

TASK FORCE MEMBERS

Co-Chairs:

The Honorable Joe Crowley
The Honorable Mike Rogers

Members:

Professor Ravi Anupindi, University of Michigan
Professor Susan Helper, Case Western Reserve University
3M
Tom Kelly, IDX
Johnson & Johnson
MITRE Corporation
Siemens Government Technologies, Inc.
Kristi Rogers, Principal to Principal

Graduate Student Fellows (University of Michigan):

David Horvath Avril Prakash Julie Sierks

RECOMMENDATIONS SUMMARY

The COVID-19 pandemic ("the pandemic") is ushering in a new normal and we must grab this opportunity to evolve our national response because unfortunately, the next crisis is likely around the corner.

Today we have an opportunity to put our American ingenuity and innovation to work to develop next-generation emergency response solutions, transform our supporting critical infrastructure, and strengthen our national and economic security. Our manufacturing and its supporting supply chains are not only core to our national response, but also our national and economic security. Given this, **our national preparedness must receive the same attention and visibility as our national defense**.

During the pandemic, numerous agencies with overlapping and often duplicative authorities muddled the government's response capability. It was evident that appropriate planning and coordination did not occur. Further, despite the existence of the Department of Homeland Security, it remains unclear which federal agency and/or department should have primary authority and accountability for national disaster preparedness and response. Clear lines of authority and communication are necessary to prepare, respond, galvanize the private sector, and create both a whole-of-government and a whole-of-nation approach.

COVID-19 also highlighted systemic weaknesses and vulnerabilities in global supply chains, specifically for critical goods. American manufacturing and supply chains have been hollowed out over the years due to a myriad of factors, not the least of which are a push for lower costs, less regulation, access to the workforce, subsidization, and other non-market practices by foreign governments. Today the United States relies on a handful of foreign countries, in many cases adversarial nations, for the production of critical goods or their components. The pandemic underscored the need to strategically re-shore some and diversify other supply chains to a broader array of locations and away from a single source or regional supplier.



Unfortunately, lack of upstream visibility into the supply chains for critical goods has resulted in a lack of understanding of where these vulnerabilities exist and makes it difficult to wean the country off of an over-reliance on centralized foreign supply chains. As an example, Personal Protective Equipment (PPE) and medical device manufacturers were significantly impacted by the fact that several of the supply chains were located in China and the lack of a clear demand signal from the federal government. More specifically, the federal government was either uncertain who needed what where, unable to send a consistent message to the private sector and state governments, or both. This environment is simply counter-productive, especially in challenging times, and a threat to our national security.

Supply chains with increased visibility, transparency, modernization, and improved resiliency are imperative for national preparedness. We refer to this as *supply chain illumination*. This Task Force specifically looked at the supply chains of pharmaceuticals, medical equipment, and PPE. Members of the Task Force include U.S.-based global companies, U.S. domestic companies, and international companies. We interviewed United States Government (USG) senior executives in related departments and agencies, state and local officials, senior public and private hospital system administrators, other industry representatives, and additional policy experts (please refer to Appendix 1 for the list).

Our assessment of the pandemic-related challenges affecting the U.S.'s supply chain for critical medical goods highlights heightened vulnerabilities, as detailed in the following pages, in terms of preparedness for future public health or any other national disasters. Upon identifying these vulnerabilities, subsequent deeper assessments focused on identifying underlying issues and solutions (the recommendations) through the lens of strengthening U.S. national and economic security.

The following are whole-of-government recommendations, which will require coordination between the executive branch, legislative branch, and private sector for effective execution. The Task Force stands ready to assist. Thank you for this opportunity to present our findings and solutions.

SUMMARY

#1 TRANSFORM THE NATIONAL RESPONSE COORDINATION CENTER TO A MODERNIZED NATIONAL PREPAREDNESS, COORDINATION & RESPONSE CENTER (NPCRC) WITHIN THE DEPARTMENT OF HOMELAND SECURITY, REPORTING DIRECTLY TO THE PRESIDENT OF THE UNITED STATES.

It is imperative that only ONE organization plan and *prepare for*, coordinate, and respond to national disasters and emergencies. The pandemic, due to its longer duration and international systemic shock, exposed gaps in preparedness and response. It is imperative that we rethink our preparedness and response strategy. The National Preparedness, Coordination & Response Center (NPCRC) would:

- 1. Collaborate across the whole-of-government to continuously monitor, prevent, prepare for, and respond to a pandemic, biochemical threats, and other natural or human-made national disasters to maintain a common operational picture across relevant organizations. (This may necessitate amending the Stafford Act).
- 2. Dynamically realign federal priorities.

- 3. Draw staff from other agencies/departments to ensure "jointness".
- 4. Consolidate federal resources and plans. NPCRC should immediately implement a review of all existing disaster and response plans to identify gaps and ensure there are no duplications of effort and/or resources.

#2 ESTABLISH A NATIONAL SUPPLY CHAIN INSTITUTE (SCI) WITHIN THE DEPARTMENT OF COMMERCE TO RESEARCH, SUPPORT, AND COORDINATE DIRECTLY WITH THE NPCRC AND INDUSTRY.

