**Written Statement of Robert B. Handfield, PhD, before the U.S. Senate Committee on Homeland Security and Governmental Affairs, May 19, 2021**

My name is Dr. Robert Handfield, and I currently serve as the Bank of America Distinguished University Professor of Supply Chain Management in the Poole College of Management at North Carolina State University, and Executive Director of the Supply Chain Resource Cooperative. I have studied purchasing and supply chain management for more than 30 years, and have a notable number of research publications in the field. I have also served as a supply chain consultant to more than 40 Fortune 100 companies, spanning the fields of healthcare, pharmaceuticals, industrial manufacturing, oil and gas, electronics, and have worked in government acquisition (including the VA, GSA, and DoD). I have also written several textbooks in purchasing which are used globally in academia.

In March 2020, a group of us in academia and government began working with the various national supply chain task forces responding to COVID-19. We were quickly met with the overwhelming realization that our country was not prepared to respond to the supply chain needs. Not only were we not prepared, but existing response structure had left us dependent on overseas supply chains that cut us off from much needed PPE and other medical supplies. During this period, the scarcity in critical supplies, medical and otherwise, resulted in a new tragedy of the commons. One in which the pasture being grazed is covered in human lives. Our recommendations for a renewed SNS were described in an article in the Milbank Quarterly, and the Harvard Business Review, both published in 2020.

In March 2020, I began volunteering my expert advice to the Department of the Air Force Acquisition Task Force, under the Department of Defense Joint Acquisition Task Force. One of my professional academic colleagues is an Active Duty Air Force officer who was completing his PhD at UNC Chapel Hill and was also asked to support the task force. He had asked for my advice during the initial emergency response. I continued to volunteer advice from March to June of 2020. During this time I provided advice and information regarding market intelligence and analysis for supply of PPE, N95 masks, gowns and gloves, ventilators, testing kits, and other key material. This task led me to have hundreds of Zoom calls with individuals in different federal agencies (DoD, FEMA, DHS, Strategic National Stockpile, DLA, GSA), state agencies (NASPO, GRA), private sector companies (manufacturers of pharmaceuticals, textiles, medical devices, distributors), universities and hospitals (UNC, WakeMed, National Hospital Association), as well as other subject matter experts. At the same time I began to receive similar requests for advice from a host of state agencies and private companies. My colleagues and I developed a presentation for SNS 2.0 made for the Principal Deputy Assistant Secretary of Defense for Logistics at OSD based on our research, expertise and observations during the initial response. Many of these recommendations are further developed in my testimony today.

In this response I have brought to bear industry knowledge and current experiences to develop insights into what happened, what went wrong, and how to fix it. I should also note that I wrote a position paper for the IBM Center for the Business of Government published in 2011 based on the SARS pandemic, titled “Planning for the Inevitable: The Role of the Federal Supply Chain in

Planning for National Emergencies". Many of the recommendations made in this report, if they had been followed, would have led to I believe a much better response to COVID. (I would be happy to help support your team, if there is an opportunity to do so on a subcontract basis.)

In this testimony today, I will begin by describing the state of the Strategic National Stockpile and the state of U.S. medical supply chain readiness prior to January 2020, including the longstanding reliable on foreign sources for critical drugs and medical supplies. I will then describe the events that occurred during January and February 2020, including the Defense Production Act, Strategic National Stockpile, and emergency contracting capabilities. I will also discuss federal roles and responsibilities during the initial response to COVID-19 related to preparation for, mitigation of, and coordination with states, hospital systems, and others to address anticipated medical supply shortages. I should also emphasize that this responsibility is not just that of the federal government; as documented in our Harvard Business Review article in 2021, all states, government agencies, and private sector companies need to be better prepared in the future. Finally, I will discuss needed reforms to strengthen U.S. medical supply chain vulnerabilities and better prepare for future public health emergencies, and the guiding principles for my vision of a renewed SNS 2.0.

Table 1 – Supply Shortages During COVID

| | | |
|---|---|---|
| Masks (Surgical and N95 respirator) | Belgians modified snorkeling ma | https://www.medscape.com/viewarticle/927732 |
| Goggles | Potential sources of PPEs: -High school/University chemistry/biology/engineering labs – goggles, gloves, aprons -Oil fields and construction v | |
| Face Shields | | |
| Gowns/Gloves, Shoe covers | Reach out to construction compar | |
| Lab supplies (broad) (test kits &reagents for them) | | |
| Isolation Stethoscopes | | |
| Biohazard bags | | |
| Sanitizers | Isopropanol & Ethanol suppliers/ | |
| Expiratory CO2 Detector | | needed to help rapidly verify tracheal intubation |
| Laryngoscopes | Must have durable and disposable | |
| Macintosh Blades | size 2-4 | |
| Miller Blades | size 2-4 | |
| Glidescopes and Blades | | necessary for very difficult intubations - 1 per hosptital likely sufficient |
| Endotracheal (ET) Tubes | Sizes 6-8 (5 tubes) | Prefer subglotic suction port to decreate Ventilator Associated Pneumonia (VAP) |
| ET Tube Securing devices | | |
| Durable Cloth Medical Tape | | Can be used a substitute for securing devices |
| Laryngeal Mask Airways | | Necessary to support patients for short periods when intubation is very difficult |
| 10 CC syringes | | Necessary to inflate ET tube |
| Cuff Pressure Manometers | | Necessary |
| bougie intubation tubes | | necessary for very difficult intubations |
| nasal and oral airway devices | | necessary to assure sufficient ventilation before intubation |
| Expiratory CO2 in-line sensor adaptors | | |
| ECG Monitoring Contacts | | |
| Pulse Oximetry devices (stickers and carriable devices for isolation) | | |
| Suction Supplies | | Necessary to maintain airways |
| Canisters | | will require multiple with extended vent requirements |
| Tubing | | |
| Endotracheal Suction Catheters | | |
| Red Rubber Suction Catheters | | |
| 50 PSI O2 and Air Wall Adapters | | |
| Tracheostomy Kits | | |
| Ambu Bags/Masks | | |
| Viral Expiratory Filters | | necessary for both ventilators and ambu bags |
| PEEP Valves - adjustable or 5/7.5/10 cmH2O | | necessary for patients with Acutre Respiratory Distress Syndrome (ARDS) when patient is off of ventilator |
| Travel Ventilators | | |
| Travel Vent Circuits | | |
| Inline Nebulizer Adaptor and Small Volume Nebulizers | | necessary to administer aerosolized medications |
| Heated Ventilator Circuits | | prefer heated circuits to decreate incidence of VAP |
| Humidifiers | | |
| Heat and Moisture Exchangers | | prefer humidified circuit but necessary for transport and as substitute to humidifier |
| Patient Restraints | | necessary to prevent involuntary extubation |
| 18 and 22 mm adaptors | | necessary to assure PEEP valve/HME/in-line nebulizer compatibility |
| Brochoscopy Kits | | |
| Vaccine - Rapid Production | | |
| Therapeutic Drugs - Rapid Production | | |
| Furosemide | | Medical community has found that diuretics are critical in treating COVID patients |
| Propofol | | Necessary for sedation of intubated patients |
| succinylcholine | | paralytic necessary for intubation procedure and to manage most critical vent patients |
| Midazolam | | Necessary for sedation of intubated patients |
| Environmental | | |
| Healthcare (RRT-RN-MD) | | |
| Quick Accredidation for ICU/Vent capability | | |
| Beds and Associated Facilities Supply | | |
| Wheel chairs, mobile beds/stretchers | | to move/transfer patients |
| IV fluids | | |
| Oxygen cylinders | | |
| Refrigerators/Freezers for medications/samples and others | | |
| Parts and/or access to 3D printers and raw material sto m | https://3dprintingindustry.com/ne | |
| No-contact infrared thermometers calibrated for humans | | |
| Refrigerated/cold-chain trucks | | in case of overwhelming cases of deaths |
| Food, beverages, water | Access to them - For healthcare wo | |
| Dialysis machines, accessories and medications | | |
| Anesthesia, CPAP/BiPAP machines that can be modified t | https://www.fda.gov/media/1363 | if number of patients needing ventilators increase exponentially |
| Manufacturing locations that can produce PPEs with exis | Access to raw materials to prepare | if dearth of PPEs occur. Exports of PPEs (except probably only from China) are being restricted. |
| Space: Temporay testing/disinfection spaces outside the I | https://twitter.com/CNNSitRoom | |
| Self-swab test kits to be potentially launched this week | to be potentially launched this w | Potential for overload of testing with self-swab test kits. |
| Batteries (as required) for equipments | | |

