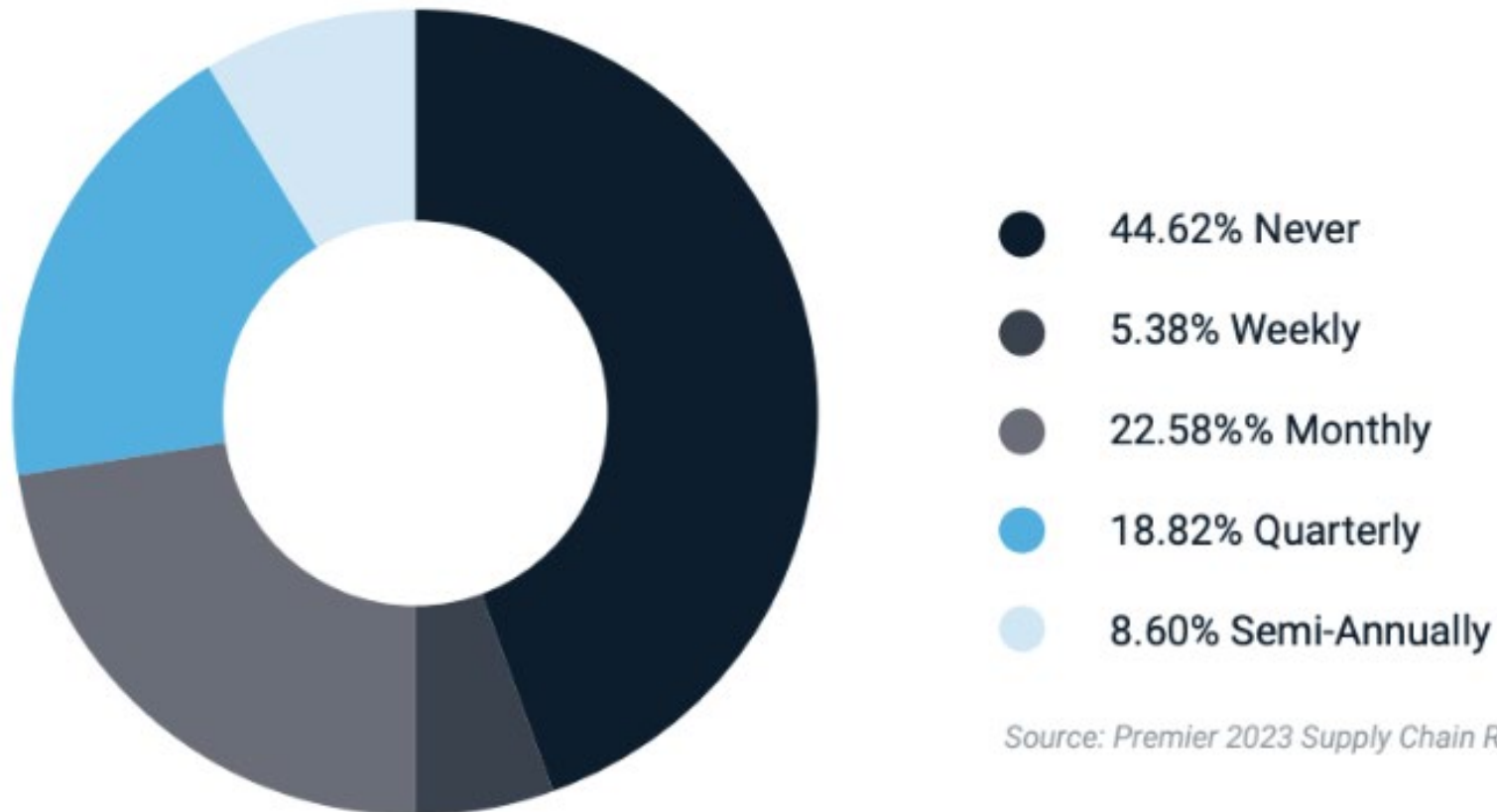
Source: Premier 2023 Supply Chain Resiliency Survey

<https://premierinc.com/newsroom/blog/new-premier-data-highlights-healthcare-supply-chain-landscape-challenges-and-strategies-for-success>



# Supply Chain Shortages in Healthcare

**In 2022, how frequently did your organization have to cancel or reschedule cases due to product shortages?**



Source: Premier 2023 Supply Chain Resiliency Survey



# Supply Chain Shortages in Healthcare

How much time is your team / organization spending on mitigating supply chain risk or navigating product disruptions?



- 21.64% Less than 10 hours per week
- 36.60% Between 10 and 20 hours per week
- 36.84% More than 20 hours per week
- 2.92% Other (please specify) (1)

Source: Premier 2023 Supply Chain Resiliency Survey



# Recent Major Supply Chain Shortages

- N-95s
- Surgical sterile gowns
- Procedure gloves
- Procedure gowns
- CPAP machines
- Blood collection tubes
- OR tourniquets
- IV fluids
- IV contrast
- Butterfly needles
- Suction catheters
- Heparin
- Epinephrine
- Packed red blood cells
- Platelets
- Immunoglobulin
- Lidocaine
- Atropine
- Epi-pens





# Coordination of the Institutional Response

- Convening stakeholders from multiple affected medical services can quickly become complex
- Requires strong medical and emergency management leadership
- Inventory management and product allocations can be extremely labor intensive
- Requires frequent and transparent communication to clinical and patient stakeholders



# Regional Coordination

- Healthcare coalitions generally lack the authority to coordinate distribution of scarce medical supplies or to compel sharing of inventory levels
- Public health authorities vary, but resource sharing is very rarely mandated
- Larger health systems may weather shortages more easily than smaller hospitals and other healthcare facilities
  - Nursing homes, EMS services and others similar entities are especially vulnerable
  - Can lead to situations of haves/have nots
- At the extremes, can lead to adoption of crisis standards of care strategies for unequal reasons in unequal ways



# Specific Requests from a Healthcare System's Perspective

## **Early Notification**

- Create incentives for communication at the earliest possible moment
- A minimum of 3 months' notice for any product discontinuations is needed to maintain continuity of clinical services

## **Development of a Standardized Format for Notification:**

- Develop a standardized reporting process for all discontinued medical devices similar to the recall notification process
  - This process for manufacturers to report should be routed through the FDA
  - The process must be mandatory and assure greater transparency from manufacturers

## **Assurance of Transition Plans:**

- Require all notifications or product discontinuations from manufacturers to include suggestions for alternative products/practices – including products from alternative manufacturers



# Specific Requests from a Healthcare System's Perspective

## **Supplier Engagement**

- Create incentives for proactive reporting by penalizing manufacturers that do not follow process from disallowing future 510K approvals for 1 year

## **Centralized Information Hub:**

- Consider maintaining a database that cross-references all like products and stores all manufacturer notifications
- Consider developing a feedback solution for organizations to provide commentary on challenges with recommended solutions
- Consider establishing a tool that enables assessment of the impacts of global/regional events on manufacturer supply chain resource disruption

## **Requirements to Develop Guidelines for On-Site Reprocessing of Single Use Components:**

- When sterile and safe solutions could exist for re-use of components designed for single use (such as ventilator tubing) during shortages, require manufacturers to develop, validate, and disseminate the solutions





**Mass General Brigham**