The Supply Chain Institute (SCI) would provide research and evaluation of supply chain strategies and support the NPCRC, other appropriate agencies (Department of Health and Human Services, etc.), and the private sector. Its purpose is to increase the visibility of our supply chains (primarily of critical goods), provide background data on supply chains, and sponsor research on techniques needed for developing resilient supply chains to support the public and private sectors. The Department of Commerce has several complimentary agencies from which the SCI could draw, including the Bureau of Industry and Security, Manufacturing Enterprise Partnership, Economic Development Administration, and the Census Bureau. Importantly, the SCI would:

- 1. Map industry supply chains (domestic and international), beginning with critical goods.
- 2. Perform current-state supply chain resiliency analysis at the global and national levels.
- 3. Work with researchers in academia and industry to develop and diffuse methods for selecting and managing suppliers, to include resilience as well as low short-term cost as a criterion.
- 4. Lead analysis to better understand demand drivers for critical goods and services on the local, state, and federal levels.

- 5. Coordinate with other entities to identify, recommend, and encourage advanced manufacturing methods that increase the resilience of firms and supply chains (such as continuous/modular manufacturing, digital twins, 3-D printing, AI, etc...).
- 6. Convene industry and sponsor research on ways to redesign products to take advantage of U.S. capabilities in things like automation and software to encourage re-shoring and/or allied regional diversification where appropriate (currently, products are often designed to take advantage of cost structures overseas e.g. cheap labor, weak environmental laws).

#3 DEVELOP, IMPLEMENT, AND MAINTAIN A SUPPLY CHAIN RESILIENCY STRATEGY TO INTEGRATE NEXT-GENERATION SOLUTIONS FOR SURGE CAPACITY, STOCKPILING, AND TRAINING/RE-SKILLING TO ENSURE PREPAREDNESS AND RAPID RESPONSE IN NATIONAL CRISES.

The benefits of investments in prevention and preparedness repeatedly demonstrate their value over the extraordinary cost of an unexpected crisis on peoples' lives and our national economy. American innovation and ingenuity must be tapped to dramatically strengthen our surge capacity. The USG should use levers to incentivize industry to assist in this national and economic security effort. Below are recommendations to develop and maintain a resiliency strategy for surge capacity and stockpiling.

- Establish the Digital Strategic National Stockpile Pilot Program and Digital Twin Exchange. The integration of technology would dramatically improve our nation's ability to meet a surge in demand during a national crisis.
- 2. **Expedite the modernization of the DOD's Organic Industrial Base (OIB).** Digital modernization allows USG manufacturing facilities to more easily align with commercial firms in key areas to provide additional capacity. This "whole supply chain" preparedness approach ensures that maximum capabilities are available.

- 3. Evolve current contracting processes during a national crisis. The USG needs to create a realistic path with more flexible contracting options to allow companies to assist in a time of national emergency. Examples exist during this pandemic and each national emergency over the past 20 years where U.S. companies offer to assist but are unable to get responses or decisions from the USG. (A few positive examples from this pandemic do exist and should be noted, i.e. Operation Warp Speed.)
- 4. Incentivize businesses large and small to adopt and integrate the Fourth Industrial Revolution technologies (AI, cloud computing, digital twin automated and advanced manufacturing, etc.). This will increase speed and productivity, both during a crisis and during normal operations. However, it is not a one-size-fits-all approach. Different types of incentives are necessary depending on the businesses' structure, size, and ability to access capital.

RECOMMENDATIONS

#1 CREATE A FORCING FUNCTION: TRANSFORM THE NATIONAL RESPONSE COORDINATION CENTER TO A MODERNIZED NPCRC WITHIN DHS THAT REPORTS DIRECTLY TO THE PRESIDENT OF THE UNITED STATES.

Based on Task Force interviews, a glaring issue that led to poor preparedness and response to the current crisis was a lack of crosstalk, cooperation, and collaboration across various agencies of the United States government (USG). Even though many agencies were conducting hard work in their respective fields, the lack of shared context and coordination across agencies made for, at the very least, inefficient and duplicative

effort and blind spots within the USG; confusion and lost valuable time within the impacted business sectors; and worse, the loss of American lives.

The Task Force specifically focused on how the pandemic impacted medical supply chains. Of those affected companies (including manufacturers and distributors) we interviewed, the vast



majority of them stated that they received numerous calls from numerous agencies and departments asking for similar, yet slightly different things, insisting on immediate help and responses, and clearly not coordinating with their fellow USG agencies. This led to mass confusion, frustration, and unnecessary delays. For example, one manufacturer at

the start of the pandemic received several large request for N95s. Specifically, FEMA was placing large orders at the same time as the Department of Health and Human Services (HHS). However, after discussions it was determined that in some instances, both agencies were aiming to provide products to the exact same regions.

As another example, a respirator manufacturer we interviewed received multiple orders for PPE from multiple federal agencies, including (but not limited to): HHS, Veterans Affairs, DHS, Department of Defense, State, and others – as well as subgroups within these agencies. As a result, particularly during the extensive time period when demand exceeded supply, certain orders were filled more rapidly than others. In turn, this led to the agencies that experienced delays sometimes concluding that those who received a shipment were essentially taking their order from them.