## What was the state of readiness of the Strategic National Stockpile and the U.S. medical supply chain prior to January 2020?

As stated in my earlier report (Handfield, 2011) the U.S. medical system has been increasingly reliant on low cost manufacturing from overseas sources, a trend that has been occurring for the last thirty years. Much of this activity has been driven by the continued pressure of the

healthcare system to buy pharmaceutical products and medical supplies at the lowest cost. Medical supplies include many of the items shown in Table 1 below, which includes surgical and N95 masks, gowns, latex gloves, catheters, single use tubing, Propofol, IV fluids bioreactor bags, and many other items. All of the products shown in Table 1 experienced significant supply shortages during the COVID crisis. Beginning as early as the 1970s many companies moved their manufacturing to low-cost regions to gain improved labor cost—often one of the highest contributors to the cost of goods sold. Offshoring was enabled by international trade agreements struck between nation states, reductions in duties and taxes and other government incentives The offshoring of production often meant that firms established large, centralized, production facilities to exploit volume advantages, in locations such as China and India. Final products were manufactured in centralized facilities and then shipped around the globe to large distribution centers in the US and Europe. Many of the distributors of these products, including companies like Cardinal, McKesson, Owens and Minor, Premier, MedAssets, and others, bought them in large quantities at discounts, and then sold them in bulk to hospitals, based on contracts that promoted a "stack 'em higher, buy 'em cheaper" mentality. This practice was also encouraged by increased pressure on hospitals by CMS and private insurance companies to reduce patient costs. For products like nitrile gloves, there emerged near monopolies like Top Glove and Viet Glove in Vietnam. For N95 masks, more than half of the world's supply came from China, and in fact, much of that was produced in the Wuhan region where COVID originated! 3M also secured all of their raw materials for masks from China, and their factory there was directed to sell only within China by the government through April 2020.

In pharmaceuticals, as more common products became generic, many of the inputs for drugs, known as Active Pharmaceutical Ingredients were sourced from India, which then sources many of their materials from China. Manufacturing is outsourced to Contract Manufacturing Organizations (CMO's) who are often evaluated based on a per unit price basis, and directed by brand pharmaceuticals to produce according to the "recipe" provided them using the suppliers they were directed to buy from.

There were inherent risks with buying low cost medical supplies and pharmaceuticals from Asia. First, there was a lack of direct control and oversight over operations, and the risk of GMP and quality problems was significantly higher. Second, most shipments were made by ocean freight, and the leadtimes for such shipments became longer and longer, as the ships became larger and slower and made more frequent stops (again to save money and drive down the cost of transportation). Distributors in the US tried to keep inventory as low as possible, and tried to keep as little safety stock on hand as possible. Domestic manufacturers of medical products could not compete with these low costs, and many went under or transferred operations to Asia. The Chinese tariffs created further problems as supply became constrained. One of the biggest risks overlooked was the remote possibility that export controls or product shortages would cut off our supplies of medical supplies, a risk which in fact came to fruition in early 2020. Another risk I observed during my work with hospital supply chains is that they often had very poor inventory management practices, with little visibility to their current inventory levels, which we referred to in our paper "Blurry Vision: Supply Chain Visibility for PPE during COVID".

During my research, I also had an opportunity to speak at length with several members who worked in the Strategic National Stockpile, and who shared with me some key insights. A bit of history regarding the origin of the SNS is important to note here, and this testimony is in no way intended to be acrimonious in nature to the hard working men and women who staffed this agency during COVID. In fact, their diligence and long hours they put in to try to react to what was an untenable situation is duly noted, and my critiques here are limited to the design of the SNS, as opposed to a direct criticism of the people working within it.

Prior to COVID, the SNS was somewhat of a "secret" organization, as they did not publicize what they did. The genesis of the organization was on bioterror, not pandemics. The SNS was thus never designed or intended to be able to respond to a pandemic such as COVID. The majority of the people working within it were inventory logisticians, not supply chain logisticians. That means most individuals did not have experience managing warehouse and transportation and acquisition activities, but were rather focused on optimizing the stockpile of goods given very limited funding. The SNS managed about 800 product lines, and spent much of their time focused on how to spread out limited funds on acquiring materials to cover threats. Prior to COVID, potential threats were often determined by HHS to determine what to invest in, but this was a public health science view of potential scenarios that might arise, and had little to do with supplying demand for products. And scientists at HHS have a difficult time predicting things. Rather, they look forensically and medically at a problem, but are generally slow and not good at predicting what is needed and how to respond to a future need. In 2017, the composition of the SNS inventory was largely determined by the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which issued a strategic plan outlining the key areas for inventory investment.[1] PHEMCE is composed of multiple agencies who assess the current set of global threats. Number one on that list was $5.7B for pandemic influenza, which included development of vaccines with BARDA, as well as replenishment of expiring material in the SNS. Unfortunately, this excellent plan was allowed to languish, and in 2018 was not restarted. This was tragic, as we would have been in a much better place if it had been carried out. For instance, the supply of N95 masks in the SNS consisted of inventory acquired during the 2009 SARS epidemic. Because these masks were acquired with one-time supplemental influenza funding, they were never replenished, and by the time COVID hit, most of them were expired and useless. In addition, $2.3B had been allocated on anthrax vaccines that were never shown to be effective, for a threat that was never really validated, which dated back to 2004. So the ability to cover all 12 of the PHEMCE areas was not possible as funding for the SNS was cut back further. Its ability to source based on risk was largely determined by scientists, and even then, often involved one-time events, never for a persistent on-going pandemic like COVID.

