Program Office for Innovation and Industrial Base Expansion

Medical Supply Chain Update

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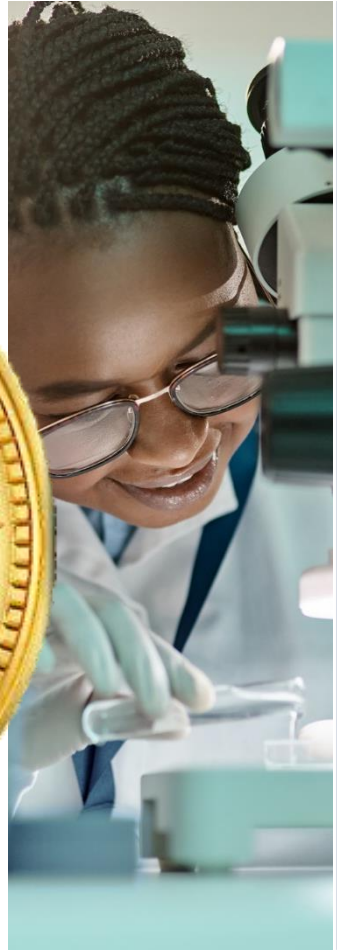
Prepared for: NASEM Committee on Security of America's Medical Product Supply Chain

ASPR Mission

Save Lives and Protect Americans from Health Security Threats



IBx Mission

Establish the permanent integrated capabilities at ASPR required for resilient domestic medical supply chain and public health industrial base lifecycle management

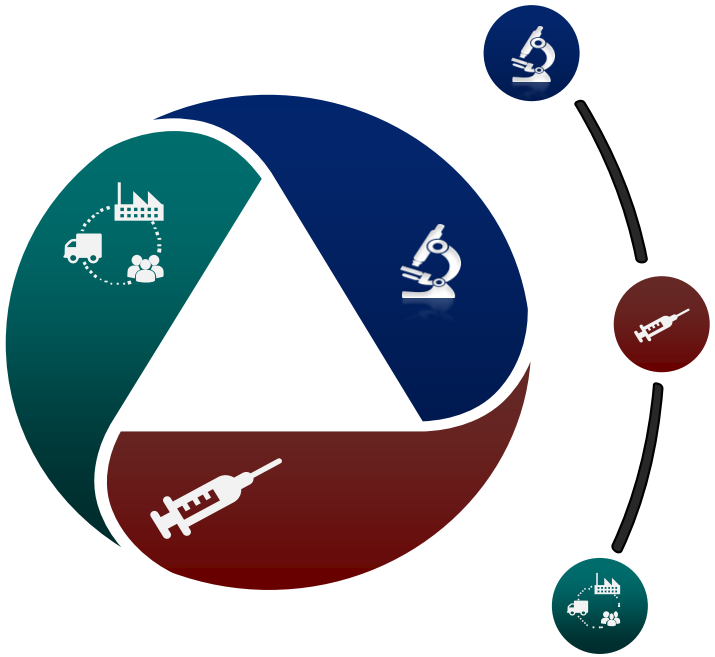
Industrial Base Expansion (IBx) Program Office

- **Execute ASPR's overall IBx vision and strategy**
  - Continuously evaluate and refine requirements – target volumes, types of investments needed, etc
  - Execute IBx programs in ASPR in support of all Divisions, inclusive of BARDA, SNS, EMMO, SIIM and ORM to address Supply Chain vulnerabilities across all medical supply sectors

- **Strengthen governance and processes**
  - Coordinate across HHS (ASPR, NIH, OASH FDA), DFC, NIST, DoD, and other stakeholders to consolidate past and near-term processes, roles, contracts, and responsibilities for efficient execution
  - Execute Medical Industrial Expansion Programs with new USG Governance -structured and consistent decision-making process Strengthen tracking & accountability mechanisms including oversight of previous acquisitions and when production is expected to deliver / come online / wane

