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 Strategic National Stockpile (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 led to uncertainty on where products were 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
- Lack of resources to contain the spread of COVID-19 in nursing homes and proactively identify emerging cases.

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. This list must be dynamic and regularly updated as technology advances, best practices are identified, and the practice of medicine evolves.
- 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 to assure adequate diversification of the supply chain.
- 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.
- Leverage technology to implement comprehensive infection prevention and antimicrobial stewardship programs in nursing homes to provide meaningful assistance with infection control.

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.
- Incentivize healthcare providers to purchase domestic manufactured critical medical supplies and drugs through programs such as tax incentives, CMS bonus payments, etc. to create committed purchasing volume for domestic suppliers and offset higher acquisition costs.

Strategic National Stockpile:

- The SNS should not only focus on the quantity on hand for critical supplies, but also focus on the time to inventory and ensuring the U.S. has contractual relationships established, including contingency and redundancy plans, to ramp up production expeditiously and efficiently upon identification of need.
- The SNS is the supply chain of last resort for health systems, alternate site providers, and first responders. Therefore, the SNS must be built by providers for providers. The SNS must also leverage analytics and insights to assist providers in the delivery of care during global pandemics that is in the best interest of patients and ensure access to the right supplies at the right time.
- 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.
- To ensure the SNS can deliver during future global pandemics, it is critical to periodically pressure test the system. Annually, without prior notice, the SNS should require all contracted manufacturers to provide the SNS with a specified quantity of product. An annual test allows the SNS to ensure all contracted manufacturers can expeditiously and efficiently ramp up production to meet surge demand, as well as ensure production lines remain operational and are maintained.

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.

Upstream and Downstream Visibility:

- Invest in a robust, real time HIT infrastructure that will provide an on-call, nimble data collection infrastructure that the nation can call upon in any future major crises. Rather than standing up an inadequate and duplicative system as we experienced during the pandemic, the nation needs a system that can track critical product availability - from the raw materials, to manufacturer, to distribution, to hospital inventory. This system would exist behind the scenes and be ready to be "turned on" in a moment's notice. This information would inform dynamic and appropriate product allocation and distribution strategies, minimize hoarding, and enable powerful and accurate prediction, enabling the nation to manage supplies during the crisis.
- The nation also needs modernize its public health syndromic surveillance system so that infected patients can be identified earlier through symptom information. Reliance on testing, particularly early on in an emergency, can delay insights for and misinform public health officials.

Addressing the Gray Market:

To combat the gray market and ensure supply chain integrity, Premier offers the following recommendations:

- Establish a national, centralized clearinghouse to vet all gray market offers regarding vaccine availability. A clearinghouse approach would remove the risk and guess work from efforts by healthcare providers, states and other entities to secure a reliable supply of vaccine. The clearinghouse should:
  - Hold all payments in escrow until testing is validated;
  - Test lot samples through a certification process;
  - Permit the sale of products that are validated; and
  - Confiscate and take appropriate action against the gray market actor if the product is not validated.
- Require entities associated with the distribution of vaccine and ancillary supplies to implement checks and balances systems, similar to suspicious order monitoring requirements for controlled substances, to identify potential diversion of vaccine to the gray market.
- Promote the reporting of gray market offers to the FDA Office of Criminal Investigations and share reported incidents with the Federal Trade Commission (FTC).
- Implement civil monetary penalties (CMPs) for entities selling vaccine to the gray market.
- Establish best practices for security to minimize diversion from sites.

Infection Prevention Clinical Surveillance:

- COVID-19 has brought to the forefront the specific challenges nursing homes face in containing the spread of infectious disease. The virus has accelerated at nursing homes because residents are generally vulnerable to its complications and more susceptible in the contained space of the facilities. While data about infections in nursing homes is limited, the CDC notes that, even prior to the pandemic, a staggering 1 to 3 million serious infections occur every year in these facilities and as many as 380,000 people die of the infections in nursing homes every year.
- Infection prevention oversight and training at nursing homes is a challenge in and of itself with limited staffing and several layers or reporting requirements. This challenge is compounded by limited Electronic Health Record (EHR) functionality at the sites. Without a comprehensive infection prevention surveillance workflow, the surveillance, tracking, documenting and reporting of epidemiologically significant organisms and infection is difficult for everyday risks, such as multi-drug resistant organisms, but also when an outbreak like COVID-19 occurs.
- Clinical analytics technologies are currently widely leveraged in hospitals and acute setting to detect patient care issues through surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs. These systems utilize data from EHRs and have significantly helped clinicians and pharmacists in acute settings identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Those health systems already utilizing clinical surveillance technology were well positioned to respond to COVID-19 before the pandemic hit.
- Unfortunately, clinical analytics technologies are currently not widely used in nursing homes. Nursing homes should have the same access to tools that will help them combat infection spread during any future outbreaks of COVID-19 and during their day-to-day operations, but unfortunately funding remains a significant barrier. Nursing homes are already challenged with meeting their more visible needs, such as testing and securing adequate PPE levels at their sites,

but a comprehensive approach is additionally needed to ensure data collection is efficient, non-duplicative and being analyzed in ways that are helpful for facilities.