The SNS had been part of the CDC for more than 10 years, and in the last two years, was transferred over to ASPR as part of the HHS. This was not really the right place for it to reside, as again it reported up to medical scientists, not emergency response agencies. Their leader Greg Burrell had retired in November 2019 and did not even have a deputy director assigned and was leaderless. The agency did not have enough warehouse capacity to procuring and storing

[1] https://www.phe.gov/Preparedness/mcm/phemce/phemce-myb/FY2018-2022/Pages/exec-summary.aspx

materials, even if they had done so. And there was little precedence for them to store products and sell them into the market, as so much of their inventory went to waste and had to be given for free to the public in the event of an event. Having significant appropriations associated with disposal of expired goods was not an option.

Despite these problems, the SNS did have early indicators of a pandemic that was imminent in January 2020. On January 29, the SNS issued an Analysis of Logistics Summary (ALES), a new reporting mechanism it was piloting for the first time. The ALES asked for a response from key distributors, who all responded that they were all on allocation of PPE on February 1 from suppliers in China, and even noted that they had heard China was nationalizing product and they were experiencing an inability to get transportation to the ports for exports of these goods. By February 3, all of the distributors were being slammed with requests for PPE, which they did not have. One quote I recall is that "I was shocked at how many manufacturers and distributors have so little visibility into their tier 2, 3, and 4 suppliers." Members of the SNS spoke leaders up the chain of command within the HHS, but again, these were scientists who did not understand how supply chains operated, and despite an SNS briefing predicting what would happen, they were not listened to. By March, when the DPA was enacted, it was much too late to obtain PPE and supplies, as distributors and manufacturers were unable to get products out of China. I also spoke to many state CPO's who experienced the same issue, and some of them in fact had their shipments commandeered by HHS and FEMA later that summer at the ports.

**Table 2.** Organizations Consulted During COVID

| **Government** | **Provider** | **Intermediaries** | **Other Industries** |
|---|---|---|---|
| Department of the Air Force COVID-19 Task Force | Cleveland Clinic Health Systems | Medline Industries | National Council of Textile Organizations |
| Joint Acquisition team Task Force | Summa Health | Public Spend Forum's GovShop | American Apparel and Footwear Association |
| Federal Supply Chain Task Force | Kaiser Health | | American Association of Textile Chemists |
| FEMA DHHD Capacity Enhancement Team | Eastbrook Healthcare Center | | Colorists, India (Association of the Nonwovens Fabrics Industry |
| FEMA Products Team | Envision Healthcare | | The Association of and Voice of U.S. Sewn Products Industry |
| FEMA Initial "War Room" Team | Banner Health | | North Carolina Healthcare Association |

| | | | |
|---|---|---|---|
| FEMA Tower Team | Montage Health | | American Public Power |
| Joint DOD Healthcare Team | | | Beroe, Inc. |
| JAIC Project SALUS Team | | | Helena COVID-19 Network Project |
| | | | Resilinc |
| DOE | | | Exiger |
| CBRN Office FEMA | | | Govini |
| Biomedical Advanced Research and Development Authority (BARDA) | | | |

**Federal Roles and Responsibilities in Responding to COVID and Medical Shortages**

During the COVID pandemic, the federal response suffered from a number of problems which we observed through discussions with personnel across a number of agencies shown in Table 2.

1. A singular lack of federal-level market intelligence and supply chain transparency left the government ill prepared. Because the SNS was never designed to anticipate every risk, it was forced to prepare for a wide variety of possible disruptions by mounting a response with little intelligence. To be better prepared, a multi-agency collaborative effort that relies on multiple sources of information is required. The Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents describes a number of agencies that should be involved on the medical side, including DHS, DOT, NIH, CDC, ASPR, USAID, DOD, USDA, FDA and others.[2] But there also needs to be a supply chain facing organization, that is prepared to provide insights into categories of medical supplies and the state of those markets, that is responsible for developing acquisition and logistics strategies to ensure management of these items. To prepare for emergencies, category strategies need to be established for critical supplies in order to understand the current state of supply capacity, constraints, and export restrictions.[3] Supply market research is particularly important for items like PPE, for which there is a notable lack of domestic manufacturers to support a surge in demand.

[2] https://www.prolific.com/qwiki.cgi?mode=previewSynd&uuid=VAXM1WWF9J6RQ336F82Q7WSFK6QT.

[3] Defense Pricing and Contracting. n.d. Contingency contracting. https://www.acq.osd.mil/dpap/pacc/cc/index.html. Accessed September 3, 2020.10. Monczka R, Handfield R, Giunipero L, Patterson J. *Purchasing and Supply Chain Management*. 7th ed. Cincinnati, OH: Southwestern Publishing, College Division; 2019.

2. A lack of technology for material visibility within the SNS, FEMA, and state procurement offices led to a lack of demand insights and the inability to detect shortages in hospitals and the national stockpile. There were no barcode-tracking systems to monitor where inventory was in the system or to find the expiration dates of materials in storage. One cannot manage what one cannot see. The SNS relies on a manual count of inventory and manual updates to its antiquated Department of Defense material system, with an antiquated inventory management system providing no visibility into materials' expiration dates, similar to recent findings reported in regard to the Veterans Affairs' COVID-19 inventory readiness.[4] For instance, an audit of the SNS stockpiles in January 2020 revealed that the stock of N95 masks, gowns, and gloves had been depleted during the H1N1 pandemic a decade earlier and never replenished, and many of the masks were past their expiration dates.[5] We further discovered that significant shortages of PPE were not being reported publicly by the CDC during this period. A report by the **National Healthcare Safety Network (NHSN)** recorded on June 10, 2020, which is part of the CDC, is the nation's most widely used healthcare-associated infection tracking system, and reported that 40% of hospitals could not get N-95 masks.