- **Define longer-term plan for IBx sustainability**
  - Leverage the Critical Infrastructure Partnership Advisory Council Title I, Title III, and Title VII authorities under DPA to commercialize solutions that build resiliency
  - Continue to assess dynamically what is needed to sustain or re-activate domestic production capacity for future pandemics / public health emergencies

IBx Expansion Priorities – Future State



Focus Areas

- Vaccine Production and Administration
- Platform Technology Development
  - Therapeutic Production and Delivery
  - Priority Medicines on Demand
- PPE Expansion
  - Establish new sub-tier manufacturing capacities – NBR, Melt-Blown, Assembly
  - Materials Science Applications for PPE Reuse
- Diagnostic commercialization, production and fielding

Transform Development and Fielding

- Direct Partnerships with DARPA, DFC, NIH RAD-X, and large technology partner for rapid realization
- Public Private Partnerships that leverage opportunities within and outside of Government
- Modernize domestic pharmaceutical manufacturing with Priority Medicines on Demand
- Change distribution/administration paradigms

Targeted Investment Strategy

- Well placed, performance-based investments
- External partnering to realize capability – e.g. meddevicenetwork.org, DFC investments, BARDA Ventures
- Flexible funding and ROI-driven approaches

100 Day Report Background

- On June 8, 2021, the White House released its 100-day supply chain review of critical industries.
- The Executive Order directed the Administration to immediately launch a 100-day review and strategy to address vulnerabilities in the supply chains of four key product categories, including pharmaceuticals.
- The 100-day pharmaceutical review and report was led by the Department of Health and Human Services (HHS), notably the FDA and ASPR.

100-Day Set of Actions/Four Pillars for Building Resilient Pharmaceutical Supply Chains

1. Boost Local Production and Foster International Cooperation
2. Promote research and development that establishes innovative manufacturing processes and production technologies to strengthen supply chain resilience
3. Create robust quality management maturity to ensure consistent and reliable drug manufacturing and quality performance
4. Leverage data to improve supply chain resilience

HHS Plan of Action

1 Boost Local Production and Foster International Cooperation

1. Leverage the Defense Production Act and Current Public-Private Partnerships to Establish a Consortium for Advanced Manufacturing and Onshoring of Domestic Essential Medicines Production.
    - Special priority should be given to strengthen the supply chain for sterile injectable products which are critical in acute care health care settings

2. Utilize the Development Finance Corporation Loan Program to encourage and enhance domestic medical supply increased production.

3. Collaborate with allies to develop supply chains that are diverse and complementary.

HHS Plan of Action

2 Promote research and development that establishes innovative manufacturing processes and production technologies to strengthen supply chain resilience

1. Develop fully integrated and smaller footprint platforms that will reduce supply chain demands for raw materials, increase domestic pharmaceutical manufacturing surge capacity, and more broadly improve technological capabilities that can lead to the manufacturing of APIs and supportive care fluids.

2. The Department of Health and Human Services will make an initial commitment of $60 million in funding from the American Rescue Plan to develop novel platform technologies to increase domestic manufacturing capacity for API. Greater API production domestically will help reduce reliance on global supply chains for medications that are in shortage, particularly during times of crisis.

3. HHS will also develop a strategy for facilitating a wider adoption of novel methods for commercial production of pharmaceuticals and biologics.

HHS Plan of Action

3 **Create robust quality management maturity to ensure consistent and reliable drug manufacturing and quality performance.**

1. Recognize and reward manufacturers for mature quality systems that focus on:
   - continuous improvement
   - business continuity plans; and
   - early detection of supply chain issues.

HHS Plan of Action

4 Leverage data to improve supply chain resilience

1. Establish new initiatives to collect additional supply chain data to improve proactive surveillance, oversight and supply chain resiliency.

The following are several critical sources of new data necessary to support such surveillance work (as noted in the White House report, some may require additional legislative authority in order for HHS to collect):

1. Drug manufacturing volume information and reporting;
2. Complete registration and listing requirements;
3. Distribution data on prescription drugs and certain biological products;
4. Requiring manufacturers to notify FDA of an increase in demand; and
5. Requiring that the labeling of API and finished product labeling include original manufacturers.

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