Not only was the size and scale of the demand and where the supplies were needed unclear, but it was also unclear which USG entity was responsible. Other USG departments, state and local governments, and industry assume that the Department of Homeland Security (DHS) is responsible in times of a national disaster. When the Federal Emergency Management Administration (FEMA) merely functions as a support body with no other DHS authority assuming control, it further exacerbates the confusion. Why is this the case when it seems to be clear in statute and there is an existing response infrastructure?

According to the National Response Framework's Fourth Edition:

"...the statutory mission of DHS is to act as a focal point regarding natural and human-caused crises and emergency planning. Pursuant to the Homeland Security Act and Presidential directive, the Secretary of Homeland Security is the principal federal official for domestic incident management. The Secretary of Homeland Security coordinates preparedness activities within the United States to respond to and recover from terrorist attacks, major disasters, and other emergencies. The Secretary of Homeland Security coordinates with federal entities to provide for federal unity of efforts for domestic incident management."

"...The Secretary of Homeland Security does the following during response:

- Ensures that overall federal actions are unified, complete, and synchronized to prevent unfilled gaps in the Federal Government's overarching effort. This coordinated approach ensures that the federal actions undertaken by DHS and other departments and agencies are harmonized and mutually supportive.
- Executes these coordination responsibilities, in part, by engaging directly with the
 President and relevant Cabinet, department, agency, and DHS component heads, as



is necessary, to ensure a focused, efficient, and unified federal preparedness posture. All federal departments and agencies, in turn, cooperate with the Secretary of Homeland Security in executing domestic incident management duties."

On 30 March 2011, President Barrack Obama issued the Presidential Policy Directive/PPD-8, National Preparedness, to replace the Homeland Security PPD of 2003. It requires DHS to coordinate with other Federal agencies and with State, local, and Tribal governments to develop a National Preparedness Goal. Specifically, PPD 8 states: "This directive is aimed at strengthening the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the Nation, including acts of terrorism, cyberattacks, pandemics, and catastrophic natural disasters."²

¹ National Response Framework Fourth Edition Oct 28, 2019, p. 34-35

² https://www.fema.gov/emergency-managers/national-preparedness

Further, the Bush Administration produced the 2006 "National Strategy for Pandemic Influenza Implementation Plan". And, the Obama Administration produced the "Playbook for Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents" in 2016-2017.

Clearly, presidential directives, statutory authority, plans, frameworks, and operation centers exist within the USG. Unfortunately, when it was time to implement during the COVID pandemic there was a lack of coordination, collaboration, communication, and unity of effort, all of which are clearly stated objectives in the NRF and the National Incident Management System.

What is the issue? Are there too many plans? Is there not enough preparation? Or, are the existing plans not sufficiently focused on execution?

WHY A FORCING FUNCTION IS THE SOLUTION — NPCRC

A forcing function is a catalyst that changes default behavior in the future, or more relevantly, forces action and produces a result.

It must be made clear across the whole of government, and more importantly institutionalized, that DHS is the coordinating and accountable organization, fulfilling its statutory mission "to act as a



focal point regarding natural and human-caused crises and emergency planning" and "...executes these coordination responsibilities, in part, by engaging directly with the President and relevant Cabinet, department, agency, and DHS component heads, as is necessary, to ensure a focused, efficient, and unified federal preparedness posture."

³ National Response Framework Fourth Edition 28 Oct 2019, p. 34-35

For the past two decades in each and every national disaster there has been confusion as to which agency or department has the lead when and where. Even with the creation of the Department of Homeland Security post-9/11 confusion remains. The recent 2019 Crimson Contagion joint exercise highlighted an example: "Existing statutory authorities and policies tasking HHS to lead the federal government's response to an influenza pandemic are insufficient, and policies are often in conflict with one another, which resulted in confusion among exercise participants." Further, one of the key findings of the Crimson Contagion exercise was that there remains a lack of clarity in operational coordination regarding the roles and responsibility of agencies and in the coordination of information, guidance, and actions of federal agencies, state agencies, and the health sector. Yet, during the COVID pandemic the confusion occurred again: wasting, time, money, effort and worse, costing lives. It is time that this "confusion" be addressed before the next national disaster.

A forcing function is imperative to ensure that when the next national emergency occurs there is no doubt who is responsible for planning and coordinating the response across the whole-of-government and community. The Department of Homeland Security must be the primary lead – it was created for this.

The Task Force recommends that the forcing function for strengthened preparedness and disaster response should be the transformation of the National Response Coordination Center to the permanent National Preparedness, Coordination & Response Center (NPCRC). Permanency is recommended to provide the missing thorough and regular preparation. Permanency is necessary to eliminate the confusion of who is responsible and accountable. This organization could consume FEMA, or it could be housed within FEMA. It would report to the Secretary of Homeland Security and brief POTUS/VPOTUS or the National Security Council (NSC) quarterly. This presentation would be similar to the President's Daily Brief (PDB). An evolution at DHS is necessary and the NPCRC is a first step.

NPCRC will collaborate across the whole-of-government for a unity of effort to continuously monitor, prepare for, and respond to a pandemic, biochemical threats, and other natural or man-made disasters to maintain a common operational picture across relevant organizations, dynamically realign priorities, prepare, and shorten response time

⁴ Crimson Contagion Report, Page 11

to crisis events. This will necessitate a consolidation of resources and plans. NPCRC should immediately implement a review of the below, in coordination with all relevant agencies to include HHS, specifically HHS' Assistant Secretary of Preparedness and Response (ASPR), CDC and the Strategic National Stockpile (SNS) to ensure there are no duplications of effort and/or resources, and identify gaps. Some functions and roles may need to evolve and/or disappear.