3. The federal government's reliance on health care suppliers that are primarily overseas and beholden to the export policies and priorities of other nations has led to significant shortages. Even 3M in the United States was not able to produce masks because all the sources of materials (fabric, elastics, nose bands) were produced in China. My discussions with state CPO's suggested that partnerships with private sector companies, such as the association between the state of Michigan and General Motors, facilitated access to Chinese suppliers through assets that were on the ground in Shanghai. Many distributors were unable to get supplies, and were inundated with promises from bogus suppliers in Asia that they could produce masks. They were also flooded with orders from hospitals, who were desperate and were placing orders with everyone, making it difficult to understand what the actual demand levels really were. Donald Trump**'s** Executive Order 13909, which was issued on March 18, allowed the government to "determine...the proper nationwide priorities and allocation of all health and medical resources...for responding to the spread of COVID-19 within the United States." Project Airbridge was designed to airlift masks from China, but it was never revealed the actual number of masks and supplies that were acquired.

4. Disparate means of communication and coordination among public agencies were apparent to everyone. Today the Division of the Strategic National Stockpile occupies

[4] US Government Accountability Office. VA acquisition management: supply chain management and COVID19 response. Report no. GAO-20-638T. Washington, DC; 2020.

[5] Bender M, Ballhaus R. How Trump sowed COVID supply chaos. "Try getting it yourselves." *Wall Street Journal*. August 31, 2020. https://www.wsj.com/articles/how-trump-sowed-COVID-supply-chaos-try-getting-it-yourselves-11598893051#comments_sector. Accessed October 12, 2020.

a low level within the Office of the Assistant Secretary for Preparedness and Response (ASPR), a group of public-health experts in the Department of Health and Human Services. In this location, the SNS has little influence and national visibility and is not resourced appropriately, often with reduced budgets. In this location, managers struggle to get access to information from other agencies, and they have little national visibility to enable them to request such information. Ideally, the SNS would require the opinions of experts from many sectors, including epidemiology, health care, distribution, occupational safety, cyber security, drug administration, the intelligence community, the State Department, state agencies, and public health.

5. The SNS lacks strategic sourcing, forecasting, and planning capability. Preparing for a pandemic requires the ability to monitor many different things at once, from the dynamics of the Asian health-care market to the shifting nature of supply and demand across multiple categories such as PPE, drugs, vaccines, ventilators, and testing kits. A significant investment needs to be made in staffing the SNS with experienced supply management professionals, who are knowledgeable in developing category strategies for these materials. Many of these issues were problematic because of a lack of visibility technology, a lack of a barcoding system for track and trace of material locations, expiration dates, and consumption, and a lack of market intelligence on what was happening in the supply markets for these items.

6. Reactionary planning and interventionist strategies (e.g., universities stepping in to rapidly produce face shields using 3D printing) were used to fill gaps for whatever category of material was in short supply on any given day. A detailed advance plan that includes both third-party sourcing as well as domestic production sources that can be used as redundant stopgap measures is needed to ensure that hospitals are never put in the position of having to forage for PPE or other critical materials in an emergency.

7. Hospitals lack visibility into their needs and a mechanism to compel the reporting of need metrics (e.g., inventory and use data). A system of real-time inventory availability, transportation movements, and consumption rates for critical materials is imperative, as are insights into the global supply of a shifting list of materials.

8. The early depletion of the strategic stockpile in February 2020 produced an inability to replenish and distribute materials on a timely basis, because their expiration dates could not be readily found. Our research suggests that a lack of funding and a small budget hobbled the ability of personnel to acquire the PPE that they knew in January were going to be in short supply.

9. Multiple shortages of critical hospital supplies, which raise the number of life-threatening supply shortages, exposed health care workers to risks that have further lowered our country's ability to respond. The SNS ran out of most materials in late

March 2020.[24] A secure strategic-sourcing plan for health care supply acquisition that goes beyond monitoring materials in the stockpile is needed to respond quickly to emergencies.

10. Federal agencies were competing with one another over their decision rights and ownership of issues. An equitable and fair means of deploying materials in the stockpile that is based on need and avoids random allocations is necessary for our national health care policy. Today, no such policy exists, as there has never been a situation comparable to COVID whereby every state in the country required emergency medical supplies.

11. State procurement agencies were operating independently, which led to hoarding and gaps throughout the country, often with the bigger and more populous states getting priority and the less populated or lower-funded states being left out. A system for tracking inventory across state lines and creating a commons-based system of supply that shows the nationwide demand and supply requirements is needed for the equitable distribution and allocation of materials.

The Defense Production Act was invoked for PPE essentially after the fact, as the global supply of raw materials to produce these goods was already backlogged by April. Government edicts to control production will not function in a global supply chain that does not have raw materials available domestically. This situation reveals a lack of adequacy, capability, and governance to create and manage a commons to respond to a national pandemic situation. We attribute this to a number of inherent problems in both the national pandemic response and the general lack of integration across the entire US health care system.

To address these issues, the SNS needs a new mission and vision to enable it to function more effectively in a world where global supply chains have exposed its vulnerabilities. We could not find an effective interface between those in the SNS who manage the supply chain and those who manage the clinical and emergency issues (in the CDC, FEMA, and HHS), as well as a governance structure to coordinate these agencies. In civilian health care delivery, group purchasing organizations (GPOs) frequently serve an outsourcing function for the strategic sourcing and contracting for hospitals and integrated delivery systems. For the military, the Defense Logistics Agency (DLA) theoretically acts as a similar sourcing and contracting agency. In both the civilian and military environments, commercial distributors provide sourcing, anticipate demand, and carry out logistics and inventory management services.

As COVID-19 progressed, both GPOs and distributors recognized that while in normal times these organizations successfully managed this interface to secure goods, they were not prepared to meet the needs of the evolving pandemic. Importantly, they did not see themselves as stewards to reduce the risks associated with their customers, which would have made them a quasi-commons. Instead, they acted as supporting cost savings and product management in a health care delivery system dominated by just-in-time efficiencies rather than just-in-case management.

**Principles for a Renewed SNS 2.0**

I will also lay out the principles for a what I believe is renewed SNS 2.0. In general, I believe the stated objectives the future state SNS has a strong appeal, but I believe there is an opportunity to influence this model in a more proactive and innovative manner. The ideas of having a control-tower to create real-time visibility to the current state of material in the stockpile is a good one, but there remains a number of challenges with respect to data governance, as well as the source of the data, for creating a control tower initiative. As described in my book The LIVING Supply Chain, the challenge will be to ensure the right data is available to the right people at the right time to make decisions. However, my biggest concern is that the overall stockpile construct in its current form within ASPR does not recognize the realities of current global healthcare supply chains. I am a co-author on a paper that was published in the Milbank Quarterly, developed a full basis for how to govern the national federal pandemic response. I have additional research papers published in the Harvard Business Review and the Journal of Purchasing and Supply Management that also develops further insights on these issues.

