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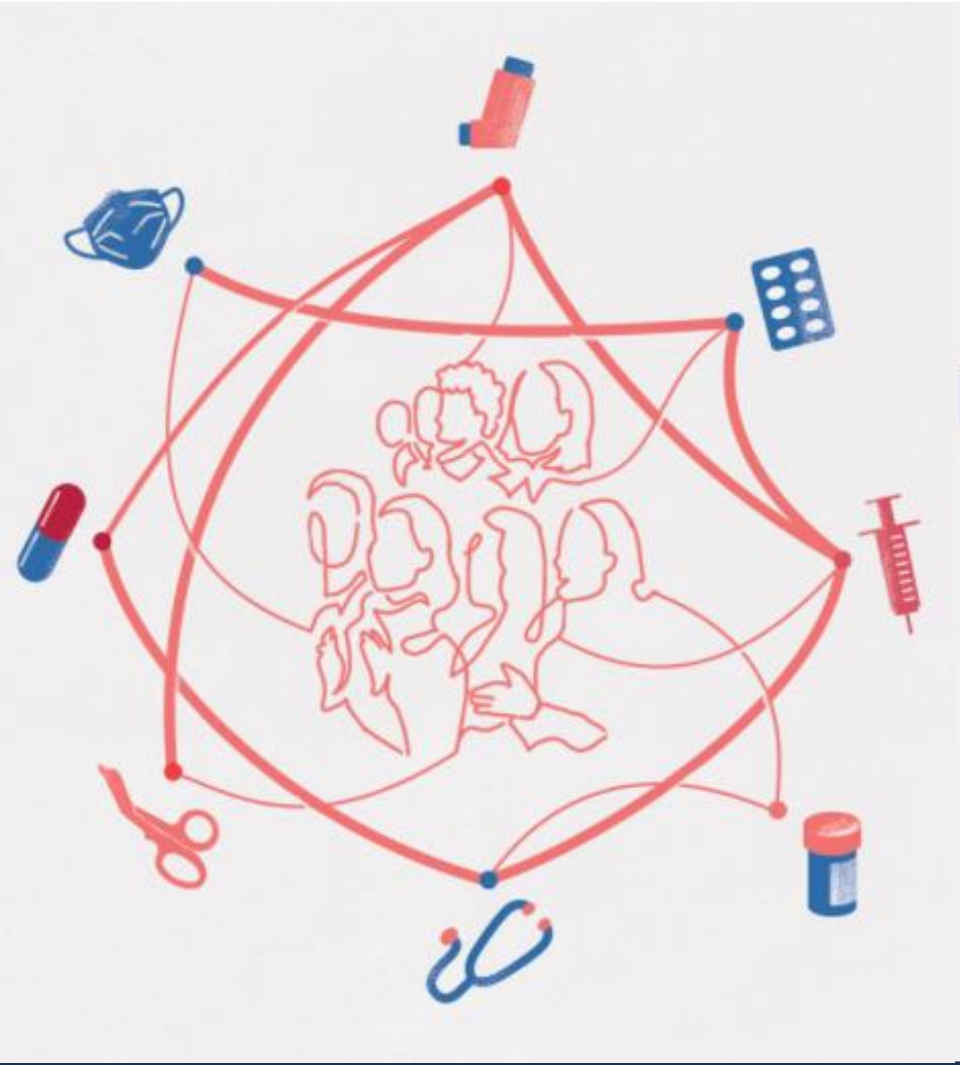

BUILDING RESILIENCE

into the Nation's

MEDICAL PRODUCT SUPPLY CHAINS

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Study Sponsor

- HHS Office of the Assistant Secretary for Preparedness and Response

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Statement of Task

CARES Act

- Recent disasters and health emergencies have increased recognition of the fragility of the U.S. medical supply chain and underscored the need to explore potential policy, regulatory, and systems solutions to prevent and mitigate the impacts of shortages on public health, national security, and patient care.
- Section 3101 of the CARES Act, signed into law on March 27, 2020, directed the HHS Secretary to enter into an agreement with the National Academies to establish an ad hoc committee to examine the security and resilience of the U.S. medical product supply chain.