- FEMA's National Incident Response Management System
- FEMA's National Risk & Capability Assessment, National Preparedness Report 20205
- FEMA's Plan of Action to Establish a National Strategy for the Manufacture,
 Allocation, and Distribution of Personal Protective Equipment (PPE) To Respond to
 COVID-19; Implemented Under the Voluntary Agreement for the Manufacture and
 Distribution of Critical Healthcare Resources Necessary To Respond to a Pandemic
 (appeared on 8 December 2020 as submitted to the Office of Management and
 Budget for review and clearance)
- National Strategy for Pandemic Influenza Implementation Plan, 2006
- Playbook for Early Response to High-Consequence Emerging Infectious Disease Threats and Biological Incidents, 2015
- National Business Emergency Operations Center.

The NPCRC would include representatives from the whole-of-government to include:

- FEMA (possible chair)
- Permanent representation from:
 - Other DHS components as deemed necessary by the chair
 - Dept. of Health & Human Services (HHS)
 - CDC, FDA, ASPR, BARDA, Strategic National Stockpile (SNS)
 - Department of Commerce
 - Supply Chain Institute (as recommended by this Task Force)
 - Department of Treasury
 - Department of Transportation
 - Office of the Director of National Intelligence (ODNI)
 - Department of Defense
 - EPA

⁵ https://www.fema.gov/sites/default/files/documents/fema_2020-national-preparedness-report.pdf

- Representation from state/local government (i.e., National Governors Association and US Conference of Mayors, etc.)
- National Chamber of Commerce
- NOTE: These individuals could also be the Emergency Support Function (ESF)
 Coordinators as described in the NRF⁶

By including representation from across the federal, state, and local governments and the private sector, the NPCRC will be able to effectively manage its common operational picture and place it in the context to holistically inform the Executive. It will serve as a horizontal mechanism across verticals and share not only threat/readiness data but also data from private sector participants related to critical production capabilities. The NPCRC working with the Supply Chain Institute will provide the government with dramatically improved visibility to better inform the prioritization and distribution of resources before, during, and after a national emergency.

Prior to execution, agencies and private participants must sign a commitment to dedicate resources (a funded and billeted representative) to ensure that the NPCRC will successfully exist in an enduring capacity. The NPCRC will be continuous, though staffing may fluctuate based upon necessary activity.

Critical to the success of the NPCRC will be the mitigation of private organizations' privacy concerns about data sharing. Further, it is noted that this data may be proprietary. Accordingly, NPCRC will:

- 1. Ensure the effective management of merged information via the masking of critical data, and exceedingly controlled access to unmasked data (analogous to the handling of TS-SCI data).⁷
- 2. Integrate blockchain technology as an effective tactical measure to enhance data integrity.

⁶ National Response Framework Fourth Edition 28 Oct 2019, p.37-42

⁷ This is a similar idea to the FAA, which receives engine performance data from every airline that is sent in an anonymized form to MITRE for analysis: https://www.mitre.org/publications/project-stories/fusing-aviation-data-a-new-approach-to-keeping-skies-safer

#2 ESTABLISH A NATIONAL SUPPLY CHAIN INSTITUTE (SCI)

Complex supply chains can create vulnerabilities and the pandemic exposed vulnerabilities in several critical goods' supply chains, specifically PPE, pharmaceuticals, and other medical supplies. These vulnerabilities include: lack of transparency, vast amounts of production located in non-allied nations, and weaknesses in supply and demand signaling



by local, state, and federal government. These vulnerabilities are national and economic security threats, costing time, wasting resources, and leading to the unnecessary loss of life.

Specifically, the outsized reliance on a handful of countries for production (in this case, China), a lack of supply chain transparency, and a fragmented national supply chain strategy contribute to shortages of PPE and other medical supplies.⁸ The nation is missing information about the demand for critical commodities, making it difficult to effectively allocate supply.⁹ Discussions with industry emphasized the importance of creating a trusted traceability network at the product and process levels to help solve supply chain challenges. Managing the nation's demand signal is critical to our businesses' abilities to optimally put products and services in the right place at the right time.

DHS/FEMA leads the nation in crisis response and coordination. The USG has no similar institution for preparedness and continuous improvement of supply chain and

⁸ Harvard Business Review: Why the U.S. Still Has a Severe Shortage of Medical Supplies

⁹ The PART Act of 2020 requires pharmaceutical and medical device manufacturers to make critical data available to the FDA.

operational resiliency on an industry-specific basis. The result is that the preparation to perspiration ratio of our national preparedness is upside down.



SCI IS A PREPAREDNESS AND RESILIENCY SOLUTION

It was noted in FEMA's COVID-19 Initial Assessment Report Finding 2.5, released January 2021 that, "[it] coordinated with private sector partners to expand domestic manufacturing of scarce resources but lacked a coordinated strategy across the operation for involving the private sector, which resulted in inconsistent communication, guidance, and direction."¹⁰

The proposed Supply Chain Institute is necessary to create a comprehensive solution and strategy to address supply chain vulnerabilities for critical goods as identified by the NPCRC. The SCI would be charged with researching strategies to mitigate national, health, economic, and climate security risks to improve preparedness and to better manage the response during crises.