The idea behind the SNS is not so much to focus on resiliency as the outcome, but rather to create a supply chain that is immune to shocks that may occur, including a wide variety of potential disruptions. A key component of a future state SNS is the ability to withstand different requirements that need to be pulled together on short notice. This requires advanced planning, effective category intelligence, and strategic sourcing plans for every key **need that might arise in an emergency.** The Pandemic Planning Team needs to develop demand sensing capabilities, war-gaming situations/simulations to inform category strategies, and capacity requirements that span both domestic and global sources. Requirements should embed industry standards to create maximum flexibility and increase alternatives in the event of need. This is the opposite of stockpiling of items, but rather involves contractual requirements and effective supplier development to ensure availability of supplies. We can begin with National Response Framework (NRF) items, and build on other requirements based on wargaming and simulations to assess what might be needed under different scenarios.

Increasing the stockpile size is simply going to create more waste. We advocate a "living" stockpile that covers and increases the number of sites. For instance, a number of DoD/VA Facilities carrying excess capacity can act as stockpile so long as they are tracked in real time. This requires enhanced data management to provide real-time view of material, and a FIFO inventory management approach to utilize stock that will minimize waste assuring fresh stock for the national stockpile, and minimize obsolescence. Private firms such as Amazon offer "buy and hold" inventory management options that could also be scaled to act as living stockpiles in addition to or in place of the DoD/VA clinic option. This approach would also utilize current sourcing research practices to ensure goods are state of the art, and aligned with the realities of the supply market situation, through focused category management and market intelligence.

We have to establish an SNS that is positioned with demand-sensing capabilities, that drive the people within the supply chain into action, to prepare and fight against the invader. And we need

to train our national supply chain system on how to prepare for this response. Supply chain immunity, in the case of massive disruptions of life-saving products and services, means the ability to survive, plain and simple. It is important, but many of us in the fight have noticed that the concept itself is not enough. We need the 'how', not just the 'what' in times of how to act in emergencies. We need to know how to prevent recent supply chain failures from reoccurring, should there be another pandemic or global event that affects all global supply chains. What we need is a plan for ongoing and persistent immunity for the SNS.

1. **Emerging Technologies**

Contractual requirements must be supplemented by inventory visibility systems tied to a control tower, as well as blockchain (or other distributed ledger) transaction channels. A blockchain creates a trusted network of suppliers, through a private and secure technology network, that allows instantaneous ordering, payment, and notification of receipt. A missing component of the COVID response was the inability to track where products were coming from, where they were being sent, and who was receiving them. The hoarding that is occurring can be prevented by inventory visibility systems, that employ barcode and QR code tracking of material through the supply chain, through a trusted network of distributors and manufacturers. Consumption of supplies should also be tracked, so that supply allocation decisions can be made in real-time based on daily or even hourly updates on what is happening vs. self-reporting demand that can contribute heavily to the tragedy of the commons scenario. This technology is not overly expensive to create (Handfield and Linton, 2017), but requires a centralized mandate and infrastructure to pull required data into a data lake that can serve as the single source of truth. This data lake must be curated carefully by a centralized group of information technology (IT) professionals, to ensure that data quality, reliability, and timeliness is not compromised. Traceability and transparency can reduce the risk of profiteering, counterfeiting and quality degradation in critical supply chains as well. We mandate that blockchain and visibility are critical features not a nice to have for the future strategic national stockpile (SNS) and should be used by all healthcare logistics functions.

2. **How to create manufacturing surge capacity?**

Asking Manufacturers to reserve capacity/quantities of material to supplement the SNS is not going to happen. We now know we cannot rely on this strategy – foreign manufacturers will voluntarily or be forced to serve their country's needs first. Analysis I conducted with the S&P Market Intelligence shows how exports into the US were restricted during this period. Our manufacturers most often rely upon foreign supply chains, and this is not going to change overnight. Companies like 3M could not get masks delivered from This is simply not a workable proposition. Reserving manufacturing capacity is simply not possible, as most of the time this requires significant advance notice to scale up, and manufacturers do not have control over the capacity of their tier two suppliers in foreign countries. We are not going to be able to control manufacturing capacity which even if contractually reserved, and many of these products

unavailable to tap into during the COVID crisis (and remain so today) During any major global crisis, this will similarly be the case.

### 3. What industries can be re-shored?

There are problems with the idea of re-shoring manufacturing to the United States. My discussions with manufacturing executives suggest that once an organization commits to outsourcing to third parties in low-cost countries, there is a minimum planning horizon of five years involved, as this requires supplier qualification, audits, start-up, quality certification, and on-going ramp-up. In many industries, sourcing executives have embedded their supply chains in Asian regions, noting that *"…these jobs will never return to Western countries.*" As an example, 80% of the world's production of certain medical products are produced by four manufacturers in one province in China. To establish alternative sources that are competitive, qualified, and at-scale would cost much more than the 25% in tariffs companies are paying today in the U.S. to import from China.

In my research I developed a framework of supply chain strategies for geopolitical risk mitigation (see Figure 1), which provides some guidelines to the federal supply chain on whether to adopt centralized/regionalized or localized supply chain designs according to how entrenched their suppliers are in a particular geographic location as well as how severe the geopolitical disruption is perceived to be.


**Figure 1: Framework for Supply Chain Strategies for Geopolitical Risk Mitigation**

The Y-axis of Figure 1 shows the shifts in the external business environment, which have rendered it difficult to localize or shift the supply base, because of the entrenched nature of the supply

base, or the cost-prohibitive elements for doing so. We note here that many Chinese industries were established with government investment, and the cost of capital for developing local sources is a significant barrier for investing in local supply capacity. The X-axis refers to the perceived likelihood of on-going political risk and disruption that is likely to continue, including the likelihood of on-going tariffs, customs duties, quotas, and export restrictions, resulting from a major and ongoing geopolitical event such as Brexit or the US-China trade war. In general, there are four strategies that emerge.

**Strategy 1: "Grin and Bear It"** - *High difficulty of reshoring, High likelihood of on-going geopolitical risk*. The increasing cost of moving products from an overseas supplier has been escalating, not just because of labor costs but also because of transportation costs, tariffs, duties, and supply discontinuity have dramatically increased the discussions around localization This perception has escalated following the COVID-19 crisis, as borders were suddenly shut down for critical materials like PPE and ventilators. However, there are some economic factors that simply cannot be overcome, where entrenched supply bases produce a "Grin-and-Bear-It" approach. This approach recognizes that in some industries, supply chain redesign is difficult, if not impossible, such as in the electronics industry where the epicenter of component manufacturing and final assembly is in Asia. Under the "Grin-and-Bear-It" approach, we suggest companies will prioritize short-term tactical efforts such as building redundancies and holding inventory at different points in the supply chain. Other tactical strategies may include moving production to nearby locations (such as Vietnam) or transshipping through nearby locations to allow for a change in the country of origin customs label and the avoidance of tariffs.