Charge to the Committee

- Assess and evaluate the dependence of the United States on critical drugs and devices that are sourced or manufactured outside of the United States.
- Provide recommendations to improve the resiliency of the supply chain for critical drugs and devices and address supply vulnerabilities or potential disruptions of such products that would significantly affect or pose a threat to public health security or national security, as appropriate, which may include strategies to—
  - promote supply chain redundancy and contingency planning;
  - encourage domestic manufacturing, including consideration of economic impacts, if any;
  - improve supply chain information gaps;
  - improve planning considerations for medical product supply chain capacity during public health emergencies; and
  - promote the accessibility of such drugs and devices.

Study Approach

Study Methods

- Iterative review of current and relevant literature
- 5 virtual committee meetings and numerous monthly committee calls held between September 2020 and October 2021
- 6 public meetings, including one workshop and a summary of this workshop is captured in: *The Security of America's Medical Product Supply Chain: Considerations for Critical Drugs and Devices: Proceedings of a Workshop—in Brief*

Report Organization

- **PART I: OVERVIEW OF GLOBAL MEDICAL PRODUCT SUPPLY CHAINS**
- **Chapter 1**: Introduction
- **Chapter 2**: Understanding Medical Product Supply Chains
- **Chapter 3**: Globalization of U.S. Medical Product Supply Chains
- **Chapter 4**: Causes and Consequences of Medical Product Supply Chain Failures
- **PART II: MEASURES FOR ENHANCING THE RESILIENCY OF MEDICAL PRODUCT SUPPLY CHAINS**
- **Chapter 5**: A Framework for Resilient Medical Product Supply Chains
- **Chapter 6**: Awareness Measures for Resilient Medical Product Supply Chains
- **Chapter 7**: Mitigation Measures for Resilient Medical Product Supply Chains
- **Chapter 8**: Preparedness Measures for Resilient Medical Product Supply Chains
- **Chapter 9:** Response Measures for Resilient Medical Product Supply Chains

Background

Understanding Medical Product Supply Chains

- Medical product supply chains are complex, multi-stage, global systems that involve people, processes, technologies, and policies.
- The report categorizes the products into:
  - ***Drugs***
    - *Originator drugs* (drug or biological products approved by FDA through an ANDA or BLA)
    - *Generic drugs* (approved by the FDA through an ANDA or BLA)
  - ***Medical Devices***
    - *Simple medical devices* (Class I)
    - *Complex medical devices* (Class II and III)
- Production processes and supply chains for drugs and devices vary considerably depending on product.

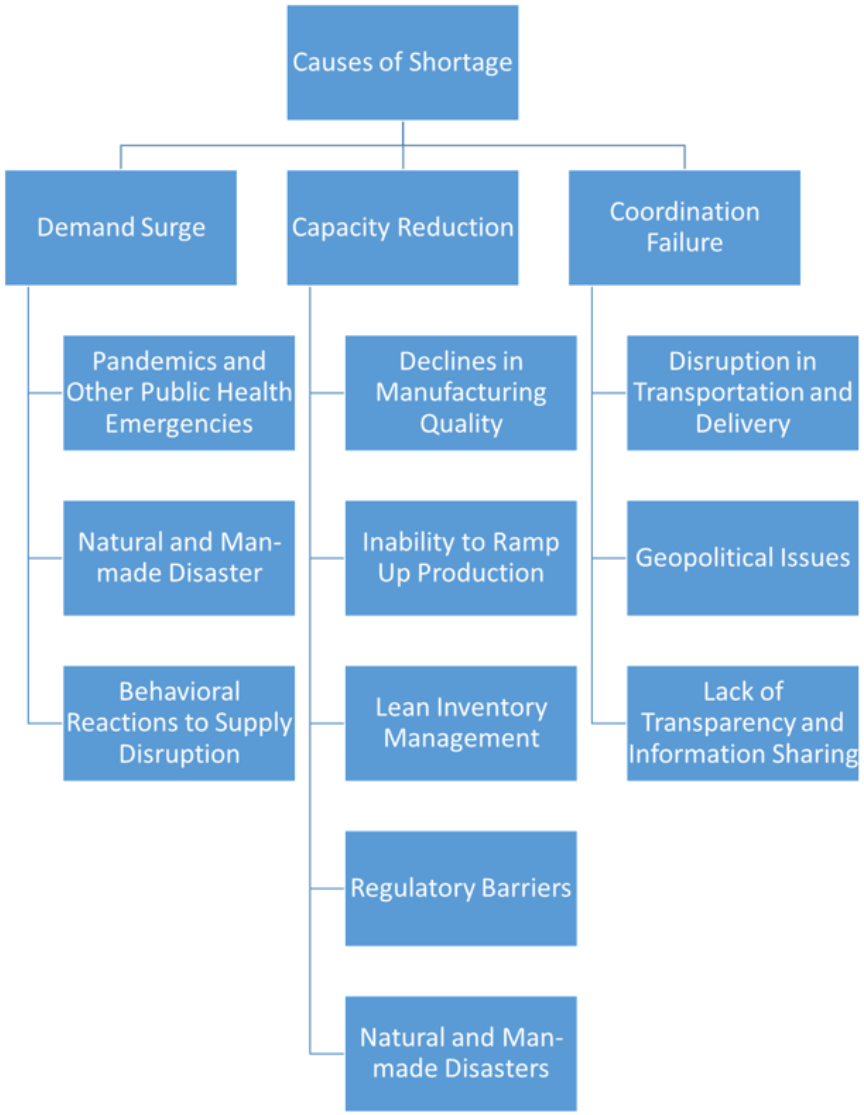
Understanding Medical Product Supply Chains