As a research body focusing on all sources of supply chain risk, the SCI should be a Bureau within the Department of Commerce (DOC). Just as the National Institutes of Health are the federal focal points for health research, the SCI could be the focus for supply chain research. SCI will play an advisory role to NPCRC on supply chain matters of

¹⁰ https://www.fema.gov/disasters/coronavirus/data-resources/initial-assessment-report p. 143

national security and public health response. The Department of Commerce has several complimentary agencies from which the SCI could draw, including the Bureau of Industry and Security, Manufacturing Enterprise Partnership, Economic Development Administration, the International Trade Administration, and the Census Bureau.

(Note: As explained below, the SCI would be complementary to not duplicative of the Manufacturing Extension Partnership within DOC. SCI will build upon FEMA's Supply Chain Resilience Guide 2019¹¹ and further, review, coordinate, subsume, and/or incorporate the Supply Chain Analysis Network (SCAN) activated by FEMA in March 2020 to use data and analysis to highlight key supply chain features, structure, conditions, and relationships relevant to decision-making during disaster response.)

The SCI will also create and maintain risk management playbooks based on their findings, though will not have operational responsibility. The SCI will provide regular reporting to the NPCRC. The SCI will have the expertise to simulate/identify emerging challenges through their research and partnerships to identify vulnerabilities and increase supply chain preparedness. The SCI will need to rely heavily on the private sector and academia for support, participation, and data.

Importantly, the SCI should include representation from critical infrastructure sectors to influence strategies for right-shoring appropriate supply, diversification (regionally and sources), industry-specific regulations, etc. Further, the SCI should be empowered to continuously and measurably improve, test, and assure the resiliency of a specific industry supply chain using all means and tools available to do so.

The SCI will incorporate the work of the Resilient Manufacturing Task Force Act of 2020¹² — "the responsibility for promoting national economic resilience lies with the Federal Government, which must not miss the opportunity presented by the COVID-19 pandemic to learn from that crisis and prepare the United States to better withstand future emergencies"; and, the Make PPE in America Act (introduced by Senators Peters and Portman)."

¹¹ https://www.fema.gov/sites/default/files/2020-07/supply-chain-resilience-guide.pdf

¹² To require the Secretary of Commerce to establish a task force to identify vulnerabilities in supply chains for United States entities and other purposes.

The SCI should have the following capabilities:

- 1. Map national and global supply chain commodities identified by DHS (possibly NPCRC or FEMA) as critical.
 - A. Create a standard for mapping the locations of sub-tier suppliers and identifying upstream logistical bottlenecks.
 - B. Collaborate with partners in the corporate and academic sectors to create digital shadows of the value chain for products and processes of critical goods (work is being done in this area in companies such as Siemens, IBM, and GE, among others).¹³
 - C. Work with academia and the National Academies of Sciences, Engineering, and Medicine to study the collection of data on supply chains. A potential model is the US Chamber of Commerce's work with the US Census Bureau to create a standard for learning and employment records that employers can use to keep track of employee information. Once this is done, firms can easily opt in to have certain fields within this information automatically uploaded to secure servers at statistical agencies.
- 2. Perform current-state supply chain resiliency analysis at the global and national levels.
 - A. Determine vulnerabilities and levels of stockpiles, surge capacity needed, etc (in coordination with the SNS).
 - B. Analyze the networks to locate vulnerabilities, create risk mitigation plans, and develop processes for surge manufacturing/resilient manufacturing to respond in crises.

¹³ Digital twins are dynamic, collect data over a process or product's lifetime, and will help the SCI create a trusted traceability network for critical goods to increase preparedness and inform a rapid response during crises (https://new.siemens.com/global/en/company/stories/research-technologies/digitaltwin/digital-twin.html)

¹⁴ https://www.uschamberfoundation.org/t3-innovation/meet-network Participation in such an effort could be made a condition of receiving government contracts or other government funds greater than a certain threshold since such data would be needed to determine compliance with proposed requirements for government prime contractors and their subcontractors to provide "good jobs."

- C. Assign points of accountability and authority for market intelligence, mapping the industrial base/current sources, threat assessment, and availability of critical medicines. Include regular accountability reports to Congress.
- 3. Work with researchers in academia and business to develop and diffuse methods for selecting and managing suppliers to include resilience as well as low short-term cost as a criterion.¹⁵
 - A. Measuring resilience is not a straightforward task, since crises are often hard to predict and different kinds of crises require different kinds of response. Such measurement is complicated by tradeoff between resiliency and efficiency that is often emphasized in business transactions.
 - B. The SCI staff will work with partners in academia, business, and government to develop and diffuse methods that will help organizations.
 - 1) Measure resilience
 - 2) Understand how to value resilience in comparison with other desirable supplier attributes; and,
 - 3) Design organizational processes and incentives that make use of these metrics in selecting and managing suppliers.
- 4. Lead demand analysis to better understand demand needs for critical goods and services on the local, state, and federal levels. This would be a continual or at least a bi-annual assessment. Getting a clear understanding of the demand for critical goods and services is essential to develop preparedness and coordinate an appropriate response. SCI will develop such capabilities and inform NPCRC for appropriate action.
 - A. Provide visibility to accurate information. PPE and medical manufacturers were significantly affected during this pandemic by the lack of a clear demand signal from the end consumer. Orders for one particular need were