**Strategy 2: "Explore Your Options"**- *Low difficulty of reshoring, High likelihood of on-going geopolitical risk*. The movement towards localization strategies is a function of the supply chain logics that prioritize the avoidance of uncertainty and risk, and an acknowledgment of the importance of lowering the total landed costs of goods, which occurs naturally as suppliers are located closer to customers. Localization is particularly relevant due to the size/cost ratio of goods with large, bulky, and low-margin items (such as food and beverages, vehicles, fabrications) being manufactured closer to the point of consumption because they are expensive to transport. There is also an opportunity to increase domestic sourcing to exploit local market knowledge and drive growth. Consider the case of mobile phone technology and how local producers in India and China have taken massive market share by moving towards regional supply chains that produce locally for local markets. Proximity drives lower costs by being closer to customers and closer to the point of sale. For the same reason, Amazon is opening Distribution Centers close to major centers of demand in the United States, with many US retailers moving to a same-day or next-day logistics delivery model.

**Strategy 3: "Tactical Warfare"**- *High difficulty of reshoring, Lower likelihood of on-going geopolitical risk.* For some products, such as pharmaceuticals, medical supplies, healthcare products, and complex tooling, we may see reduced tariff barriers as access to these products is deemed critical following the COVID crisis. For instance, we are unlikely to see a sudden surge of local production of high volume, low-cost medical products in Western economies. For products within this quadrant, the expectation is that geopolitical risks will not be ongoing, with such risks

not perceived as being not substantial enough to justify the cost of relocating production. Companies in this quadrant will adopt short-term tactical measures such as tariff avoidance, regional distribution centers with inventory, and national stockpiles of goods. However, if there is maintained political pressure for these types of goods to be produced locally, such as pharmaceuticals to treat the symptoms of COVID-19 or PPE, these industries will consider shifting production on-shore. In addition, we may see manufacturing, heavy engineering, and oil and gas seek to develop local suppliers of engineered products, to ensure business continuity and develop secondary sources of supply, even though costs may increase.

**Strategy 4: "Buy Local"** - *Low difficulty of reshoring, Low likelihood of on-going geopolitical risk.* For those products that are subject to local cultural differentiation and local sources of supply, we will see localized supply chain designs dominate, with this category expected to grow further as consumer demand for local products increases. Industries in this sector include food, especially fresh fruit, vegetables, and meat, as well as complex health products such as customized pharmaceutical products (gene therapies) and ventilators. For example, we are beginning to observe new start-up companies in areas such as customized apparel, who are seeking to develop digital apparel production capabilities in response to consumers who are seeking customized clothing and want it delivered within 48 hours, and localized capabilities will become important for this sector. We now map the industries in our study to the four strategies shown in Figure 1 to provide an indicative framework for supply chain designs (see Figure 2).

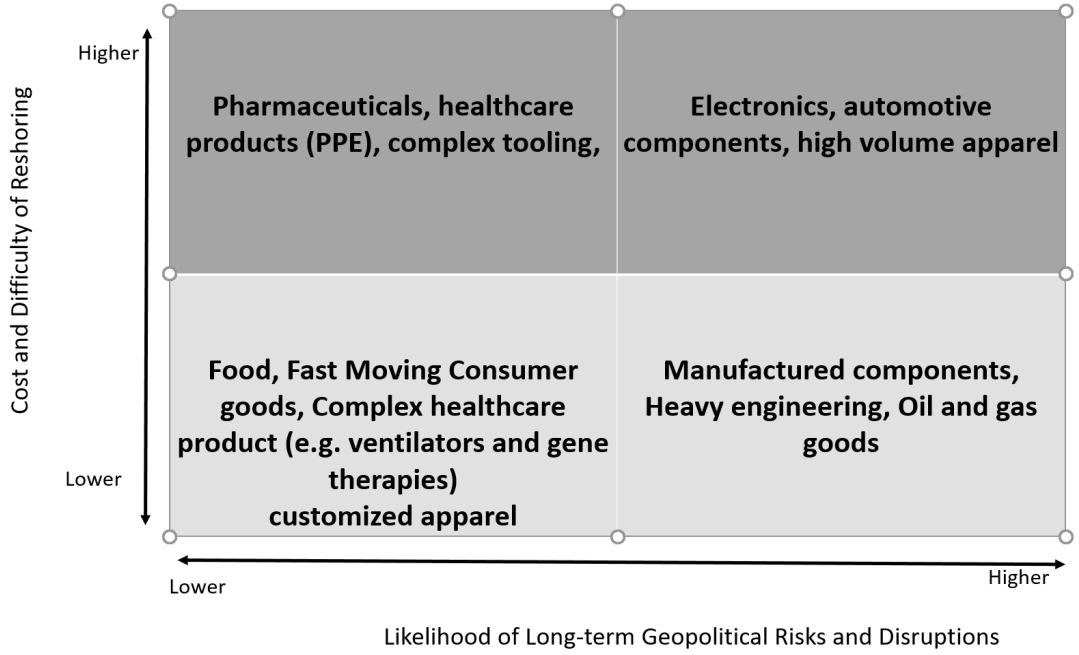


**Figure 2: Indicative mapping of supply chain risk mitigation strategies by industry**

### 4. How to develop a flexible sourcing stockpile?

We need to move away from the idea of simply increasing the Strategic National Stockpile, and think more in terms of the "Strategic National Sourcing" framework. What is needed is

a sophisticated approach for development of category strategies, combined with deep supply market intelligence around how to construct strategies to mitigate risk. "Supply market intelligence can be defined as a process for creating competitive advantage and reducing risk through increased knowledge of supply market dynamics and supply base composition." (Handfield, 2010, p. 43)[6]. I use the term "supply" in this definition and construct label, but this idea applies directly to services as well (i.e., you can gain knowledge about the dynamics and composition of available service providers.). Market research, in a public context, is the collecting and analyzing of information about capabilities within the market to satisfy agency needs (Federal Acquisition Regulation, Subpart 2). This can consist of surveillance and investigation techniques. Surveillance is a continuous awareness process whereas investigation consists of targeted, comprehensive analysis for a direct need. We note that supply chains and markets can be viewed as having informational attributes that can be viewed in the aggregate or at discrete, finite levels. We can 'zoom in' or 'zoom out'. It can also be viewed along a temporal dimensional attribute. Any future governance framework should consider these attributes and look for useful, analogous frameworks from which to learn.

**5. How to organize equitable distribution?**

Fifth, asking distributors to warehouse goods and then be responsible for distribution is not feasible. I have written two books on pharmaceutical and healthcare distribution (Handfield, 2012; 2013)[7], which have highlighted a number of structural issues with healthcare distribution that make it problematic for distributors to house finished goods inventory buffers or at point of care. One of the biggest challenges is the allocation of goods, which historically has been not equitable. During the COVID crisis, the SNS failed to serve a large number of healthcare institutions, namely smaller hospitals in less populated states. This was clear during many of the conversations I had with the National Association of State Procurement Officers as well as with the National Governors Association. Further, private distributors and GPO's will always first serve their primary customers based on who has the greatest buying power and based on prior existing relationships, and there is thus a need for increased visibility and fair allocation mechanisms that are transparent to all. (Note that the CDC NHSN has the data to demonstrate that major shortages of PPE and masks were not equitably distributed.).

