On February 24, 2021, President Biden with a bipartisan group of Congressional leaders, announced an Executive Order (EO) “to address an issue of both concern to our economic security, as well as our national security: the resilience and reliability of our critical supply chains”.

The recent stress on the logistics system has been unprecedented. Since the start of the pandemic, the strain COVID-19 put on the medical supply chain from raw materials to finished product, and distribution was not similar to a hurricane, earthquake, tornado, or wild fire. Nor was it like several of these calamities all occurring at one time. Furthermore, the response effort is beyond even the scope of a dirty bomb or terrorist chemical attack in multiple US cities at the same time. The pandemic is a global war with each country racing to get the same logistics stocks, raw materials, and distribution channels all at the same time.

The COVID-19 pandemic was one of the first mass whole-of-nation mobilizations in modern memory for most Americans. The COVID-19 pandemic has handed us the chance to massively stress test our logistics systems in the heat of the fire, see how it responds and require us to make
real time adjustments. If we seize on this opportunity, it will make both our logistics system more resilient, diverse, and secure for the U.S. and markets around the world.

The supply chain does not exist in a vacuum. During the pandemic the impact of structural problems, observed human response to the existing, and behavior from bad actors – all impacted supply, demand, and integrity of the supply chain.

This article articulates three specific policy recommendations the President and Congress can implement to significantly enhance the resiliency, diversity, readiness and security of the U.S. supply chain. The focus is on the medical supply chain, but the applicability of the principles can be applied to other industries. The matrix at the end of the article summaries the recommendations to:

- Enhance the “Just-in-time” inventory or “stockless production” systems used by the medical industry with a more resilient, diverse, and secure structure.
- Expedite the ability to increase market transparency, integrity, and transaction time in the medical supply chain to build a more resilient, diverse, and secure structure.
- Enhance the resiliency, diversity, and security of the Strategic National Stockpile to respond to future events.

In business school and operational management, one learns how organizations have three key management controls to address challenges: increase revenue, decrease costs, or change the process. The supply chain challenges highlighted in the pandemic are a cry for innovative process or policy changes. We are now facing “a change the process or policy” moment in history. The President and Congress have an opportunity to implement these three enhancements to build a more resilient, diverse, and secure structure for the U.S. supply chain.

“Leaders win through logistics. Vision, sure. Strategy, yes. But when you go to war, you need to have both toilet paper and bullets at the right place at the right time. In other words, you must win through superior logistics.”

– Tom Peters

I. **“Just-in-time” inventory or “stockless production” in Medical Systems – Can it be enhanced by having certain items in place prior to the need?**

**Problem:**
The pandemic demonstrated most US hospitals only maintain days or weeks of excess critical supplies required to respond to a hazard event, emergency, or pandemic. These policies increase the supply chain risk to the system. We observed a higher resupply request rate by hospitals at the start of the pandemic, even if a hospital was not yet impacted by the disease. The resupply requests quickly exceeded the distributor’s on-hand stocks. The increased orders sent a higher than usual demand signal to the manufacturers. The lag-time to deliver and enhance capacity of the manufacturers to respond to the increased orders required longer response times, and the need to expand capacity – where excess capacity existed. For example, if a plant had the ability to add an additional production shift, it would take cash to finance the hiring and training of new staff before product can flow out of the effort. In some cases, the
ability to expand capacity takes more cash and longer lead times as facility construction is needed.

**Background:**
In the 1980s and 1990s the concept of “just-in-time” inventory or “stockless production” techniques began to expand throughout US medical systems as a tool to eliminate waste, reduce costs, and to reduce storage carrying costs by only having on-hand a 3–10-day supply of inventory.

A “just-in-time” inventory system has many positive financial attributes for American organizations, to include hospitals. For example, it can reduce costly space requirements and financial carrying costs that impact the cost of health care. Even so, the bottom-line cost on hospitals for supplies is significant, even with “just-in-time” technique. A 2017 article noted the average hospital spent $3.8 million on supplies or 15 percent of their costs in the year 2013 with a patient average supply cost of $4,470\textsuperscript{iii}. The downside of this method is it reduces local facility surge capacity of the hospital and supplier during emergency events.