- Two important insights:
  1. There is no one-size-fits-all strategy for increasing the resilience of supply chains for all medical products.
     - Different medical product supply chains, different markets, and different risk profiles all require different interventions. The key challenge is to match measures to products in a cost-effective manner.
  2. Current medical products classification schemes are based on clinical importance. Decisions about how to enhance medical product supply chain resilience will need to account for include shortage risks.
     - The committee defines the term *supply chain critical* medical products as those that are both medically essential and vulnerable to shortages.

Globalization of U.S. Medical Product Supply Chains

- U.S. medical product companies have increasingly sourced production of products, components, and raw materials from locations around the globe.
  - Benefits: lower manufacturing costs, increased supply security, improved affordability of drugs (generics)
  - Drawbacks: challenging to inspect and regulate international production, issues regarding quality and safety of products, lack of transparency in sourcing and supply chains, difficult to assess supply chain vulnerabilities
- Globalization issues have led to calls for onshoring of medical product manufacturing.
  - Moving final assembly: limited impact on supply reliability, leaves input supplies vulnerable to disruptions
  - Moving all stages: logistically daunting for supply chains with more than a few stages, will significantly increase operating costs
- Onshoring can be part of a cost-effective strategy to enhance medical product supply chain resilience but it must be vetted financially against alternatives.
  - A framework is needed for systematically enumerating alternatives.

