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Original Scholarship

A Commons for a Supply Chain in the Post-COVID-19 Era: The Case for a Reformed Strategic National Stockpile

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Policy Points:

- Reflecting on current response deficiencies, we offer a model for a national contingency supply chain cell (NCSCC) construct to manage the medical materials supply chain in support of emergencies, such as COVID-19. We develop the following:
  - a framework for governance and response to enable a globally independent supply chain;
  - a flexible structure to accommodate the requirements of state and county health systems for receiving and distributing materials; and
  - a national material "control tower" to improve transparency and real-time access to material status and location.

Context: Much of the discussion about the failure of the COVID-19 supply chain has centered on personal protective equipment (PPE) and the degree of vulnerability of care. Prior research on supply chain risks have focused on mitigating the risk of disruptions of specific purchased materials within a bounded region or on the shifting status of cross-border export restrictions. But COVID-19 has impacted every purchase category, region, and border. This paper is responsive to the National Academies of Sciences, Engineering and

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Medicine recommendation to study and monitor disasters and to provide governments with course of action to satisfy legislative mandates.

Methods: Our analysis draws on our observations of the responses to COVID-19 in regard to acquisition and contracting problem-solving, our review of field discussions and interactions with experts, a critique of existing proposals for managing the strategic national stockpile in the United States a mapping of the responses to national contingency planning phases, and the identification of gaps in current national healthcare response policy frameworks and proposals.

Findings: Current proposals call for augmenting a system that has failed to deliver the needed response to COVID-19. These proposals do not address the key attributes for pandemic plan renewal: flexibility, traceability and transparency, persistence and responsiveness, global independence, and equitable access. We offer a commons-based framework for achieving the opportunities and risks which are responsive to a constellation of intelligence assets working in and across focal targets of global supply chain risk.

Conclusions: The United States needs a "commons-based strategy" that is not simply a stockpile repository but instead is a network of repositories, fluid inventories, and analytic monitoring governed by the experts. We need a coordinated effort, a "commons" that will direct both conventional and new suppliers to meet demands and to eliminate hoarding and other behaviors.

Keywords: strategic national stockpile, COVID-19, supply chain disruptions, personal protective equipment.

How many people knew or cared about supply chains before January 2020? Today it is on the tip of everyone's tongue and the subject of discussion in the nightly news. Supply chains are key to managing many complex system problems: supplying the troops in World War II, putting together a NASA mission to reach the moon in eight years, producing great tasting and safe food in restaurants, running your own home, filling your car's gas tank or recharging its batteries, and ensuring power in your home. Then in January 2020 the coronavirus arrived. Now we all know that supply chains affect the supply of toilet paper, yeast, milk, eggs, meat, masks, personal protective equipment (PPE), ventilators, and polymerase chain reaction (PCR) and antibody tests. Even though the importance and urgency of supply chain management is widely understood today, our national government and health care systems have known this for at least 20 years,

having been warned by a series of major epidemics ranging from SARS (2002), H5N1 avian influenza (2003), H3N2 influenza (2008, 2018), MERS (2012), Ebola (2014), and Zika (2015).[1]

The public now knows how important it is to design, implement, and manage an emergency medical response system that is commensurate with the standards of one of the world's leading countries. System and supply chain thinking must be the backbone and the infrastructure of such a system, as prior experiences with the H1N1 pandemic and the Ebola epidemic have shown.[2] The D-Day invasion during World War II would never have succeeded without superb logistics, and the same is true for health care, whether it is for diagnosing diseases, performing tests, treating cancer, supporting transplantation, or dealing with emergency crises. A national health care supply chain policy is essential to public welfare.

In this era of COVID-19, even though the failure of the US health-sector supply chain has become obvious, few explanations of how to address it have followed. Much of the discussion has pertained to personal protective equipment (PPE), but the vulnerability of providing patient care in the face of disruptions extends even deeper into the supply chains. We have experienced shortages in the available supply of beds, pharmaceuticals, critical devices, and human resources. Prior research on supply chain risks has generally focused on identifying and mitigating the risks stemming from disruptions of a single purchased material, a specific region, or a specific cross-border export restriction. This response, however, has not been effective during a period of mass contagion affecting the entire global supply chain. Unlike our national response to previous pandemics (H1N1 and Ebola), which were restricted to a much smaller population and died out quickly, the COVID crisis has spread to every country and industrial sector in the world, owing to its highly contagious nature, introducing a new era of pandemic risk.