Furthermore, as noted in a 2017 “Supply Chain Dive” article, some of the larger medical systems began to move to “self-distribution models” to further improve supply chain management costs\textsuperscript{iv}. The self-distribution model is a process to bring in-house its “just-in-time” distribution process from a distributor-based model to further reduce operational supply costs. Again, a positive for bottom line health care cost with downside on surge capacity during broad scale emergencies.

**Analysis:**
Are there policies the federal government can implement now that will enhance the ability of hospitals to respond in times of emergency surges, but do so without impacting the very valuable “just-in-time” or “self-distributions models” that reduce long term health care costs?

**What if...for certain key Personal Protection Equipment (PPE) items (N-95s, Nitrile gloves, Surgical Masks, etc.,) the federal government had a policy requiring hospitals who participate in Medicare (over 6,000 US hospitals in 2019\textsuperscript{v}) to maintain a supply bubble of 90 days of its average usage rate of a select number of PPE items?**

- A supply bubble is not a stockpile, but a rotational stock of items used on a routine basis. The bubble expands the hospital’s readiness to meet emergency demands while maintaining their overall supply policies.
  - Note: the quantity of the limited PPE bubble should be based on each hospital’s average usage rate, not on a government specific quantity.
- Reduces some of the early resupply requests from hospitals not in the immediate threat – providing the supply chain more time to respond as the hospital will have on-hand a more robust stock of anticipated PPE.
- Provides distributors with more time to re-balance re-supply requests to the highest affected areas in their network.
- Provides manufacturers with more time to expand capacity and thus reduce shortages.
A similar policy could be applied by other countries or the World Health Organization to reduce global immediate resupply demand to further enhance the time of the market to respond.

_The US Centers for Medicare & Medicaid Services (CMS) could be the implementing arm for a federal Emergency Response Limited PPE Supply Bubble policy._

The US Centers for Medicare & Medicaid Services (CMS) manages participation of hospitals in the Medicare program through an accreditation process. The CMS Medicare program with its accreditation process is a viable option to implement, oversee, and offset the initial financial carrying cost of a limited supply bubble policy. The accreditation function is used to promote improved patient quality and safety concerns for Medicare beneficiaries, which benefits all patients. No doubt, ensuring Medicare program hospitals are prepared to support Medicare beneficiaries during a disaster is not so dissimilar. The CMS reimbursement mechanism could provide a structure to support this policy for participating hospitals.

**Recommendation:**

The President can work with Congress to require hospitals who participate in Medicare program to maintain a supply bubble of 90 days of its average usage rate of a select number of PPE items to enhance the resiliency, diversity, and security of the medical supply chain for emergencies from pandemic to other national security events.

The CMS already supports policies related to Medicare beneficiary safety and quality. Such an extension further supports the safety and quality of care for not only Medicare beneficiary but all citizens during an emergency.

_“The Line between disorder and order lies in logistics…” – Sun Tzu_

## II. PPE Medical Supply Chain Integrity, Speed, and Transaction Validation – Can it be put on hyper-speed?

**Problem:**

Market integrity is a business environment that is fair, safe, and provides confidence to all the actors from factory to end user. During the COVID-19 pandemic as demand on PPE supply chains was overloaded, the vacuum created between excessive need and shortage resulted in an environment which promoted the growth of bad actors. An example is the expansion of the “Gray Market” where bad actors offer unofficial, unauthorized or other supply not intended by the original manufacturer into the supply chain. This then pollutes the market with poor quality supplies and increases mistrust in the process.

**Background:**

The supply chain transaction verification process is limited in the types of tools it uses to quickly verify official authorized manufacturing, chain of custody or other key elements. In a normal PPE market, the manufacturers, intermediaries, and end users take time to validate each transaction – primarily through paper document reviews, calls, and manual processes. Verification increases the integrity of the PPE supply chain and transactional steps but is not a
failsafe and takes time. The past year, excessive demand and matching time pressures, appears to have increased the participation of bad actors in search of a quick profit. One continues to hear stories of offers to sell supplies that after several weeks of review, turn out as highly probable Gray Market products, no products, or other red flags identified on the quality of product. In fairness, the vast majority of the players are honest business professionals who want a fair business environment. However, the gaps and seams in the system allow a handful of “Gray Market” bad actors to dramatically slow down the process -- at a time when speed is measured in saved lives.