Causes and Consequences of Medical Product Supply Chain Failures



Medical Product Supply Chain Resilience Framework

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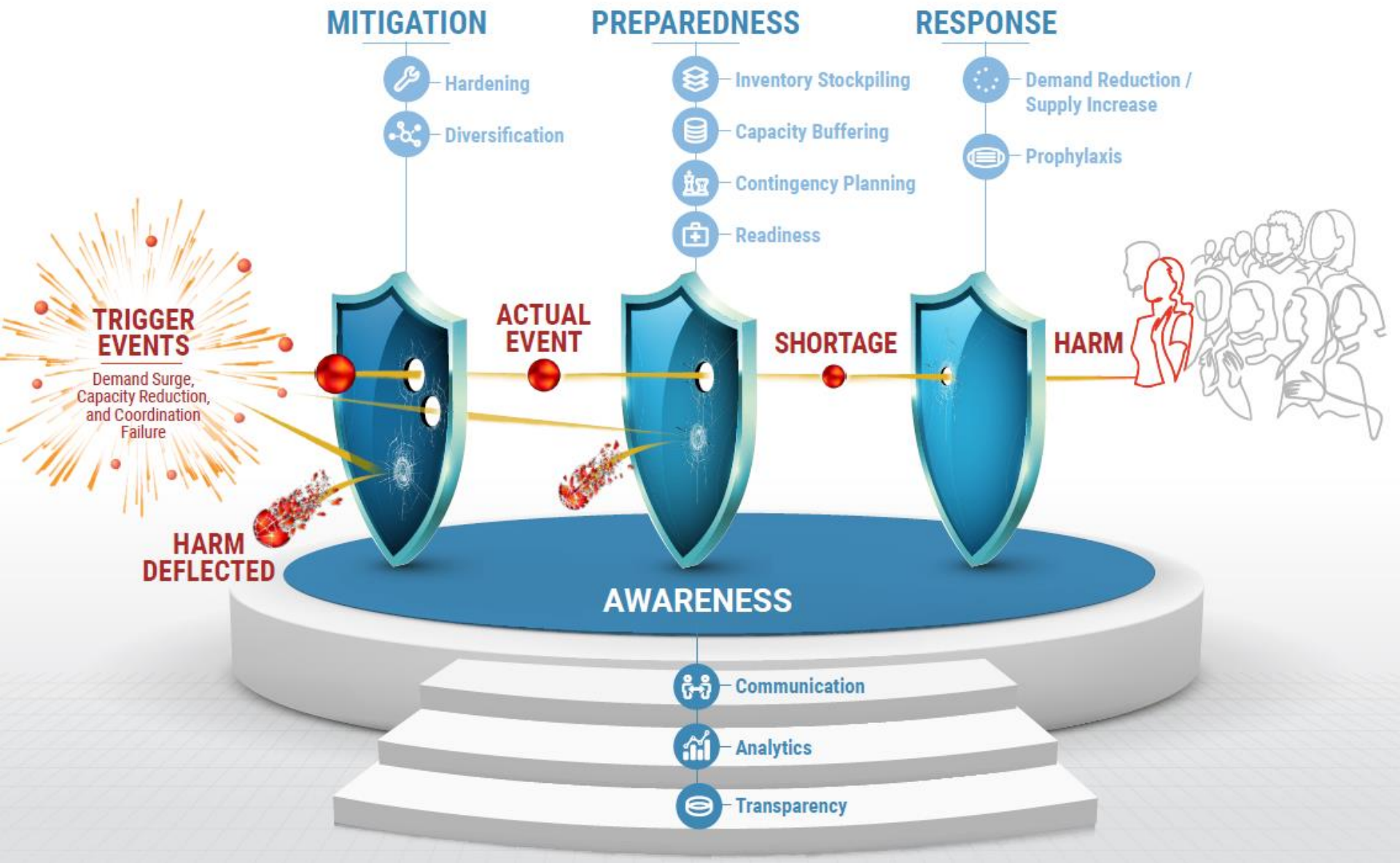
MITIGATION
Hardening
Diversification
PREPAREDNESS
Inventory Stockpiling
Capacity Buffering
Contingency Planning
Readiness
RESPONSE
Demand Reduction / Supply Increase
Prophylaxis
TRIGGER EVENTS
Demand Surge, Capacity Reduction, and Coordination Failure
ACTUAL EVENT
SHORTAGE
HARM
HARM DEFLECTED
AWARENESS
Communication
Analytics
Transparency

Awareness

Awareness Measures

- Awareness across an entire medical product supply chain requires:
  1. Making data from both regulators and industry ***transparent*** and available
  2. A***nalyzing*** and processing data into useful information
  3. C***ommunicating*** the information to those responsible for mitigation, preparedness, and response

- Improving awareness can be done both immediately and over time to increase end-to-end awareness and to identify/mitigate risks
  - Short-term: Identify areas upstream in the medical product supply chain that can be made immediately transparent
  - Long-term: Collect, compile, and disseminate medical product supply chain data from various stakeholders on where and how medical products are made

- Benefits of identifying risks: end users can factor supply reliability into their purchasing decisions; policy makers can focus programs on areas of greatest vulnerability; designing new/more effective resilience measures

Awareness Recommendations

<u>RECOMMENDATION 1 (Public Transparency)</u> The FDA should take steps to make sourcing, quality, volume, and capacity information publicly available for all medical products approved or cleared for sale in the U.S.

- ***Drug manufacturers*** should publicly disclose manufacturing location(s) (city, country, FEI) for their APIs and FDFs; and their sources of raw materials (APIs, excipients, etc.).
- ***Medical device manufacturers*** should publicly disclose manufacturing location(s) (city, country, FEI) for the primary manufacturing and final assembly steps for all medical devices and major components sold in the U.S.
- ***FDA*** should publicly disclose risk-based site-selection model scores, OPQ scores, and FEIs for all drug and medical device manufacturing facilities that make drugs/devices sold in the U.S.
- ***FDA*** should make sourcing and quality information part of drug/device approval/clearance processes and on an ongoing basis in order to retain a license or clearance to sell in the U.S.
- Drug volume data reported to FDA, as mandated by the CARES Act, should be made available in a publicly accessible database. This requirement should be expanded to include reporting of capacity, in addition to volume, and should be required for medical devices, in addition to drugs.
- ***Congress*** should make the necessary amendments to permit public disclosure of all the information referenced in this recommendation including the reporting of sourcing, quality, capacity, and volume information for drugs and devices.