A strategy that centers on only one country or industry sector, when all sectors have workers that must stay at home and not work, is clearly not adequate. Indeed, the pandemic playbook operationalized during the H1N1 and Ebola crises during the Obama administration assessed the country's preparedness for a pandemic.[3] This playbook addressed issues such as border screening, public health infrastructure, diagnostic testing, clinical care, political response, and funding. But the playbook does not even mention a supply chain for critical health care materials, as it assumes that supplies will be abundantly available for acquisition by the

government. Accordingly, we believe that although the country might have been better prepared if this playbook had been followed, it nonetheless did not address the impact of disruptions in the global supply chain. Therefore, a new, post-COVID-19 supply chain system for dealing with pandemics is needed, as many different categories of health care materials can shut down our hospitals and our economy (beyond PPE, ventilators, and dialysis machines).

In this article we offer a model for managing a health care supply chain "commons" on a national scale in support of emergencies. We invoke the concept of a "commons" to suggest that during a global event such as COVID-19, critical products need to be (1) abundant, (2) credible/usable, and (3) accessible in ways to meet the needs of populations. Our discussion owes much to Garrett Harden's coining of the term "tragedy of the commons,"[4] with its applicability to self-interest and use in the depletion of common goods, especially natural resources. Hardin's 1968 Tragedy of the Commons model is concerned with the use of common property resources, their rights, and their eventual overexploitation or degradation. In a 1998 retrospective, Harden pointed out that an important omission in his original conceptualization of the problem was the extent to which exploitation of the commons is managed—with the caveat that "the devil is in the details."[5] A large body of research has demonstrated the viability of resource management options, with a strong focus on institutional arrangements.[6] Our research, focusing on common products needed in times of stress, considers institutional arrangements, especially the design and governance of the national stockpile, which is intended to be a commons for the nation.

The idea of common goods is now recognized as extending to other areas[7] and is well suited to our focus on the issues of design, development, and governance for critical medical supplies as common resources. The importance of these features has long been well known, as has the role of the public sector.[6] Also important to our discussion of critical medical products and their supply chains is the contention that for public health and the health of the public, government agencies must understand that their core competency is not in operating supply chains, as is the case in fully centralized systems. Instead, especially in a geographically large and structurally diverse nation, people in government health care must see themselves in a crisis as *stewards*, providing vision, guidance, and oversight to ensure that private-sector supply chains achieve

results, that is, serving the needs of the population to improve and maintain their health.

Stewardship does not require the direct control of services and facilities; rather, stewards are responsible for engaging and orchestrating different partners to achieve common development goals.[8] And as is increasingly recognized by public health and has become evident in the initial months of the COVID-19 pandemic in the United States, the private sector has an important role, and government can learn from the commercial sector.[8(p408)]

Methods

Much of our discussion is grounded in our observations of the COVID-19 supply chain response during the spring of 2020 to help inform a framework for managing future wide-scale contingencies like pandemics and climate change. From the earliest days of the crisis, all five of us were involved daily in planning responses to acquisition and contracting challenges, and we kept a record of the major discussions and interactions as they progressed. We noticed early on in these discussions that all agencies, firms, and governments were facing significant challenges in governance, command and control, data management, market intelligence regarding available technology, and the risk expertise of the personnel in the supply chain.

To address these shortfalls, our team began reviewing existing approaches to managing the strategic national stockpile and contingency sourcing and pandemic plans in the United States, and then we mapped out the supply chain's responses to the national contingency-planning phases. The Department of Defense, Federal Emergency Management Agency (FEMA) Emergency Management, FEMA National Response Framework, and the Homeland Security Supply Chain Resilience Guide all have different contingency phasing, from four to six stages, ranging from some form of planning and preparation to some form of transitional recovery. These phases dictate the agencies' overarching mission or goal, the time horizon for action, and the various stakeholders to consider during a crisis or contingency (force majeure, war, etc.). These phased plans were developed to help with communication and control, resource allocation, and assignment of responsibilities, as well as to help determine the agencies' tactics, techniques, and procedures. The Department of

Defense defines the sourcing or contracting during a contingency as "all contracting performed in a contingency environment, including military operations, stability operations, natural disasters, humanitarian, and other calamitous events."[9]

Our team also reviewed the literature on the supply chain's resilience, the strategic national stockpile (SNS), stockpile strategies (i.e., pooling), asset management, inventory management, and GPO contracting. Once the literature review was completed, we assembled an expert panel consisting of subject matter experts in federal acquisition and law, health care policy and supply chains, global sourcing and market intelligence, global textile manufacturing and technology, advanced supply chain data management, durable medical device and pharmaceutical start-up markets, and global emergency response planning. These members were tasked with interviewing stakeholders and developing an attribute map of those features that would define an optimal national contingency response governance model. Discussions took place with members of defense and other federal supply chain task forces, the SNS, hospital administrators, managers of medical service firms, large state utility agencies, group purchasing organizations (GPOs), as well as with academic experts and nonprofit organizations specializing in health care and artificial intelligence. See Table 1 for a list of organizations consulted.

