

# Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation's Healthcare Critical Infrastructure\*

Recommendations from September 20, 2018 Summit:



## Regulatory

1. Develop a list of critical drugs. Use the WHO Model Lists of Essential Medicines and other existing resources, as a starting point to define what a shortage is and develop a list of critical drugs needed 1) for emergency response and 2) for saving and preserving life. Using historical data and manufacturing input, address why these drugs have been on the shortage list. The critical list can be used to:
  - a. Stabilize the availability of critical drugs by working with manufacturers and the Food and Drug Administration (FDA) to create redundant product in multiple locations in anticipation of natural disasters and other supply chain threats;
  - b. Assess the quality of pharmaceutical manufacturers measured against the importance of drugs on the critical list.
  - c. Work with the private sector for greater transparency surrounding the source of raw materials and manufacturing locations so providers can more easily assess pharmaceutical product quality. The FDA has proposed a star rating system for pharmaceutical manufacturers, which could increase transparency.
2. Create a multi-stakeholder advisory panel with the FDA to address key issues, such as the possibility of creating a stockpile of critical drugs, the logistics of warehousing such excess pharmaceutical inventory and where the excess inventory should be stored.
3. Enhance communication with the entire drug supply chain, including healthcare providers during, or in advance of, a public health emergency or other event that may create a drug shortage. FDA should provide the health care community with information simultaneously on the type of products that may be impacted and the expected duration of the impact. To prevent hoarding of inventory that could result from such communication, manufacturers could put product on allocation to ensure that remaining supply is distributed equitably.

4. Streamline regulations to incentivize increased manufacturing production.
  - a. Compounding regulations: 503(b) outsourcers need incentives to make drugs in short supply; it's costly to ramp up for only a short duration.
  - b. Global regulatory environment: there are multiple agencies internationally, all with competing requirements for manufacturers.
  - c. Aligns with FDA's initiative to harmonize international technical standards for approval of generic drugs.
5. Engage CMS to discuss the practice of citing hospitals that use medications after the guaranteed stability period in product labeling. This may, for example, address a powder after it is solubilized, which can contribute to unnecessary medical waste.
  - a. There are situations where evidence exists in the literature that stability goes well beyond the period of time listed in product labeling. However, CMS/TJC will cite a hospital even though the organization has evaluated this evidence and revised the date based on that. This warrants further discussion with CMS to see what might be needed to avoid or address drug shortage situations.
6. Encourage FDA to consider how reducing the number of unapproved (pre-1938 FD & C) drugs on the market might impact shortages.
  - a. FDA has been assisting companies with finding opportunities to legally market older "grandfathered" products that are currently marketed without the required FDA approval. While the FDA approval process ensures that marketed drugs meet current FDA standards for safety, efficacy, quality, and labeling— there have been concerns that these efforts to bring widely used but unapproved drugs into compliance with current FDA requirements have resulted in drug shortages.

## Legislative

1. Enact legislation that requires a notification requirement for medical product devices and equipment needed to administer medications, similar to the legislation enacted in 2012 that requires drug manufacturers to notify the Food and Drug Administration "of any changes in production that is reasonably likely to lead to reduction in supply" of a covered drug in the U.S.
  - a. E.g. fluid containers to dilute medications for infusion
2. Enact legislation requiring a risk assessment of foreign source active pharmaceutical ingredients (APIs).
  - a. Relying predominantly on other countries for the necessary ingredients to manufacture crucial drugs puts the U.S. at risk.
3. Require federal government authorities with jurisdiction over national security to conduct an analysis of domestic drug and medical device manufacturing capability and capacity for critical products to assess whether a threat to national security exists.
4. Require a GAO study to examine all aspects of the drug supply chain to see if there are any new issues exacerbating drug shortages.

## Legislative and Regulatory

1. Develop incentives for drug manufacturers to have contingency or redundant production plans for their pharmaceutical products on the critical drug list. The back-up plan should include prioritizing the most medically necessary products, qualifying third party suppliers across their network, and increasing production and inventory for API and finished goods.
2. Investigate developing a system of paying suppliers to hold inventory, perhaps similar to the system employed by the DoD/Defense Logistics Agency. Consider partnering with the DoD to create contractual leverage with drug manufacturers for civilian hospitals.
3. Incentivize manufacturers and work with the FDA to repackage pharmaceuticals according to the amount of medication commonly used to reduce waste (E.g. only a 30 mL vial of a drug is available when most common volume needed is 5 mL).
4. Create an Office of Clinical Affairs within the Drug Enforcement Agency (DEA), so DEA personnel will be available to address the clinical side of medication shortages of controlled substances, rather than just the diversion enforcement aspect.

#### **Market/Non-Legislative or Regulatory**

1. Standardize medical concentration, containers, and sizes to stabilize pharmaceutical supply and reduce the probability of patient harm due to constantly needing to change concentrations and associated technology. Standardizing products reduces the risk of adverse drug events when shortage products are substituted. Standardizing the concentration of compounded products within organizations also helps provide a critical mass for industry to consider making previously unavailable products available.
2. Identify tools that address supply access, such as Pfizer's web access tool, which provides information about happenings at Pfizer's facilities, latest product updates and a Q&A forum.
3. Ensure hospital staff, health care providers and pharmacies have capacity to manage drug shortages.
  - a. Ensure early notification of predictable medication shortages and medication substitutes so staff can build necessary information into communication efforts.
  - b. Work with medical and specialty organizations to ensure necessary information is built into educational efforts, such as national guidelines and continuing education.
4. Examine how changes in United States Pharmacopeia (USP) standards for drugs with a solid historical safety record can affect supply, and whether these changes are necessary.
  - a. Consult with USP representatives about pharmaceutical regulations that may lack an evidence base.
5. Request that electronic health record (EHR) vendors make changes to their systems to ease the burden of making drug product changes when a shortage occurs. An example would be some sort of tool that makes changes to various integrated technology databases at the same time (like EHR and smart pump drug libraries, or automated dispensing cabinets and pharmacy inventory systems).

\*These are not consensus recommendations as they were offered after the day's discussion as potential policy and marketplace changes that help prevent and mitigate drug shortages. Attendees at the meeting do not necessarily endorse the recommendations brought forth.