Leaning Forward Together for Medical Device Supply Chain Resilience

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By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. The United States needs resilient, diverse, and secure supply chains to ensure our economic prosperity and national security. Pandemics and other biological threats, cyber-attacks, climate shocks and extreme weather events, terrorist attacks, geopolitical and economic competition, and other conditions can reduce critical manufacturing capacity and the availability and integrity of critical goods, products, and services…

More resilient supply chains are secure and diverse — facilitating greater domestic production, a range of supply, built-in redundancies, adequate stockpiles, safe and secure digital networks, and a world-class American manufacturing base and workforce. Moreover, close cooperation on resilient supply chains with allies and partners who share our values will foster collective economic and national security and strengthen the capacity to respond to international disasters and emergencies.
Today’s Supply Chain Complexities

Supply chain disruptions pre-date COVID and will continue in the future

**Just in Time Delivery**
Minimizing inventory costs + increasing risk from disruption

**Sole-Source Suppliers**
Supply base consolidation

**Labor + Logistics**
Shortage of workers + transportation bottlenecks

**Climate Change**
More frequent weather disruptions + natural disasters

**Geopolitical Competition**
Increased trade disruption + competition for resources

**Demand Shocks**
Increased demand due to pandemic or post-pandemic illnesses
Disruptions Impact Public Health + National Security

*We need a more resilient supply chain to protect patients and providers*
Our Challenge

No single entity can resolve these issues on its own. We must work collaboratively to proactively identify and address vulnerabilities.
Why the FDA Should be Involved?

Supply chain resiliency is directly aligned to the FDA’s mission

Patient Perspective  Domain Expertise  Mission Alignment
The Resilient Supply Chain Program (RSCP)

**Vision:**
The CDRH envisions resilient public health supply chains that promote the availability of safe and effective medical devices for consumers, patients, and health care providers.

**Mission:**
Strengthen public health supply chains by proactively monitoring, assessing, and communicating risks and vulnerabilities to prevent shortages of medical devices.
RSCP’s Value Proposition

A permanent, proactive capability to prevent and respond to shortages

Engage Proactively
Reactive mitigation to proactive planning

Convene Stakeholders
Information sharing + coordinated action

Increase Resilience
Program support for resilience building

Streamline Government Engagement
Central coordinator with Federal agencies
What We Need From You

We are seeking input, feedback, and collaboration on:

- RSCP program activities
- Methods of collaboration and information sharing
- Defining medical device resiliency
- Identifying innovative methods for promoting device availability
Our Mission: Public Health

Help us build a program that provides value to patients, healthcare workers, and the medical device industry.