¹⁵ <u>Value first, cost later: Total value contribution as a new approach to sourcing decisions</u> - Gray - 2020 - Journal of Operations Management - Wiley Online Library

- made by many institutions to many suppliers, many times. The pattern put the world's largest manufacturers into a position where they could no longer determine who, what, and where the actual need was.
- B. Requires a multidisciplinary team of epidemiology, behavioral economists, strategic sourcing, supply chain experts, and representatives from the private sector, because the model needs to incorporate knowledge of disease management, inventory burn rates, disease progression, demand usage, and production capabilities, among other inputs.¹⁶
 - 1) This action relates to a recently released call from the Biden Administration's National Strategy for Preparedness and Response for the establishment of an "integrated, National Center for Epidemic Forecasting and Outbreak Analytics." Such epidemiological forecasting will be an important input to the broader capability to assess demand for critical health goods.
- C. NOTE: The demand assessment task will require data. Routine, exhaustive (across all facilities in the nation) demand data sharing is not feasible. One approach is to sample and extrapolate. For example, demand data for the identified commodities can be captured from a select sample of large, medium, and small hospitals, a variety of outpatient facilities, nursing homes, prisons, etc., and partner with VA hospitals to understand how data is and could be managed in partnership with US statistical agencies. (Research technology can support and integrate information from disparate data sources, and could consider partnering with technology companies such as IBM with capabilities in this area.)

¹⁶ The N95 shortage emphasizes why it is important to have a multidisciplinary team involved in creating demand models (The Washington Post: <u>The N95 shortage America can't seem to fix</u>) because they must account for inventory, usage rates, human behavior, international supply chain complexity, among other inputs.

https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/21/national-security-directive-united-states-global-leadership-to-strengthen-the-international-covid-19-response-and-to-advance-global-health-security-and-biological-preparedness/

¹⁸ E.g., getusPPE.org shows that PPE shortages are acute in non-hospital facilities that are typically unreached.

- 5. Coordinate with other entities to identify, recommend, and encourage advanced manufacturing methods that increase the resilience of firms and supply chains (such as continuous/modular manufacturing, digital twins, 3-D printing, AI, etc.).
 - A. For example, FDA's partnership with the National Institute of Science and Technology (NIST) to "accelerate the adoption of advanced and smart manufacturing technologies to strengthen the nation's public health infrastructure." ¹⁹
 - B. FDA's ongoing efforts including a partnership between the Center for Drug Evaluation & Research (CDER) and Center for Biologics Evaluation & Research (CBER) to create an advanced manufacturing center of excellence.
 - C. SCI should make the appropriate recommendations to either the Department of Commerce or NPCRC for the issuance grants and loans to companies that re-shore production of critical goods, or the component parts of critical goods
- 6. Convene supply chain actors and sponsor research on ways to redesign products to take advantage of US manufacturing capabilities in things like automation, software, and skilled labor. (Currently, products are often designed to take



¹⁹ The partnership between the FDA and NIST is intended to increase U.S. medical supply chain resilience and advanced domestic manufacturing of drugs, biological products, and medical devices through the adoption of 21st-century manufacturing technologies. https://www.fda.gov/news-events/fda-voices/accelerating-adoption-advanced-manufacturing-technologies-strengthen-our-public-health

advantage of Chinese cost structure, e.g., cheap labor, weak environmental laws, generous industrial subsidies).

- A. SCI should explore the possibility that some supply chains could be competitive if:
 - 1) Products were redesigned to build on US capabilities in automation, software, and skilled labor (rather than designed for assembly with lowwage labor)
 - 2) Investments were made to bring the production of key inputs back to the US
 - 3) Key customers agreed on a methodology for taking into account the greater quality, responsiveness, and resilience of the U.S.-based supply chain.

#3 DEVELOP, IMPLEMENT, AND MAINTAIN A SUPPLY CHAIN RESILIENCY STRATEGY TO INTEGRATE NEXT-GENERATION SOLUTIONS FOR SURGE CAPACITY, STOCKPILING, AND TRAINING/RE-SKILLING OF WORKERS TO INCREASE PREPAREDNESS AND RAPID RESPONSE IN NATIONAL CRISES

The United States government does not place the same emphasis on planning and preparedness as it does on defense (military). The benefits of investments in prevention and preparedness repeatedly demonstrate their value over the extraordinary cost of an unexpected crisis on individual lives, economics, and the very social fabric of the United States. Although the USG maintains detailed plans, numerous procedures, and interagency guidelines, they appeared ineffective or simply not followed during the COVID-19 pandemic. The pandemic exposed a lack of national and industrial resiliency and the forgotten significance of our supply chains' strength, diversity, and transparency.

Further, the pandemic exposed our outdated Strategic National Stockpile, a bureaucracy that has a stranglehold on the adoption of digital transformation, archaic contracting procedures, and enormous skills gap, or better stated, a huge number of unemployed Americans who lack the necessary skills to perform much-needed advanced



manufacturing jobs. (One recent study by Deloitte found that more than 2.4 million US manufacturing jobs would go unfilled from 2018 to 2028 due to this skills gap and retirements.)