Each interview was conducted as part of the expert's official duties in supporting various areas of the COVID-19 response, and all the experts asked their interviewees about their positive and negative experiences related to the response. These interviews delved into areas of response governance, data management, command and control, personnel expertise, and market intelligence regarding the supplies, services, and software available to aid the response. Our expert team members were then asked to classify those discovered features as "nonnegotiables" (features required in a positive model), "tolerables" (unavoidable negative model features), "differentiators" (positive features setting the model apart from others), "dissatisfiers" (negative features reducing the model's utility), "exciters" (positive features making users want to use the model), and "enragers" (negative features creating negative emotions that make users actively avoid using the model).

This review and comparison produced a gap analysis of current frameworks and interview responses, which helped us arrive at our recommended framework (resulting in the National Contingency Supply Chain Cell that we describe later) as a means of filling these gaps for

Table 1. Organizations Consulted

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
Federal Emergency Management Agency (FEMA) Department of Health and Human Services 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 US Sewn Products Industry
FEMA Initial "War Room" Team	Banner Health		North Carolina Healthcare Association
FEMA Tower Team	Montage Health		American Public Power
Defence Health Agency (DHA)			Beroe, Inc.
Army, Navy and Airforce Representatives			Helena COVID-19 Network Project
Joint Artificial Intelligence Center Project SALUS Team			Resilinc
Department of Energy			Exiger
Chemical, Biological, Radiological, and Nuclear Office, FEMA			Govini
Biomedical Advanced Research and Development Authority (BARDA)			

future contingencies. While this proposed framework certainly will be difficult to establish, we believe it offers important insights that can be used as a basis for debate.

Background

Beginning in 2015, a standing committee of the National Academies of Sciences, Engineering and Medicine led a standing committee to inform Strategic National Stockpile (SNS) decision-making. This committee included

> state and local public health officials, representatives of medical manufacturing and distribution companies, logistics managers, representatives of emergency medical services and emergency medicine practitioners, and experts in relevant fields, such as risk modeling and Food and Drug Administration (FDA) regulatory issues."[11]

In 2018, the National Academies standing committee held a workshop entitled, "Impact of the Global Medical Supply Chain on SNS Operations and Communications. This workshop included discussions regarding gaps in the global medical supply chain, issues between the SNS and state and local governments regarding the deliveries of needed assets, and concepts regarding the SNS's strategic communications. In summary, the committee noted that

1. The SNS is well run and effective, but its mission has grown while supply chains have grown leaner and budgets have not increased to support these challenges.
2. Last-mile distribution is jeopardized by underfunded and disorganized state and local public health departments.
3. National health security is dependent on medical supply chains.
4. The SNS should have the critical function of communicating with partners across the supply chain and with policymakers who influence the supply chain.
5. There are strategic issues behind the tactical challenges faced by the SNS.
6. Research on pediatric medical countermeasures is sorely needed.
7. Studying and monitoring previous disaster response can improve preparedness.

One of the most telling takeaways from these proceedings came from the committee's chair, Tara O'Toole, vice president of In-Q-Tel, who noted: "obsession with cost and profit has now infiltrated our sense of public health and how we are going to take care of each other in the most dire circumstances."[10(p44)] This is especially important, since one assessment of the public health supply chain has been that in public health, "the bottom line is saving and improving lives, which should be as powerful a motivator for rethinking supply systems as profit is in the commercial sector."[8]

Legislative Response to COVID-19

Many of the issues noted by the committee have not been resolved and have become even more glaringly apparent in the midst of the COVID-19 response. The media have highlighted the severe lack of PPE, medical supplies, and testing capabilities, which has been attributed to ineffective preparation by the CDC, FEMA, and HHS.[12] On April 29, 2020, US senators, including minority leader Charles Schumer (D-NY), introduced the Medical Supply Transparency and Delivery Act, which was inserted in the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act on May 12, 2020.[13] This legislation's purpose is to "provide for the expedited and *transparent procurement and distribution* of equipment and supplies needed to combat COVID-19 [italics added]."

The bill requires that the executive branch use all the authority under the Defense Product Act (DPA) of 1950 to mobilize an equitable and transparent process. The bill charges the executive branch to, among other things:

1. Publicly report national assessments on a weekly basis to determine national critical equipment supplies and requirements. This would include identifying those industry sectors and manufacturers most ready to fill orders, stockpiles that could be refurbished or repaired, manufacturers that could expand production into PPE and medical supplies, and supplies and equipment that could be redistributed to new hotspots. These reports would also include direct outreach to essential employees and health care workers.