The impact of the expanded PPE supply from the “Gray Market” has not only affected health care providers but procurement officials, importers, financing teams, and legitimate manufacturers. It can add weeks for true holders of PPE to gain financing and contract options to deliver legitimate product. Rightfully so, every step in the process now requires increased due diligence from legitimate business professionals to somewhat prevent these “Gray Market” supplies from entering the system. These steps add time and cost in procuring PPE to front line staff.

Analysis:
What policy tools can be used to expedite the ability to increase market transparency, integrity, and transaction time in the medical supply chain to build a more resilient, diverse, and secure structure?

A blockchain is a decentralized, distributed record or “ledger” of transactions in which the transactions are stored in a permanent and near inalterable way using cryptographic techniques. The method on how the ledger is maintained is the authentication process to create trust for the participants in the trade, throughout the life of the transaction.

Thus, a blockchain serves as a tool to track transactions over a value chain of events to ensure market integrity.

A RFID chip or similar technology linked to the blockchain with an ability to be read from a distance, with characteristics to support long-transport, and unique identification code can prove shipment validity for the transaction. Jointly, such tools can increase the speed and accuracy for validation of potential and actual orders. If such a tool was integrated into a solution – the hyper-speed of the validation process could be reduced from weeks to hours. It would lower intermediate transaction costs that are passed along to the end user while supporting faster times to deliver end products – nothing ships until the deal is final.

Imagine a blockchain network linked with RFID chips on PPE pallets or boxes departing a factory. The enhanced ability for potential buyers to significantly reduce or eliminate “Gray Market” PPE from entering a hospital system is dramatic, by increasing market integrity with reduced manual validation of supply inventory allocations and finance.

Failing forward is a technique to leverage system failures to accelerate future success. The expansion of the “Gray Market” for PPE creates a fall forward opportunity to build a more resilient, diverse, and secure supply chain.
The U.S. has used independent standard bodies to build a bridge between evolving standards to build more resilient, diverse, and secure market places in the U.S. economy. The Joint Commission is such a body that was created in 1951 to improve the quality and safety of hospitals. In fact, the CMS relies on the Joint Commission to serve as the accreditation body for hospitals that participate in the Medicare and Medicaid program certification vii.

**Recommendation:**
The President can work with Congress to facilitate through legislation the development of not-for-profit body made up of industry leaders in the supply chain enterprise to develop a adopt a foundational set of technical blockchain standards. Furthermore, require the Department of Defense (DoD), General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) to jointly partner with the independent body and issues FAR changes to promote and require executive agencies use these standards in acquiring goods and services.

A partnership between and industry and U.S. procurement organizations can serve as the fulcrum to promote and adopt blockchain standards in the legitimate medical supply chain for PPE manufacturers, distributors, and intermediaries in the U.S. and around the globe. The independent body could recommend the technology be linked to a physical system, like RFID, linked to the blockchain. The policy goal is to increase market transparency, integrity, and transaction time in the medical supply chain to build a more resilient, diverse, and secure structure.

This recommendation requires federal action and collaboration with industry partners. The creation of an adaptable framework can ensure the supply chain custody and financial data integrity from the point of manufacturer to the end user is ensured while expediting authentication. The benefits will not only expedite and simplify the transactional encounters – it can lower the overall supply chain costs.

The characteristics of such adaptable blockchain framework could facilitate or include:

- Authentication to determine whether someone or something is, in fact, who or what it is declaring to be to establish trust in the transaction. Blockchain authentications can provide such authentications into the supply chain.
- Use of these technologies to link US Food and Drug Administration PPE certifications and approvals from manufacturer to end buyer.
- A data system to analyze functions for forecasting raw material, financing, shipping, and other components based on demand signals.
- Although industry developed, the government should be a full partner for these voluntary guidelines with incorporation of such blockchain standards into the federal procurement process.
- The suggestion could facilitate a more in-depth discussion on how to support a trading zone to streamline the financing issues in the broader supply chain.