The healthcare industry was largely unprepared for a sudden surge in demand for critical medical end-items. State and local governments, hospitals, and frontline healthcare workers were in a desperate scramble to obtain coronavirus test kits as well as, ventilators, face masks, and PPE. Without sufficient stockpiles of such crucial supplies and an inadequate ability to rapidly resupply, our healthcare systems were unable to meet critical needs. Moreover, with skyrocketing demand and an inability to accurately predict the types of commodities and quantities needed in advance, governments and supply chains were stymied in how to rapidly address shortfalls.

The Defense Production Act (DPA) was necessary and implemented, unfortunately it was slow to respond. Several recommendations below describe ways in which technology, innovation, and sufficient planning and preparation could alleviate the need for the DPA and also strengthen its effectiveness when it is necessary.

Simply put, we must be better prepared to dynamically address critical needs in a timely fashion using the latest technology available. This is a national and economic security imperative.

DEVELOPING A RESILIENCY STRATEGY

Gone are the days when it made sense from an economic or national security standpoint to only physically stock and replenish shelves in USG warehouses. Technology exists to dramatically strengthen our surge capacity and the Strategic National Stockpile. But, American innovation and ingenuity must be tapped to do so — and this is our national resiliency conundrum.

A stockpiling strategy needs to be supported by an appropriate rapid response capability to replenish the stockpile. Such rapid response is possible using advanced manufacturing capability for which appropriately trained manpower is also needed.

Industry may need to be incentivized to assist in this national and economic security effort. The USG should create a path to allow companies to help. An unfortunate reoccurring theme in the national emergencies over the past 20 years is the confusion and slow-pace of federal response contracting.

The question is: what mechanisms will get businesses to act? The following are a few recommendations.

- 1. Establish the Digital Strategic National Stockpile Pilot Program and Digital Twin Exchange Pilot Program. This will dramatically increase resiliency, allow for flexible responses to unpredictable crises by ensuring scalable production of the latest version of vital end-items and create much-needed manufacturing jobs. Again, these are pilot programs to identify concerns or challenges and create solutions, such as protecting intellectual property (IP) and addressing liability issues. The programs should explore ideas such as the following.
 - A. Create a secure government IP library of critical products' digital twins, production processes, and performance data, as well as a network of validated manufacturers (both commercial and facilities in the USG Organic Industrial Base). Notes:
 - 1) Industry is currently implementing technologies to securely hold IP and data rights.
 - 2) Digital assets can be protected very securely in an exchange/digital escrow via blockchain technology.
 - 3) The IP owner in the contract would have the ability to monitor and get all data stemming from the production as part of the digital twin exchange.
 - 4) Each entity that receives the digital twin during a crisis would have been pre-identified as "surge manufacturers."
 - A. Include a 3-sided marketplace that brings together a) IP owners/OEMs, b) production facilities and, c) end-users/distributors (some may be overlapping) in a virtual exchange system.
 - B. Stockpile inputs that go into critical products as identified by SCI research and the NPCRC.
 - C. Hold IP securely in digital escrow and require a verifiable "standard of proof", using digital evidence of quality during the production.

- 1) This will allow rapid development, manufacturing, and logistics while creating new revenue streams for all participants and validate endproducts to meet OEM, government, or industry standards.
- 2) Moreover, it would allow for decentralized local production, which would help communities utilize untapped manufacturing capacity and create jobs, not only during a crisis but in the day-to-day commercial market.
- A. Initiate a vendor-managed inventory at the SNS.
- B. Address licensing during the pilot program to confront the issues and concerns in coordination with industry leaders.

2. Modernize the Defense Department's Organic Industrial Base (OIB)

- A. Invest in infrastructure repairs to existing DOD OIB facilities.
- B. Upgrade to digitally transform the OIB.
 - Digital modernization would allow USG manufacturing facilities to more easily align with commercial firms in key areas to provide additional capacity.
 - 2) This "whole supply chain" preparedness approach ensures that maximum capabilities are brought to bear during a crisis. The "whole supply chain" refers to public (DOD OIB) facilities and infrastructure AND industry.
 - 3) Two options exist upon completion of the digital transformation:
 - OIB facilities could be tapped to work with the SNS and use their capacity when the use of digital twins are necessary or,
 - OIB facilities could hold, per an appropriate contractual agreement, the digital twin IP and work with the private sector/industry per the contract when the need arises.
- C. The returns on investment would be the creation of American jobs, the strengthening of our resiliency and surge capacity, increased visibility of USG manufacturing capability, and production flexibility.