2. Establish an executive officer to oversee acquisition and logistics for COVID-19 equipment production and delivery, with all the authorities available under the DPA. The executive officer would issue major purchase orders under the DPA, oversee the distribution of critical medical supplies and make recommendations to the president about increasing the national production capacity of supplies.
3. Ensure that all unused supplies in excess of need will be turned over to the SNS.
4. Increase transparency regarding the distribution of supplies and equipment by publicly posting all states' requests for assistance, metrics, and criteria for the amount and destination of distribution, metrics for determining hotspots and areas of future concern, and production and procurement benchmarks.

Most of the bill's requirements are in line with our team's recommendations based on our experiences during the COVID-19 response. But parts of the bill do foreshadow a return to the status quo. The bill states: "The office of the Executive Officer *shall terminate* 30 days after the Executive Officer certifies in writing to Congress that all needs of States and Indian Tribes identified in reports submitted under subsection (c) have been met and all Federal Government stockpiles have been replenished [italics added]."

The United States has a concerning record of treating responses to national emergencies as a light switch that can be flipped on and off. If COVID-19 has taught us anything, it is that persistent awareness is key to preparedness. Indeed, previous efforts to create a national pandemic preparation program soon fell into disrepair after the SARS virus faded into distant memory.[2] Supply chains cannot be altered or forcibly manipulated in a typical life-threatening need window (72 or fewer hours in our recent experience). Supply chains, especially health care supply chains, must be persistently managed and illuminated to meet the needs of a national pandemic response. Given that most of our health care products are sourced globally, we can neither reverse these sourcing decisions to bring them onboard nor mandate that other countries keep their borders open to provide needed supplies to the United States. Although the US government has suddenly realized the necessity of supply chain stewardship and management during a pandemic, politicians are not yet fully aware of the complexity of global sourcing, the risks inherent in

offshoring critical supplies, and the pathways available to stave off the next great crisis. Nor do they appear to embrace the ways in which the private sector can be mobilized to meet the challenge of developing the commons needed to deal with the pandemic.

These observations suggest that the government is becoming increasingly aware of the criticality of a supply chain but may not be fully aware of the risks and opportunities to avoid the next crisis. The Department of Homeland Security's Supply Chain Resilience Guide for 2018-2020 proposed that the "most effective way to deliver the needed supplies to a disaster-impacted area is by re-establishing pre-disaster supply chains. Building resilience within, and providing for the rapid restoration of, supply chain systems is key to responding to any catastrophic incident."[14] We believe that merely restoring a system that has failed to deliver the needed results is not sufficient. Rather, an entirely new model is needed to create incentives and invest in capabilities that provide a more battle-ready plan for future biological invasions. We also note that between the time this manuscript was written and published the agency has removed the 2018-2020 Strategic Plan and replaced it with the 2020-2023 Strategic Plan that makes no mention of reestablishing predisaster supply chains.[15]

Conceptual Framework

In the United States, there has been an assumption that despite the complexities of the US health care system and risks in a supply chain dependent on global sourcing, the Strategic National Stockpile (SNS), in concert with products held by suppliers/distributors, would buffer the country from unanticipated disruptions. This assumption largely ignores the complexities and fragmentation of the health care system,[16] as well as the offshoring of low-cost supplies that have pervaded hospitals' sourcing strategies, which have rendered health care largely dependent on supplies from the other side of the world. Notably, these policies are driven by a misplaced reliance on pursuing low-cost supplies at the expense of higher risks of disruption during a pandemic, policies that have been criticized elsewhere.[17] Despite analysts' signals of inadequacy, both policymakers and stakeholders have come to see the SNS as a reliable backup: a stockpile in place for the common good and a backstop that would be adequate and available to meet the community's needs.

Our research, however, suggests that the SNS was never designed to be a backstop. While not perfectly analogous to economists' conceptualization of "the tragedy of the commons,"[4,18-20] a somewhat broader idea of a commons failure is instead a suitable metaphor for what we have experienced in the United States since COVID-19 first crossed our borders.

Much of the discussion of common goods refers to the rights of access, governance, and distribution of public goods.[4,18] Undoubtedly the concern for rights to the use of common goods is important, as many may want access. But the production and distribution of public goods also are concerns.[7] Commons require definitions, specifications of common goods, construction, maintenance, and replenishment, because they may be depleted even when access is well managed and use over time is uneven. During COVID-19, there have been massive shortages in the materials and pharmaceutical supply chains, including hospital supplies (which have come to be known as PPE), medicines, testing kits, reagents, sanitizers, and other necessities. Moreover, these shortages have been in the government-designed commons as well as in the reserves held by commercial and hospital-managed consortia. The design and development of a center-managed commons, for use in an environment of mutual need, are therefore of utmost importance.