"My logisticians are a humorless lot... they know if my campaign fails, they are the first ones I will slay." - Alexander the Great
III. **How to enhance the resiliency, diversity, and security of the Strategic National Stockpile to respond to future events.**

**Problem:**
The SNS does not have a Working Capital Fund (WCF) or tools to most effectively manage its operations to best serve its mission. A WCF is a financial tool used by the government to increase business efficiency by restructuring the way in which money is used. A WCF authority in the SNS can increase its effectiveness and reduce the long-term sustainment costs.

The SNS does not have a WCF to allow it operate like a business to rotate stock prior to its expiration on a full-cost recovery basis. It is a tool to allow a government organization to operate more like a business than a traditional government service. For example, with this tool it could more quickly scale services in response to events, secure funds from sales of expiring products to replace stock in lieu of wasting expired stock.

**Background:**
The Strategic National Stockpile (SNS), established in 1999, grew to contain about $8 billion in medical assets prior to the COVID-19 pandemic. In 2002, the name SNS was given and Congress expanded the mission from vaccines and antidotes to respond to biological or chemical agent events. Over time the mission grew “to provide for the emergency health security of the United States…in the event of a bioterrorist attack or other public health emergency.” The Congressional Research Service (CRS) in 2020, pre-COVID, identified that the SNS had inventory of 38 drugs and 44 medical supplies.

Response to chemical, biological, radiological and nuclear (CBRM) events was further expanded to a broader all-hazards focus. The SNS mission covered events like hurricanes, fires, and other natural events like pandemics. It is not clear that the items in the stockpile or base funding is align to the expanded mission. In theory, Congress provided annual funding to purchase new products and replace expiring stocks. If funding does not support the mission – the program has to build in risk or areas that may not be supported due to the level of funding.

**Analysis:**
The 2020 CRS report identified that since the SNS’s initial funding, the SNS budget never really went above $700 million of support in any one year. Most years were funded at below $600 million a year. In a stock pile without a way to revolve the items for replacement -- funding is more critical. A stockpile without an ability to rotate items will need to dispose of expired stock and pay full replacement value at current day costs. Ironically, a number of the items in the SNS are used by its sister organizations within the Department of Health and Human Services (HHS). It also costs to dispose of unused expired stock. The effect of an expanding mission, flat funding, and no ability to generate revenue through a rotation program further expanded the risk of the SNS to be ready to meet its full range of mission areas.

How could a WCF improve the SNS? Imagine if the average SNS inventory item has a service life of five years. An annual funding of $600 million a year would take 13 years to replace the $8 billion asset level. A funding level of $700 million a year would take 11 years. This is a
crude analysis as it does not assume any inflationary price increases, nor the need to purchase additional or new items. However, the point is demonstrated that mission risk or increased likelihood that the SNS funding would not support critical needs would appear to increase each year that was underfunded.

If the SNS had a WCF prior to the pandemic, it could have explored how to use the authority to increase its response and partnership options with the private sector.

Imagine a SNS with a WCF and policy direction to establish arrangements, such as, stock replenishment with other agencies to rotate expiring items at a reasonable period before expiration on a reimbursable basis. The reimbursement costs, which today would go to a vendor, would now go to the SNS for non-expired items. These funds would be used by the SNS to replace those items with fresh stock without a need for additional tax dollars for replacement.

Knowing the historical funding level in the SNS – this policy alone with no other changes will buy down or decrease the speed of operational risk in the SNS. It can promote a higher degree of strategic planning capability and enhanced management capabilities in the SNS to enhance its preparedness posture. It also reduces waste, has the potential to simplify SNS procurement with longer rotational contracts, and demand forecasting while reducing overall SNS costs.

**Recommendation:**
The President can work with Congress to provide the SNS with the legal authority to create a WCF. Plus, to require other federal agencies who use materials maintained in the SNS for routine operation to procure items for the SNS prior to expiration to allow the SNS to more effectively operate and increase its resiliency, diversity, and security for national events.

