Reflections and Recommendations on Preparing for the Next Surge or Pandemic

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Elements That Have Worked Well:

- Nimbleness and ingenuity of the private sector to anticipate and identify needs as well as respond quickly to fill gaps.
- Formation of the Private Sector Supply Chain Coalition to provide a coordinated and collaborative response
- Sharing of supply chain data that accounted for both supply and demand from neutral, vendor agnostic, and value orientated entities
- Regulatory flexibilities and waivers from FDA, CMS, HRSA, and CDC that were delivered rapidly
- Timely and regular access to government leaders and openness to input

Elements That Led to the Current Situation:

- In spite of efforts to counter the trend by some, a focus for the past 20+ years to move manufacturing offshore as a means to reduce costs to offset decreasing reimbursement
    - Emerging economies more willing to take greater environmental regulatory risks
    - Large populations of low-cost labor
    - Incentives provided by other nations to move manufacturing to their markets
- Lack of centralized upstream visibility into supply chain to determine source of raw materials and finished goods. This resulted in a lack of understanding of vulnerabilities, foreign reliance on manufacturing, and impact as export bans and manufacturing shutdowns were announced.
- Unprecedented demand both globally and nationally that led to an imbalance in the supply vs demand (17X increase in surge demand for N95 masks)
- Export bans and manufacturing shutdowns globally
- Insufficient supplies in the SNS and cumbersome process for accessing supplies in the stockpile.
- More reactive approach vs a proactive approach by the government at the outset. Product was not allocated to the “hot spots” because there was not clear identification of them until late.
- Fragmented approach to securing supply (private sector vs federal vs states) led to increase in prices as multiple entities competed for the same inventory and out-bid one another
- Lack of clear visibility of distributor fulfillment lead to uncertainty on where products where delivered. This continued uncertainty left providers with dwindling confidence in the normal supply chain and proliferated more maverick and forward buying, as well as hoarding. This also led to a rampant gray market and many entities purchasing counterfeit products.
- Insufficient national strategy and plan for addressing global pandemics, including confusion regarding which federal agency was responsible.
- Existence of patent restrictions that impeded access to ancillary products needed for care such as viral swabs

Goals for Moving Forward:

- Augment the existing private sector supply chain to better respond to global pandemics through diversification and transparency. The private sector supply chain is highly functioning and should be further enabled, not disrupted.
- Develop a cohesive and holistic national strategy for addressing global pandemics and stabilizing the US supply chain to respond to surge demand for critical medical supplies and drugs.
- Identify critical medical supplies and drugs needed to treat a global pandemic and associated comorbidities. This identification should occur via a public-private advisory council that includes representatives from manufacturers, GPOs, distributors, physicians, pharmacists, laboratorians, and others. Ensure there is transparency on manufacturing and raw material sources and assure adequate diversification of the supply chain for these products.
- Create upstream visibility into the supply chain to understand sources of raw materials and manufacturing facilities. This information is critical to assess vulnerabilities and prioritize what critical medical supplies and drugs should be focused on initially.
- Design stockpiles to create coordination rather than competition between state, local and national stockpiles.
- Leverage supply and demand data from GPOs, who serve as neutral, vendor-agnostic, and value-orientated entities to drive transparency in the supply chain and forecast demand needs.
- Develop a real-time national surveillance system that includes supply chain data so that there is a real-time means to identify a disease threat as early as possible as well as its implications on healthcare resources.
- Advance payment and delivery system reforms that hold providers accountable for the health of a population, budgets and transparent outcomes. This will incent improving the health of a population, which will both improve patients' comorbidities and attention to care management to sick patients. Acting within a budget helps reduce long-term financial pressure from rising healthcare costs.

Major Barriers to Domestic Manufacturing:

- Capacity
- Environmental regulations
- Labor costs
- Availability of raw materials
- Historical policy decisions that advantaged offshoring

Incentivize Domestic Manufacturing:

- Section 3101 of the CARES Act requires a report by the National Academies of Medicine (NAM) on the foreign reliance on manufacturing for critical healthcare supplies, the risk to national security, and recommendations for improving the resiliency of the supply chain. However, these recommendations are not expected to be available in the near future and, therefore, Congress should accelerate the development of this report to strengthen domestic manufacturing in the long-term.
- Offer 0% interest loans to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity. (for example – investing in automation to offset labor costs)
- Offer tax incentives to manufacturers of critical medical supplies and drugs to incentivize increasing domestic manufacturing capacity, similar to incentives provided during the 1980's and 1990's to incentivize manufacturing in Puerto Rico.
- Ensure there is at least:
    - One domestic supplier of the final form, ancillary products and raw materials for critical medical supplies and drugs.
    - Three global suppliers of the final form, ancillary products and raw materials for critical medical supplies and drugs. Global suppliers should be from geographically diverse regions.
- Incentivize the domestic farming/cultivation of raw materials needed for critical medical supplies and drugs
    - For example: cotton for PPE and swabs, pigs for Heparin, poppy for sedatives, etc.

Strategic National Stockpile:

- The SNS should maintain a minimum of a 90-day supply of critical medical supplies and drugs based upon surge demand from hot spots such as New York, Washington, Detroit, etc.
- The current process for accessing the SNS is cumbersome and state specific. Working alongside private sector partners, the Administration should create a streamlined and efficient process for accessing drugs from the SNS.
- The SNS should work proactively with GPOs to forecast demand and increase capacity/supply to avoid shortages.
- The SNS should work with GPOs to rotate soon-to-expire stock out of the SNS and into health systems at a discounted rate. This rotation is supposed to occur, but GPOs can make this happen and will ensure the SNS is continuously stocked with in-date products and allow the SNS to recoup some of their expenses associated with purchase of these products.
- The SNS should be transparent regarding distribution of supplies and drugs from the SNS. The SNS should provide, at minimum, a detailed monthly report of what supplies were distributed to where and in what quantities.
    - During a public health emergency, reporting should occur weekly
- The SNS, as well as state and local stockpiles, should be encouraged to purchase off GPO contracts to help aggregate purchasing volume and keep prices competitive.
- The SNS should work to ensure that critical medical supplies and drugs are located as close to the delivery of care as possible. This includes exploring opportunities to leverage health system warehouses in major metropolitan areas or in rural areas.
- Create a customized stockpile for nursing homes with appropriate supplies, drugs and other needs.
- Include health systems or regional buying groups as potential stockpile operators. These organizations would be responsible for managing the stockpile for the providers in a region. This would allow an efficient means to rotate inventory and assure accountability for the stockpile.

Environmental Regulations:

- EPA should reassess requirements specific to the manufacturing of critical medical supplies and drugs and provide clear guidance on the requirements needed
- Provide tax credits or incentives for manufacturers to upgrade facilities to meet EPA requirements to begin domestic manufacturing of critical medical supplies and drugs
- EPA should provide clear guidance on the use of ethylene oxide (EtO) for sterilization of medical supplies. In 2019, several states took action against EtO facilities and closed them. During COVID, Illinois and Georgia permitted EtO facilities to reopen. This was critical to avoid additional shortages of PPE and other medical supplies due to a lack of sterilization capacity. Moving forward, it is critical that EPA define what is required for sterilization with EtO and provide an opportunity for EtO sterilizers to comply with the new requirements.

Regulatory Reform:

- Review and assess the regulatory reforms, waivers and guidance documents undertaken during the pandemic and determine which of those should be maintained so as to retain greater regulatory nimbleness.

Surveillance and Analytic Infrastructure:

- Invest in a robust, real time HIT infrastructure that will provide syndromic, hospital and post-acute care surveillance that is also connected to real time resource demand data.