An equitable system for distribution is especially needed during an emergency, and a federal policy is needed. During a pandemic the demand for materials can come from many different

[6] Handfield, R. (2010). Supply Market Intelligence: Think Differently, Gain an Edge. Supply Chain Management Review, 14(6), pp. 42-44, 46-49.

[7] Handfield, Robert, *Biopharmaceutical Supply Chains, Distribution, Regulatory, Systems, and Structural Changes Ahead,* Boca Raton, FL: Taylor & Francis, June, 2012.
Handfield, Robert, *Patient-Focused Network Integration in BioPharma: Strategic Imperatives for the Years Ahead*, Boca Raton, FL: Taylor & Francis, June, 2013.

kinds of organizations. We have seen large integrated delivery systems, individual hospitals (in and outside of these systems), government delivery systems including military and VA, prisons, nursing and senior residential facilities and rural hospitals and clinics all seeking medical supplies. Importantly, all have had access or lack of access to different sources. The "alternative market" that emerged during COVID-19, consisting principally of suppliers with personal contacts in Asia that were not part of the every-day PPE production system, targeted many of these provider organizations. An equitable system will be responsive to need as opposed to demand and be guided by a set of ethical principles that facilitate triage and distribution. To have an equitable system requires input from the various provider organizations regarding demand on their systems – but also focuses on preparedness (just in case) – which, if credible, may well prevent hoarding. If we can see where things are going, we can alleviate the need to rely on distributors and vendors to allocate material to the right places, whereas a demand sensing capability at the SNS level can drive allocation to the right states and counties most in need. Resource availability is key, but we note that information availability may be just as important, if not more so. We note that current COVID19 supply strategies have become a zero-sum game given asymmetric information, and new forms of governance are required to address these shortfalls.

**6. How to develop better market intelligence?**

Having capabilities and flexibility in sourcing alternatives is a key attribute for creating supply chain immunity for the federal supply chain. There are a number of components of an SNS that cannot be sourced domestically 100%, as it may not be practical or even possible. Outsourcing of manufacturing capabilities in North America has been on-going for more than 20 years. Even today, our experience is that many DoD contracts for aircraft and naval components are not commercially available in the United States, and are often obtained through local distributors sourcing to third party manufacturers overseas. The goal should therefore be to maintain domestic sources where it makes sense, to support national security, and create a global network off trusted suppliers who are willing to become part of the blockchain/visibility network. This may also involve partnering with organizations like Resilinc that monitor global events in supply markets and map these to key global suppliers. This can facilitate an understanding of the full risk picture, promote securing national needs first, with a "cold eye" on global impacts. Early warning is the key to early action, which can prevent shortages and capacity problems from occurring if one is too late to the game. The idea is not to remove global suppliers from the field, as this is not only impossible for certain categories of material, but may be detrimental to overall supply chain risk. We need to ensure that we cannot be removed either. This policy is not to be confused with base nationalism (which would be exclusion oriented/isolationist intent on keeping others out.). Rather the goal is to create a network of suppliers that can flex and collaborate through a trusted co-determined future relationship with a major government agency. Many global suppliers would love to be part of such a network. We have learned, during the COVID-19 epidemic, that organizations, across the globe, which were involved in manufacturing non-PPE materials, were quick to ramp-up their ability to produce PPEs. What they lacked was access to distribution systems for their products, leading to disorganized approach to making

an introduction to those hospitals and locations in need. A coordinated effort might have channeled these nouveau-suppliers to meet these contractual obligations over an extended period of time. Strategies that are focused on demand shaping with suppliers also has a major impact on cost and availability of supplies, much more so than typical "strategic sourcing" RFQ's and evaluation of bids. These approaches will not function well in the case of managing the stockpile. We summarize these key actions in Table 2 below.

Table 2 – Actions

| **Objective** | **Key Result** | **Timeline** |
|---|---|---|
| Complete traceability in SNS stock | Blockchain enablement across entire SNS | 6-12 months |
| Increase SNS flexibility | DOD and VA hospitals become living stockpiles | 12 months |
| Increase SNS durability | Reduce large lot buys and move to joint-purchased phased delivery | Waterfall based on existing supplier contracts |
| Utilize SNS Volumes to Enhance DPA | Multi-year purchases with all DPA/DPA-Like Vendors | 2 months |
| Increase SNS global independence | Universities and labs funded for JIT development of critical need/fallback source material/items for SNS | 5 years |
| Increase SNS flexibility | Develop/maintain strategic sourcing plans for every key need that might arise in an emergency | 2 years |

7. **What are the skills and requirements for staffing the SNS 2.0?**

Understanding the supply market for critical items, and developing a sourcing strategy, including a risk mitigation strategy if there is an impending issue, is critical for on-going management of global events and keeping abreast of what is happening in each area. Category managers could be flow-through positions for MBA and other graduate students going through a supply management program, and could be updated on a bi-annual basis, affiliated with a major set of universities that have supply chain management programs.

Category intelligence can help establish built in triggers for preparing the SNS given early warning. There are perhaps two planning scenarios for action: generic material usage, and responsive/reactive mode. Example: should the SNS have been activated when Wuhan was "hot"? This is another argument for a "living stockpile" and persistent market intelligence in regards to having vendors with excess capacity – rapidly increasing stock would only be constrained by the carrying capacity of our government points of care. The vast majority of our defense bases have large storage facilities, even if not in the hospital itself, that could serve as stockpile locations. The risk with a warehouse stockpile is that we acquire a massive amount of goods that we waste, if they roll right into a hospital inventory they can be whittled away over time. The issue with the current use of massive contracts with large buys (in addition to the fact that the goods go stale at the same time) is that rapidly pulsing the base for more at any moment is not possible.

8. **How will federal contracting change?**

I believe that alternative contracting approaches are required to deploy a the new SNS model. First, legislation is required to ensure that DEA Level I and II pharmaceuticals have daily reporting and visibility at the SNS locations. Second, there needs to be a policy to enable mass deployment of agreements with suppliers that are simple, and identify terms such as price, delivery, and leadtimes. These should be contracted early with multiple alternative suppliers, to provide a number of different sources for different elements of PPE. Suppliers should be qualified and audited prior to agreements, to ensure they are vetted against appropriate standards such as FDA, NIOSH, and others. I also suggest that different contractual arrangements should vary based on the category of product being sourced.

