

RECOMMENDATIONS

MARCH 2022 • BUILDING RESILIENCE INTO THE NATION'S MEDICAL PRODUCT SUPPLY CHAINS

The U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response requested that the National Academies of Sciences, Engineering, and Medicine establish an ad hoc committee to examine the security and resilience of U.S. medical product supply chains. The following seven recommendations made by the committee were identified as key to building resilient supply chains for medical products.

Recommendation 1 (Public Transparency). *The U.S. Food and Drug Administration (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 United States.*

These steps include:

- a. The manufacturer for a pharmaceutical drug should be required to publicly disclose the manufacturing location, in particular the FDA Establishment Identifier (FEI), the city, and the country, for the finished dosage form (FDF), active pharmaceutical ingredient (API), major excipients, and major packaging and delivery devices for all pharmaceutical drugs sold in the United States. API manufacturers shall be required to publicly disclose the sources of raw materials. This information should be made available on the labels for all pharmaceutical drugs and in a publicly accessible database. The National Drug Code should be associated with the primary FEI (where a majority of the volume is manufactured) in the database.
- b. FDA should make publicly available its risk-based Site Selection Model scores for all pharmaceutical drug manufacturing facilities that make drugs sold in the United States. FDA should also make public the Office of Pharmaceutical Quality (OPQ) scores. The risk-based Site Selection Model scores for the API and FDF plants (e.g., FEIs) should be made available on the labels for all pharmaceutical drugs and in a publicly accessible database, and the OPQ scores should also be included in this database.
- c. The manufacturer for a medical device should be required to publicly disclose the manufacturing location, in particular the FEI, the city, and the country, for the primary manufacturing and final assembly steps for all medical devices and major components sold in the United States. This information should be made available on the labels for all medical devices and in a publicly accessible database. The part number should be associated with the primary FEI (where a majority of the volume is manufactured) in the database.
- d. The risk-based Site Selection Model score for the primary manufacturing and final assembly plants (e.g., FEIs) should be made available on the labels for all medical devices and in a publicly accessible database.
- e. Sourcing and quality information should be provided as part of the pharmaceutical drug or medical device approval or clearance processes and on an ongoing basis in order to retain a license or clearance to sell in the United States.
- f. 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.
- g. To the extent that amendments to the Trade Secrets Act at 18 U.S.C. § 1905 and to the Food, Drug, and Cosmetic Act at 21 U.S.C. § 331(j) are necessary to permit public disclosure of all of the sourcing, quality, volume, and capacity information referenced in this recommendation, Congress should make such amendments.

Recommendation 2 (Public Database). *The U.S. Food and Drug Administration (FDA), in cooperation with other U.S. government agencies, should establish a publicly accessible database containing the supply chain information acquired for medical products.*

FDA, in cooperation with other U.S. government agencies, should use the information on medical product supply chains it acquires to:

- a. Understand better the vulnerabilities of medical product supply chains as a whole.
- b. Perform risk assessments regarding the risks to the total supply of particular medical products in both normal and emergency scenarios.
- c. Coordinate, conduct, and compile research on the resilience of medical product supply chains, including by funding independent research that uses the established database.
- d. Track the ways in which increased transparency, and the prediction of potential medical product shortages through data tracking, support improved supply chain resilience and functionality.
- e. Incentivize the establishment of third-party rating system(s) for risk and quality.

Recommendation 3 (Resilience Contracting by Health Systems). *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.*

Specifically:

- a. Health systems should fortify their contracts with medical product suppliers by including failure-to-supply penalties for contracts requiring a committed purchase or purchase volume, preferentially awarding contracts to suppliers that can demonstrate superior quality and reliability, awarding contracts to multiple suppliers of the same medical product, and requiring these same standards in contracts that are negotiated by group purchasing organizations on their behalf.
- b. Health systems should budget to adequately reward a select groups of products (e.g., low-cost, low-margin, off-patent, small molecule) if guarantees are met for higher quality and assured supply levels.
- c. Health systems and medical product wholesalers should routinely enter into emergency purchasing agreements for a specified list of emergency supplies or products that guarantees product delivery in the event of an unexpected supply demand or a substantial supply disruption. They should have a good understanding of the supplier's ability to meet demand, considering commitments to other buyers.

Recommendation 4 (Stockpiling). *The Office of the Assistant Secretary for Preparedness and Response should take steps to develop strategies to modernize and optimize inventory stockpiling management for the Strategic National Stockpile (SNS) and beyond to respond to medical product shortages at the national and regional levels.*

These steps include:

- a. Consider the recommendations provided in the National Academies report *Ensuring the Effectiveness of the Public Health Emergency Medical Countermeasures Enterprise*, particularly those that focus on adopting a systems approach to managing the Strategic National Stockpile (SNS).
- b. Analyze risk levels of supply chain critical medical products and the viability of other response strategies (e.g., capacity buffering).
- c. Examine key inventory stockpiling process considerations such as:
 - Inventory system visibility.
 - Mechanisms and thresholds for the use, sharing, deployment, distribution, and allocation of stockpiled inventory in response to shortages (triggered by both emergencies and routine use) and to prevent product expiration.
 - The risks and benefits of stockpiling ingredients or components as opposed to finished goods.
 - The risks and benefits of just-in-time production or inventories in larger reserves.
 - Funding levels to meet the required inventory levels and management tasks for the regional and national stockpiles and incentives for stakeholders for holding inventory.
- d. Convene regional and local working groups composed of emergency health planners, clinicians, health care systems, and public health agencies, among others, to discuss and inform expectations for federal SNS support; national and regional stockpile content and pre-deployment positioning; regional supply capabilities and expectations; and roles and responsibilities for key stakeholders.

Recommendation 5 (Capacity Buffering). *The Office of the Assistant Secretary for Preparedness and Response (ASPR) and the U.S. Food and Drug Administration (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.*

These steps include:

- a. Government investments in capacity buffering should be aimed at all stages of the supply chain and at major public health emergencies.
- b. ASPR and FDA should develop and routinely maintain a crisis prices list of supply chain critical medical products (i.e., medically essential and supply chain vulnerable) and identify which capacity measure is a practical supplement to the stockpiled inventory. Furthermore, ASPR should develop and manage a database to coordinate inventory stockpiling and capacity buffering policies regarding a crisis prices list.
- c. ASPR and FDA should fund research and development for both advanced pharmaceutical and advanced medical technology manufacturing techniques to help make on-shoring more cost competitive. By making capacity more easily scalable, these technologies would enable firms to respond to the need for capacity buffers more quickly and cost effectively.
- d. ASPR and FDA should create public–private partnerships and support and fund capital and staff investments jointly to implement these advanced manufacturing approaches to ensure production capacity. These partnerships will provide a great depth and breadth of expertise and can be leveraged for new economic incentives and regulatory clarity.
- e. ASPR should be responsible for anticipating and assessing public health emergency demand surge for supply chain critical medical products. It should clarify production capacity, identify vulnerabilities in supply chains, and engage producers in developing plans for surge response.

Recommendation 6 (International Treaty). *Major exporters of medical products, including the United States, 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.*

Specifically:

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

Recommendation 7 (Last-Mile Management). *The Office of the Assistant Secretary for Preparedness and Response, in collaboration with the Centers for Disease Control and Prevention, 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:

- a. Determine what information needs to be shared, with whom and in what form, in order 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.
- b. 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.
- c. Develop and incorporate response plans and training for medical product shortages into public health and health care professional capabilities.

To read the full report, please visit:
<http://www.nationalacademies.org/supply-chain-resilience>

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