3. Evolve Current Contracting Processes

- A. Issue an Emergency Blanket Purchase Agreement (BPA) or Indefinite Delivery/Indefinite Quantity (IDIQ) federal contract via NPCRC now, precrisis, during the planning and preparedness phase.
 - 1. This would eliminate the procurement lag time and regulatory obstacles during the initial phase of a crisis.
 - 2. Issue the BPA or IDIQ in various verticals as identified by the NPCRC. Companies would bid on each. Awards would be made to a set number of companies/organizations in each vertical.
 - 3. Hold contract with a nominal fee paid annually to awardees to maintain capacity.
- B. Encourage the use of Other Transaction Authorities (OTAs) as recommended by the NPCRC during national emergencies while maintaining protections needed for quality control and fraud reduction.
 - OTAs are essentially contracts that are not subject to standard procurement laws or regulations like the Federal Acquisition Regulation.²⁰ OTAs are expedited, flexible vehicles for research and development, prototyping, and rapid production projects. They tend to foster engagement with nontraditional contractors and small businesses.
 - 2. OTAs would only be used until the national emergency declaration is rescinded.
 - 3. OTAs would fast-track approvals for prototype projects related to the pandemic and encourage companies to come forward with innovative solutions when they are urgently needed.
- C. Use statutory commercial item exemption to get non-traditional companies to participate in the pandemic or emergency marketplace.
 - 1. New restrictions and regulations have prevented many emerging companies from contracting with the government.
 - Most new requirements have been put in place by the executive branch, but some require legislation to overturn.

²⁰ Morrison & Foerster, GAO continues to expand the scope of "prototypes" DoD may buy through OTs

2. The exemption can significantly expand the breadth of acquisitions to which procurement can be applied, raise the dollar value of procurement contracts that can be awarded, and open up procurement opportunities to small businesses.²¹

Note: The Task Force did look at the creation and implementation of Operation Warp Speed: a <u>public-private partnership</u> (PPP) initiated by the USG to facilitate and accelerate the development, manufacturing, and distribution of <u>COVID-19 vaccines</u>, therapeutics, and diagnostics. It is a good example of a successful PPP. The use of the above mentioned improvements in contracting would enable such PPP's and other tools and contracting mechanisms to be initiated during the preparation and planning phase as opposed to waiting until AFTER a disaster.

- 4. Incentivize businesses, large and small, to adopt and integrate the Fourth Industrial Revolution technologies (AI, cloud computing, digital twin automated and advanced manufacturing, etc.). This is what will increase speed and productivity, both during a crisis and during normal operations. It is not a one-size-fits-all approach. Different types of incentives are necessary depending on the businesses' structure, size and ability to access capital.
 - A. Establish a grant program for domestic capacity expansion within critical industries as identified by NPCRC and working with the SCI. The size of the grants could be determined through competitive bidding to safeguard taxpayer funds.²²
 - 1. See Senator Ernst's Mobilize AMERICA Act as a possible example.²³
 - 2. The grant program could be run by HHS or Commerce via NPRCR.
 - 3. Emphasis and/or preference should be placed on advanced manufacturing and technological advancements.
 - B. Provide capital loan guarantees for surge manufacturing (advanced manufacturing) in critical industries (as identified by NPCRC).

²¹ Morrison & Foerster, DOD's prototype OTA guide offers insight into DoD's experiment in regulation-free acquisition

²² https://science.sciencemag.org/content/sci/371/6534/1107.full.pdf

²³ https://www.ernst.senate.gov/public/index.cfm/2020/12/ernst-incentivize-manufacturing-of-critical-medical-supplies-in-the-u-s

- 1. This may be more appealing to a small, entrepreneurial company that lacks access to capital.
- C. Issue tax credits for a business to transform facilities using advanced manufacturing technologies.
- D. Earmark federal dollars for a surge capacity where appropriate.
- 5. **Implement a "workforce of the future" public/private partnership.** This includes training and re-skilling of the workforce. We have a major skills gap that must be addressed as jobs, even at high rates of unemployment, go unfilled. Skills needed for modern manufacturing currently do not exist in our workforce at the minimum levels necessary.
 - A. Policymakers should take steps to build a pipeline of workers with the skills needed to operate a modern manufacturing facility. Without these policies, the U.S. will lack the manpower needed to grow and strengthen the manufacturing base.
 - B. NOTE: It is a much deeper discussion and likely another report. However, it is an urgent issue that deserves at least mentioning here. It remains one of the biggest manufacturing challenges.

"We must invest now in the digital tools needed to prepare for the next unforeseen or unpredictable crisis. These technologies not only provide a way to better see, secure and leverage the supply chain, but also can create much needed advanced manufacturing jobs for communities around the Nation. A key road to America's recovery and its future preparedness is a digital one."

TINA DOLPH
CHIEF EXECUTIVE OFFICER
SIEMENS GOVERNMENT TECHNOLOGIES, INC



Kristi Rogers, Co-Founder, Principal to Principal kristi@principaltoprincipal.us

Rachel Pearson, Co-Founder, Principal to Principal rachel@principaltoprincipal.us

Laura Valentine, Chief of Staff, Principal to Principal laura@principaltoprincipal.us

APPENDIX 1

Private Sector Resources

3M

Adaptive Energy LLC

Ford

Get Us PPE

Johnson & Johnson

Lockton Companies

Mayo Clinic

Medtronic

MITRE

Novartis

Resilinc

Siemens Government Technologies, Inc

Public Sector Resources

Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health & Human Services

Office of Strategy, Policy, Planning, and Requirements (SPPR), ASPR, Department of Health and Human Services

Strategic National Stockpile (SNS), ASPR/Department of Health and Human Services

Center for Drug Evaluation and Research, US Food and Drug Administration, Department of Health and Human Services

Federal Emergency Management Agency (FEMA), Department of National Security Michigan Department of Health and Human Services

###