Current State

The COVID-19 crisis arrived in the United States in February 2020 and was largely dismissed by the Trump administration as a nonthreatening issue. In particular, the CDC was convinced that it had contained the virus and retained control of all diagnostic testing, which later was revealed to have been carried out by faulty kits.[12] As the virus spread more quickly in Washington State, New York, San Francisco, and New Orleans, the administration quickly realized that the coronavirus would not be "magically going away." As the number of people being admitted to hospitals and ICUs began to escalate, one of the first signs of distress was a lack of ventilators for those experiencing significant breathing problems.[21]

We observed an intense and immediate response by the Joint Acquisition Task Force to rapidly source supplies and quickly institute a robust vendor-risk assessment process. However, this task force was at the mercy of long-standing health care supply chain and strategic national

stockpile (SNS) issues that had been forgotten after the warnings issued during the H1N1 pandemic in 2009. The energy and desire to respond effectively were significantly stifled by perennial system shortfalls and "fog of war" communication problems. Our scrutiny of the Joint Acquisition Task Force's work showed the following challenges and issues, based on emails and discussions during this period.

1. A singular lack of federal-level market intelligence and supply chain transparency left the government ill prepared. Because the SNS will never be able to anticipate every risk, it must be able to cope with a wide variety of events by mounting an "antibody" response that entails developing deep market intelligence through collaboration with multiple sources of information. 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.[9] 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. A lack of technology for material visibility led to a lack of demand insights and the inability to detect shortages in hospitals and the SNS. 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.[22] 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. In addition, many of the masks were past their expiration dates.[23]
3. The SNS'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.

4. Disparate means of communication and coordination among public agencies were apparent to everyone. Today the Division of the Strategic National Stockpile occupies 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.
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 political cronyism is necessary for our national health care policy.
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.

During a national epidemic or pandemic, information is of the essence to enable rapid and agile actions. Such information must be supported by a government that enables action to be taken in response to updates and warnings on the horizon. In turn, decision-making is enabled by information that reveals the internal resources for response, through product barcodes or other technologies, that tracks and traces capabilities and "control towers" (data-/analytics-driven dashboards) that show the current state of the materials in their supply chain in real time. The ability to track material in real time is not an innovative or expensive technology, and barcode/QR code–tracking systems have been around for 20 years or more. The problem here is that common stock keeping unit (SKU) codes were often not used, which prevented information from being transmitted in a standard format among entities in the supply chain, as well as the fact that the data entered were often incorrect and of low quality.[25] Material systems that track the location, volume, expiration date, and movement of material in a supply chain are widely available in other industries yet are conspicuously lacking in one of the most important assets managed by the federal government, the SNS. Serialization regulations may offer a solution for improved visibility in the health care supply chain in the near future. The biggest change that

is required, however, is not technology but the mindset of public- and private-sector health care leaders, and this can be achieved only through public pressure.

Even though a century separates the 1918 flu and COVID-19, we cannot assume that the current pandemic is a "black swan/once in a lifetime event," nor are other events that disrupt supplies, like emergencies caused by the weather.[26] Some people believe that we can go "back to normal" and that the old ways of working can be continued at some point in the not too distant future. Nothing could be further from the truth. The post–COVID-19 world is going to look very different, and we need a new pandemic and emergency response system for health care today. Many experts are predicting a second wave and perhaps even a third wave of COVID-19, but even if this does not happen, we know there will be other emergencies that the current system is not able to handle. It is not enough to point fingers at any particular party as the culprit—all are part of the response system, and the lack of investment in it has plagued our civilian and government health care systems for decades. We are not the first to address this issue, but we believe our article offers contemporary insights into the opportunities and risks facing this system during a one-in-a-generation national crisis.

Components of a Future State Health Care Supply Commons

What are the components of designing a health care supply chain commons that is immune to invading forces, whether it is COVID-19, a cyberattack, or any other attack on our critical supply chains for health care, food, and energy? We believe that five key attributes of an immune national supply chain system are being flexible, traceable and transparent, persistent and responsive, globally independent, and equitable. These attributes reflect the lessons learned and responses that would have created a very different picture of the COVID-19 experience we are currently facing. But they will require significant changes in the way we manage national supply chains, as well as a new governance structure for a commons to oversee and direct activity between the public and the private sector. The design of such a system requires the following attributes.

Flexible

A necessary component of a future state supply chain response is the ability to withstand different requirements that need to be pulled together. This requires advanced planning, effective category intelligence, and strategic sourcing plans for every need that might arise in an emergency. The pandemic planning team must develop war-gaming situations/simulations and capacity requirements that cover both domestic and global sources. These requirements should embed industry standards to create maximum flexibility and increase alternatives in the event of need. This is the opposite of stockpiling items, as it involves contractual requirements and effective supplier development to ensure availability of supplies. Such contracts are useless if suppliers cannot obtain supplies from global sources overseas, which means that materials must be in a secure location within US borders. Holding material in anticipation of a need will require managing inventory turns and expiration, which private-sector companies are likely in a better position to do, as they have other customers to whom they can sell material and replenish it. Ideally, the SNS should operate independently within the Department of Health and Human Services while being guided by an interagency council composed of entities like the Department of Defense, the Biomedical Advanced Research and Development Authority, the National Institute for Occupational Safety and Health, and the FDA and CDC.