Our team considered how to best prioritize task forces requirements based on approval lead times and need levels that we think would hold well for a strategic national sourcing prioritizing framework. As shown below, supplies and services should fall into one of four quadrants defined by Source Approval Lead Time (SALT) - High and Low, and Source to Need (S2N) Ratio – High and Low. SALT includes both the time to vet new sources or new materials or service personnel themselves. This became especially important during a global health emergency where products must be vetted for safety and vendors must be vetted quickly to ensure they are not simply nonqualified opportunists.

Level 1 Requirements - low S2N ratio, high SALT bar. These offers should be reviewed by a team after a detailed vetting of the firm providing the offer (i.e., we would quickly look at alternatives from a reputable supplier, but set aside unknown, overseas or broker offers unless absolutely necessary).

Level 2 Requirements – low S2N ratio, low SALT bar. Vet quickly and set up agreement quickly. Distribute these to ready-to-go execution supplies or less specialized buying offices for mass acquisition. Consider pushing these to execution offices for vetting including open source market intelligence from commercial sources like Public Spend Forum's GovShop or public information sources such as GSA Advantage.

Level 3 Requirements - high S2N ratio, high SALT bar. Establish a wave approval process. Vet sources in waves, place vetted sources on contract and plan to continuously review future sources as backups (i.e. primacy sources that are domestic and approved, secondary sources from partner nations, tertiary sourcing from export/import restricted countries as needed). Push these approval/reviews and oversight of reputable sources to execution with high levels of quality assurance and long-term oversight horizons.

Level 4 Requirements - high S2N ratio, low SALT bar. Simply let execution offices field these sources. As they come in in directly send these sources to buying offices. Don't worry about strategically sourcing these items, but require suppliers to report capacity and stock to ensure they don't slip into Level 2 requirements. Inform execution offices d1at they need to report incidences of stock-outs.

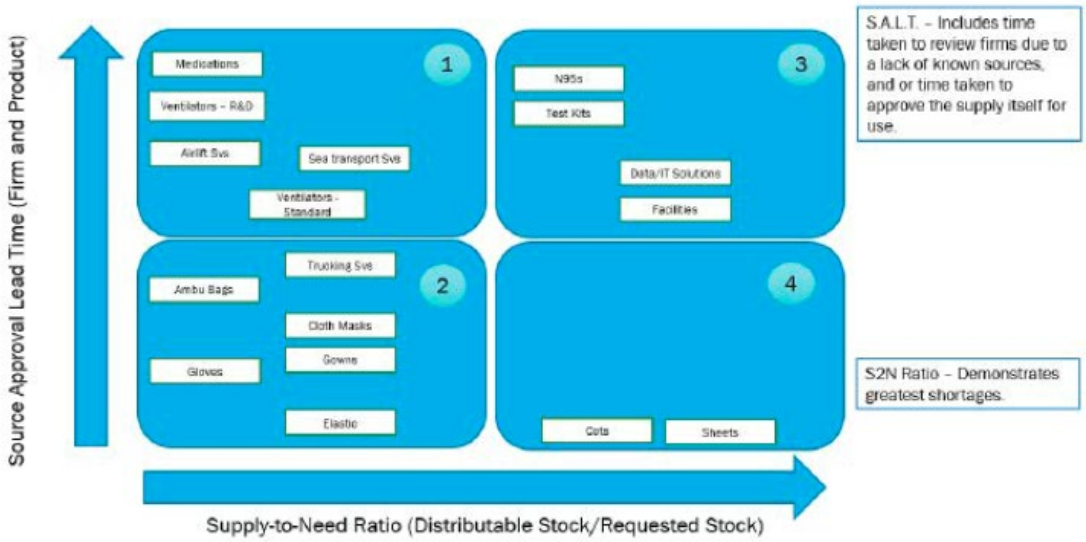

Figure Source: Finkenstadt D., "DAF ACT DASHBOARD ALT 1" developed 5 May 2020

**Conclusions:**

The idea behind the SNS is not so much to focus on resiliency as the outcome, but rather to create a supply chain that is immune to shocks that may occur, including a wide variety of potential disruptions. A key component of a future state SNS is the ability to withstand different requirements that need to be pulled together on short notice. This requires advanced planning, effective category intelligence, and strategic sourcing plans for every key **need that might arise in an emergency.**

We need the 'how', not just the 'what' in times of emergency. We need to know how to prevent recent supply chain failures from reoccurring, should there be another pandemic or global event that affects every global supply chain. What we need is a plan for ongoing and persistent immunity for the SNS.

The SNS 2.0 model we've proposed is a significant departure from previous versions of this agency. Globalization of supply chains and the reality of healthcare supply chain models will require a bold and innovative strategy for supporting our national response to pandemics, which I believe are likely to happen again. I have attempted to outline the problem and a set of possible solutions, and would be willing to support any efforts that move this forward.

**References:**


Finkenstadt, D., and Handfield, R., "Blurry Vision: Supply Chain Visibility for Personal Protective Equipment during COVID-19", *Journal of Purchasing and Supply Management*, March 28, 2021. https://doi.org/10.1016/j.pursup.2021.100689

Handfield, R., Finkenstadt, D., and Guinto, P. (2021). "How Business Leaders Can Prepare for the Next Health Crisis", *Harvard Business Review*, February 15, 2021. https://hbr.org/2021/02/how-business-leaders-can-prepare-for-the-next-health-crisis?ab=hero-main-text.

Handfield, Robert, *Biopharmaceutical Supply Chains, Distribution, Regulatory, Systems, and Structural Changes Ahead,* Boca Raton, FL: Taylor & Francis, June, 2012.

Handfield, Robert, *Patient-Focused Network Integration in BioPharma: Strategic Imperatives for the Years Ahead*, Boca Raton, FL: Taylor & Francis, June, 2013.

Handfield, R., Finkenstadt, D., Schneller, E., and Godfrey, B. A Commons for Supply Chain in the Post-COVID-19 Era: The Case for a Reformed Strategic National Stockpile. (2020) *Milbank Quarterly*, November 2, 2020. https://www.milbank.org/quarterly/articles/a-commons-for-a-supply-chain-in-the-post%E2%80%90covid%E2%80%9019-era-the-case-for-a-reformed-strategic-national-stockpile/

Handfield, R., and Linton, T. ***The LIVING Supply Chain: The Evolving Imperative of Operating in Real Time.*** Wiley: 2017.

Handfield, R. "An Investigation of the Level of Preparedness for Pandemics in the United States: Key Gaps in Critical Services and Government Infrastructure", **IBM Center for the Business of Government**. http://www.businessofgovernment.org/sites/default/files/The%20Role%20of%20the%20Federal%20Supply%20Chain%20in%20Preparing%20for%20National%20Emergencies.pdf

Handfield, R. (2010). Supply Market Intelligence: Think Differently, Gain an Edge. Supply Chain Management Review, 14(6), pp. 42-44, 46-49.