Awareness Recommendations

<u>RECOMMENDATION 2 (Public Database)</u> The FDA, in cooperation with other government agencies, should establish a publicly accessible database for the supply chain information acquired for medical products.

- ***FDA and other government agencies*** should use the acquired information to:
  - Better understand the vulnerabilities of medical product supply chains;
  - Perform risk assessments regarding the risks to total supply of particular medical products in both normal and emergency scenarios;
  - Coordinate, conduct, and compile research on medical product supply chain resilience;
  - Track ways in which increased transparency and prediction of potential medical product shortages (via data tracking) support improved supply chain resilience and functionality;
  - Incentivize the establishment of third-party rating system(s) for risk and quality.

Mitigation

Mitigation Measures

- Actions taken prior to a disruptive event to help prevent the event altogether or reduce its magnitude
  1. ***Hardening*** to reduce the chance or impact of disruption within stages of a supply chain
  2. ***Diversification*** to create parallel versions of stages to reduce the risk of catastrophic failure

- Currently, medical product manufacturers have little incentive to harden or diversify their supply chains
  - Lack of transparency
  - Leads to <u>decrease</u> in reliability and quality of medical products and <u>increase</u> of medical product shortages, particularly generic drugs

- Health systems that incorporate reliability and quality of products (not only price) into purchasing contracts can incentivize manufacturers to harden and diversify their supply

Mitigation Recommendation

<u>RECOMMENDATION 3 (Resilience Contracting by Health Systems)</u> Health systems should promote a more resilient market for medical products by deliberately incorporating quality and reliability, in addition to price, in their contracting, purchasing, and inventory decisions. When quality ratings for medical products are available, accreditation organizations for health systems should use the ratings of the products sourced by health systems in their evaluations and ratings, as well as the frequency of shortages experienced at a health system that negatively affected patient care.

- ***With medical product suppliers*:** fortify contracts to include penalties (failure to supply); preferentially award contracts to suppliers that can demonstrate superior quality and reliability; award contracts to multiple suppliers of the same medical product; require same standards in contracts that are negotiated by GPOs on their behalf; budget to adequately reward a select groups of products if guarantees are met for higher quality and assured supply levels.
- ***With medical product wholesalers*:** establish emergency purchasing agreements guaranteeing that a set list of products will be delivered in the event of a disaster.

Preparedness

Preparedness Measures

- Actions taken prior to a disruptive event to reduce the risks to health and safety if the event occurs
  1. Physical Measures
     - ***Inventory stockpiling***: Holding physical stock in preparation of a supply shortfall ***Capacity buffering:*** Using fixed cost investments to create the production capability and incurring costs only if additional supply is needed
  2. Virtual Measures
     - ***Contingency planning***: Mapping out a course of action to respond to a specific scenario
     - ***Readiness:*** Having the capabilities to manage specific scenarios to accomplish intended results
  - Some preparedness measures (capacity buffering) may enable on-shoring for certain products. For others, it imposes a significant price penalty in return for a potentially small advantage during emergencies.
  - Preparedness measures are complementary to one another and each is vital to an integrated resiliency strategy.

Preparedness Recommendations

<u>RECOMMENDATION 4 (Stockpiling)</u> ASPR should take steps to develop strategies to modernize and optimize inventory stockpiling management for the SNS and beyond to respond to medical product shortages at the national and regional levels.

- ***Consider:*** recommendations provided in NASEM report, *Ensuring the Effectiveness of the Public Health Emergency Medical Countermeasures Enterprise*, particularly those that focus on adopting a systems approach to managing the SNS.
- ***Analyze:*** risk levels of supply chain critical medical products and the viability of other response strategies.
- ***Examine*** key inventory stockpiling process including: inventory system visibility; mechanisms and thresholds for the use, sharing, deployment, distribution, and allocation of stockpiled inventory; risks and benefits of stockpiling ingredients or components and those of just-in-time production or inventories in larger reserve; funding levels to meet the required inventory.
- ***Convene:*** regional and local working groups to discuss and inform expectations for federal SNS support; national/regional stockpile content and pre-deployment positioning; regional supply capabilities and expectations; roles and responsibilities for stakeholders.