To ensure that the SNS has access to people capable of understanding a broad range of issues, 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, the SNS should be guided by a board of governors representing different agencies that facilitates coordination and input for decision-making on stockpile portfolios. This input will serve as intelligence to inform category management, which is assigned a sourcing analyst who can understand where to source materials in a complex global market (a practice already used in the Department of Defense).

Traceable and Transparent

Contractual requirements must be supplemented by inventory visibility systems, as well as blockchain 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. Blockchain is based on distributed ledger technology (DLT) that stores data on multiple servers (thousands in many cases). This method permits trusted members to see ledger entries and modifications in near real-time. During wide-scale emergencies, supplies need to be tracked with instantaneous, traceable, and verifiable methods to guard against self-serving behaviors such as PPE hoarding. Blockchain is a major leap toward mitigating such behaviors and enabling more efficient supply chain responses.

A missing component of the supply chain during COVID-19 was the inability to track where products were coming from, where they were being sent, and who was receiving them. The hoarding that ensued could have been prevented by inventory visibility systems that use barcode and QR code tracking of material through the supply chain, through a trusted network of distributors and manufacturers. Of course, this will also require that all entities agree to be part of a "commons" that seeks to optimize the public good. This is a great change that will require a shift in the private-sector view of "every man for himself."

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 versus individual self-reporting, which can contribute to the tragedy of the commons scenario. While barcodes are indeed being used in some areas of the health care supply chain, it is also common knowledge that the quality of data, even in the private sector, is horrible in health care. Our work with health care providers has shown how difficult it is to derive trustworthy data from hospitals, GPOs, and distributors in health care.[27] Traceability and transparency can also reduce the risk of profiteering, counterfeiting, and quality degradation in critical supply chains. Blockchain and visibility are critical features for the future SNS and should be used by all health care logistics functions.

Persistent and Responsive

A national response system must be decisive and efficient in making decisions based on data provided by the visibility system. It must also be persistently prepared and informed of supply chain risks and opportunities through robust market intelligence in order to avoid

the inefficiencies and costs (financial and human) of ramping up supply chain awareness. For instance, if there are ten different types of emergencies and ten different types of inventory need to be prepared, SNS's funding typically is sufficient to cover only five or six, which is equivalent to "placing a bet" on what is going to go wrong. A leadership team cannot manage what they cannot see—and so they must have clear channels of communication to review information from the experts who are best positioned to understand and derive meaning from it. Data on inventory levels, material capacity, materials in transit, consumption levels at hospitals, and unexpected disruptions need to be available in real time, consumed by a persistently prepared team of decision makers using a sensible governance structure (defined later), and deployed rapidly by senior leadership. This new form of governance to manage the SNS, the allocation of material to states, counties, and cities; and the states' agreement to adhere to this national policy may require legislation for approval. The governance structure must also have explicit criteria and triggers to enable responding to emergencies in the future.

In addition, regulations could be added to simplify federal contracting approaches. Contract agreements for every key material need that might arise could be established, using basic agreements that name the terms and conditions (and pricing in some cases) for future orders should the need arise. This would allow contingency buyers to notify suppliers to ship immediately, instead of starting to negotiate from scratch. Sourcing agreements should be supported by virtual "war rooms" where well-prepared experts could review the data, understand the current state of the supply chain, make decisions, quickly get authorization, and take immediate action. This capability would significantly improve the current response time and effectiveness of the SNS's reaction.

Globally Independent

Global independence is a key attribute for creating supply chain agility. Some of an SNS's components cannot be fully sourced domestically, as it may not be practical or even possible. Manufacturing capabilities in North America have been outsourced for more than 20 years. Thus the goal should be to maintain domestic sources where it makes sense, to support national security, and to create a global network of trusted suppliers that are willing to become part of the blockchain/visibility

network. This can facilitate an understanding of the full risk picture and promote securing national needs first, with a "cold eye" on global impacts. Early warning is essential to early action, which can prevent shortages and capacity problems from occurring if one is too late to the game. This is possible with the employment of new technologies like Resilinc's ability to provide real-time access to global threats and events that may shut down supply chains.[28] The idea is not, however, to remove global suppliers from the field, as this is not only impossible for certain categories of material but also may raise the risk to the overall supply chain. For example, it may be in our best interest to source domestically the nonwoven materials for PPE, given our recent challenges in supply distribution and quality control for masks. But we would not want a policy so isolating that it could prohibit global access to the best available vaccines.