The reduction of operational SNS future risk does not rely on just more new federal appropriations – a process change will address a portion of the cost to reduce risk. The enactment of SNS WCF authority with authority to require other federal agencies to serve as rotational stock partners can significantly increase funds available for replacement of SNS stock prior to expiration and reduce the operational response risk profile without any new SNS funds being provided. Again, not a complete answer but an effective policy solution to serve as a component of an overall solution.

**IV. Courage to Catch the Wind of Change – For the Administration and Congress to Build More Resilient, Diverse, and Secure Supply Chains:**

In closing, the President and bipartisan members of Congress who meet at the White House on February 24, 2021 have taken a step forward to Build More Resilient, Diverse, and Secure Supply Chains. Of course, the result will not occur with merely an EO, meeting, or speech but these actions can start the process. We are living in a “change the process or policy” moment of history for the supply chain. The policy recommendations outlined in this article are but a few that the President and Congress and implement in a bi-partisan manner to increase the resiliency, diversity, and security of the U.S. supply chain.
I would challenge our policy makers to think more innovatively with breakthrough thinking outside the current box. A cry for innovative process or policy changes is in the wind...do we have the courage to catch the wind and make these changes or will we let it sail past until the next crisis?

About the Author: John Bartram, J.D., MBA, is a National Academy of Public Administration (NAPA) Fellow. The CEO of Brightstar Innovations Group, LLC, a Capitol Hill veteran and retired federal Senior Executive Service career official with over 36 years of federal appropriations, healthcare, life science, defense, veterans’ affairs, and regulatory experience. An Air Force Brigadier General, John is the Reserve Mobilization Assistant to the Air Force Deputy Surgeon General. In 2020, he was mobilized for seven months as the Government-wide COVID-19 Deputy Incident Manager with HHS and FEMA.

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Attachment A.

Summary Matrix of Policy Recommendations to Build a More Resilient, Diverse, and Secure Supply Chains

<table>
<thead>
<tr>
<th>Enhancement</th>
<th>Overview</th>
<th>Who would Oversee</th>
<th>Impact</th>
</tr>
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<tbody>
<tr>
<td><strong>Hospital Level Emergency Response Limited PPE Supply Bubble Policy</strong></td>
<td>Limited to handful of PPE supply items, such as: Gloves, Coveralls, Gowns, Surgical Cap, Head Cover, Shoe Covers, Eye Protection, Face Shield, Mask, Respirator, Hand Sanitizer, Thermometer, Biohazard Bag, Specimen Swab, Transport Medium, Viral Transport Kit, and Human Remains Pouch.</td>
<td>US Centers for Medicare &amp; Medicaid Services (CMS) hospital accreditation process.</td>
<td>Ability to reduce the immediate resupply requests, provide distributors and manufacturers the ability to respond and rebalance capacity while it preserves the hospital industry’s ability to use “just-in-time” or other cost management systems.</td>
</tr>
<tr>
<td><strong>RFID Blockchain system on the PPE Supply Integrity</strong></td>
<td>Develop industry standards that could be incorporated into government PPE procurement efforts to facilitate the RFID and blockchain security systems to enhance the integrity of the supply chain.</td>
<td>Industry in partnership with Government procurement policies.</td>
<td>Creates a unique tracking system to eliminate or significantly reduce “Gray Market” PPE from entering the hospital system, speed up the validity and legitimacy of the product for the business enterprise.</td>
</tr>
<tr>
<td><strong>Working Capital Fund (WCF) for the Strategic National Stockpile (SNS)</strong></td>
<td>Congress to provide the SNS with a WCF to allow the SNS to have a tool to support full-cost recovery and lower operational risk and replenishment cost of supplies like PPE.</td>
<td>The Strategic National Stockpile (SNS) leadership and Department of Health &amp; Human Services (HHS).</td>
<td>A WCF in the SNS can increase cost transparency, efficiency, and improve mission operational success with resources better aligned to requirements to drive proactive customer engagement, detailed cost analysis, and informed demand forecasting.</td>
</tr>
</tbody>
</table>

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iv Deborah Abrams Kaplan, Dec 11, 2017, 2 ways hospitals are taking control of their supply chain | Supply Chain Dive