Preparedness Recommendations

<u>RECOMMENDATION 5 (Capacity Buffering)</u> ASPR and the FDA should take steps to cultivate capacity buffering for supply chain critical medical products where such capacity is a cost-effective complement to stockpiling and as protection against long lasting supply disruptions or demand surges.

- Aim government investments in capacity buffering at major emergencies.
- ***FDA and ASPR*** should develop a crisis prices list of supply chain critical medical products and identify the capacity that is a practical supplement to stockpiled inventory.
  - ***ASPR*** should develop and manage a database to coordinate stockpiling and surge policies management of the crisis prices list.
- ***FDA and ASPR*** should fund research and development on advanced pharmaceutical manufacturing techniques
  - Jointly create public-private partnerships to support and fund implementing these advanced manufacturing approaches
- ***ASPR*** should be responsible for assessing disaster demand surge and develop the necessary information for a transparent, unified database. ASPR should also support and fund capital investments jointly with manufactures to assure production capacity, which can quickly be directed to disaster needs.

Response

Response Measures

- Actions taken after a disruptive event to minimize the harm from and to resolve the shortage
  1. Prophylaxis Measures
  2. Demand Reduction
  3. Supply Increase
- Many medical product supply chains are ***global***, requiring response actions across international borders.
  - Lack of international cooperation (via export restrictions) may temporarily increase the availability of domestic supplies, but incurs significant human and economic costs
- Response measures at the ***local (last mile)*** level of supply chains must provide end users with the resources to get medical products in short supply to those most in need.
  - Most resource-sharing networks are based on personal relationships, not formal agreements.
  - Lack of clear guidance on the best framework(s) to use when allocating scarce medical products, resulting in inconsistent, inequitable, use between and within states and within health care systems.

Response Recommendations

<u>RECOMMENDATION 6 (International Treaty)</u> Major exporters of medical products, including the US, should negotiate a plurilateral treaty under the World Trade Organization that prohibits export bans and restrictions on key components of global medical product supply chains. Any country that violates the terms of this agreement should be subject to sanctions by other signatories of the agreement.

- The treaty should provide ***incentives*** for countries to uphold commitments and cooperate in the event of a public health crisis.
- The treaty should provide ***disincentives/sanctions***, such as reputational and legal sanctions, for violating the terms of the agreement.
- Treaty ***negotiators*** could consider adding provisions to this treaty that facilitate information sharing, particularly during medical emergencies.

Response Recommendations

<u>RECOMMENDATION 7 (Last Mile Management)</u> ASPR in collaboration with the CDC, should convene a working group of key stakeholders to examine and identify effective last mile strategies to ensure end users are able to respond in the event of medical product shortages.

The working group should:

- Determine what ***information needs to be shared, with whom and in what form***, for end users to be able to execute resource sharing, supply redistribution, substitution, adaptation, and other strategies for responding to medical product shortages at the local level.
- Develop a ***standard national ethical framework*** for allocating scarce medical products, building in previous crisis standards of care work, including attention to equity, efficiency, and additional ethical values.
- Develop and incorporate ***response plans and training for medical product shortages*** into public health and health care professional capabilities.

Concluding Thoughts

Concluding Thoughts

Taken together, the committee's seven recommendations will improve supply reliability for medical products during normal conditions and will protect public health and safety during emergencies.

Summary of Recommendations

Awareness

1. **Public Transparency**—Make sourcing, quality, volume, and capacity information publicly available for all medical products approved or cleared for sale in the United States.
2. **Public Database**—Establish a public database for the supply chain information acquired for medical products.

Mitigation

3. **Resilience Contracting by Health Systems**—Deliberately incorporate quality and reliability, in addition to price, in contracting, purchasing, and inventory decisions.

Preparedness

4. **Stockpiling**—Modernize and optimize inventory stockpiling management to respond to medical product shortages at the national and regional levels.
5. **Capacity Buffering**—Cultivate capacity buffering for supply chain critical medical products where such capacity is a cost-effective complement to stockpiling.

Response

6. **International Treaty**—Negotiate an international treaty with other major medical product exporters that rules out export bans on key components of global medical product supply chains.
7. **Last-Mile Management**—Establish a working group to examine last-mile and end user issues regarding medical product supply chains.

Public Release

March 3—Public release and public release webinar (11:00am ET)

Free PDF of the report and related materials will be made available at: https://www.nationalacademies.org/our-work/security-of-americas-medical-product-supply-chain

Thank you!

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