Equitable

During a pandemic, the demand for materials can come from many different kinds of organizations, at different times, and with claims on the common goods. We have seen large integrated delivery systems, individual hospitals (inside and outside these systems), government delivery systems, including the military and Veterans Affairs, prisons, nursing and senior residential facilities, and rural hospitals and clinics, all seeking products. Importantly, all have had access or a lack of access to different sources, especially traditional distributors and group-purchasing organizations. The "alternative markets" that emerged during COVID-19, consisting principally of pop-up "brokers" with personal contacts in Asia or Central America that were not part of the usual PPE production system, targeted many 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 and are not subject to behaviors that threaten the evolving commons.

Our analysis revealed that the SNS was never part of the distribution process, but that FEMA was exclusively responsible for distribution and that its distribution processes were not entirely equitable.[23] During the H1N1 and Ebola pandemics, the SNS used a pro-rata distribution strategy. While this strategy based on population was admittedly not terribly effective, it was the most visible and fair approach at the time,

with delivery to the states and then to public health offices in the state decided according to the state's distribution policies. A truly equitable system requires input from the various provider organizations regarding the demands on their systems, and it also focuses on preparedness ("just in case")—which, if credible, may well prevent hoarding of supplies at some locations while at the same time, other hospitals are starved of supplies. (This is also a major challenge, as we observed hospitals that were loath to share any type of information on their internal material stocks.) This equitable feature speaks directly to the necessity for a commons with an agreed-upon governance structure and rules for its utilization, such as the new National Academies guidelines for the equitable allocation of a COVID vaccine.[29]

An effective pandemic response requires that we understand how government and society will respond to a crisis. We need Strategic National "Sourcing" plans to support the SNS and cells that can manage our domestic, Pan-American, and global supply chain sites and contract strategies to ensure that our responses to contingencies are based on persistently monitored and contemporary data instead of responses based only on reaction. For instance, we may seek to establish sources for low-cost manufacturing of PPE in Mexico, energy and food supply sourcing contingencies in Canada, and capital and technology solutions in the United States, leveraging each region's expertise and resources. We also need to enlist the principal commercial supply chain intermediaries, including GPOs and distributors and the integrated delivery networks themselves to support and become trusted actors, as needed, in the commons.

It is important to determine and maintain (albeit difficult) the "right" level of safety stock in the SNS and to supplement it as needed with sources that are trusted, audited, and vetted and that maintain an available capacity and supply to replenish it on short notice. This can be enhanced with long-term investments in universities and national labs to create and maintain a capital infrastructure and to develop knowledge-based skills and human resources for just-in-time responses. Placing this capability in universities and national labs ensures that these technologies, techniques, and tools will become national core competencies again. This may also mean providing incentives for private-sector participation. An example is the auto and textile industries' ability to switch gears quickly to produce needed COVID-19 products. Supporting such agility is an important goal for ensuring product availability for the commons.

National Contingency Supply Chain Cell (NCSCC)

In this section, we propose a governance structure for a national supply chain contingency team that operates cells centering on specific category portfolios and that constantly communicate with one another. This structure creates a mechanism to achieve the continuous market intelligence and supply chain awareness that is necessary to move us from the "light switch" linear contingency model mentioned earlier to an orbital regime of market awareness and response (see the Online Appendix). Here we offer the NCSCC notional construct based on our experiences in the COVID-19 response. The concept is a hub-and-spoke system with five teams that parallels the team structure identified in the Joint Acquisition Task Force response run by the US Air Force. We believe such a structure can be deployed at a national level but have added insights based on our observation and collection of feedback from members of the Department of Defense and our understanding of the complexities of the US health care delivery system and the components of the medical materials supply chain.[30]

The five teams operate interdependently, with some of their structures located under the SNS in the Department of Health and Human Services and other parts of the multifunctional team operating across the interagency council of the Department of Defense, FEMA, and Veterans Affairs. Team 1 (Detection and Prevention), is the central team, with Teams 2 (Response), 3 (Relief), and 4 (Recovery) operating across the nation in hubs that report to these centralized cells. Team 5 (Data Management) operates at all levels, providing data feeds and updates to all team members.

The Detection and Prevention team supports supply chain awareness and the early mitigation efforts necessary to prevent national emergencies as well as to manage them should they occur. We see this team led by the Office of the Assistant Secretary for Preparedness and Response (ASPR) and in close coordination with the DoD for assisting in command and control and managing "living stockpiles" in concert with the VA. Members of this team aggregate their intelligence to a central command post/tower that has national situational awareness. A control tower is defined as a centralized analytic dashboard that identifies key performance metrics for the national stockpile as a whole but that allows

individuals to "drill down" to identify specific metrics related to material inventory levels, expiration dates, consumption, and other supply chain measures. The idea of a control tower is that it is made available to all individuals who need real-time information to be able to make decisions in their roles.[31] Today's control tower systems "scrape" data from different systems, often every minute, and collect them into a data lake, which updates the control tower in real time. These systems are also connected through mobile technology to cell phones, allowing all authorized participants in the network to see the statuses of inventory, shipments, and consumption of material in real time whenever or wherever they need to.

The Response team is concerned with the supplies and services necessary to trace, deliver, and secure crisis-response material, and the Relief team is oriented around life support and treatment concerns. The Response and Relief teams are best left under the leadership of the DoD (i.e., NORTHCOM), with ASPR, FEMA, and the VA in supporting roles.

The Recovery team maintains and responds with the supplies and services necessary to repair and return to order. Recovery is best led by FEMA in close coordination with the Army Corps of Engineers, Defense Logistics Agency, and DHHS. Finally, the Data Management team has embedded support across all cells with a centralized nerve center that collects, cleanses, and aggregates the data that go into the control tower displays, used by the Detection/Prevention team.

Team 1: Detection and Prevention

The Detection and Prevention team should vet all materials entering the system and pay attention to external market factors and clinical testing signals that may be early warnings of a potential emergency on the horizon. The team should also monitor the development of vaccines and provide key market intelligence signals to the community on episodes or factors that may affect shortages or shifts in the national stockpile or other response mechanisms. This team should work closely with the control tower (Data Management) team to update supply chain metrics not only for materials in the stockpile but also for risk factors emerging in different countries. An example of a supply chain risk warning platform is Resilinc, which provides early warning for monitoring global events

that disrupt supply chains. One of the missing links quickly discovered during the current crisis was the capability and capacity to adequately and quickly test PPE and other critical components entering the supply chains.

Team 2: Response

The Response team oversees the rapid logistic distribution of hospital supplies, medicines, and medical devices once an episode has occurred. This team also provides security services and products to states or hospitals based on immediate need and tracks chains of custody and payments to suppliers delivering to various points in the system. The Response team should also have access to the "burn rate" of states and hospitals using supplies and should update forecasts and acquisition requirements on a timely basis through an interface between Team 1 and Team 5. Team 2 would also use prenegotiated agreements for emergency response materials with private-sector suppliers in each state, accessing them through normal order management systems. Ordering systems could be connected through the control tower to automatically replenish inventory as it is consumed by states or hospitals.

Team 3: Relief

Humanitarian relief efforts are needed to provide at-risk communities with food, water, shelter, first aid, PPE, durable medical supplies, treatment medications, and emergency medical services. The Relief team will also need to track where the materials are distributed and have a deployed field force for ensuring they arrive at the correct locations securely and safely.

Team 4: Recovery

The Recovery team is responsible for recovery efforts during an emergency and afterward. It should specialize and be involved in the construction of and supplies for destroyed or impacted field locations, assessing and assigning economic restoration analysis, and offering counseling services for those experiencing severe trauma and the death of loved ones, as well as other services that can help people return to normal activities.

Team 5: Data Management

The Data Management team will work across all the teams to provide mobile data analytics to support activities in the field or wherever required. The team will develop a system to scrape information from different sources (both internal and external to the government), cleanse, aggregate, and update it into analytical indicators that are displayed in real time in a control tower environment to provide, for example, expiration dates, usage rates, minimum order quantities (MOQs), current suppliers, and other risks in each category.

Another need this team will address is maintaining a list of approved, trusted suppliers that can quickly provide needed materials and products. Data quality is important in any crisis. Incomplete reports, missing data, multiple estimates, and other data-quality problems during the current crisis have hampered efforts all across the country. Many systems (and even states) are still years behind other industries in transferring data by means of faxes and unsecure telephone calls.[25] This team must be statutorily empowered to collect necessary information from all entities that may need assistance. The team would leverage the legal requirement to motivate need agencies (e.g., local and state governments, private health care organizations) to provide data and data access. The team's task would be to work with all entities (specifically any accredited health care providers) to create either a standard interface for automated data pulls or a means by which the entity could quickly provide inventory and usage data. Ideally, this would take place before a crisis and, when not automated, be subject to random auditing (structured auditing during crises) to ensure that accuracy/diligence is ingrained in the organizations before it is too late. Should organizations not comply, their SNS aid eligibility would be suspended until they do comply.

In a center-led pandemic organization, these teams must work together. For example, while conducting prevention surveys of major hospital risks, the Detection and Prevention team notes that PPE is a high-risk area. It would then put the other teams on alert and into action based on the specific risks identified. In this way, a shortage of PPE could be better handled if a cell structure is in place, in which the Detection and Prevention team notifies the Relief team that it needs to start strategically sourcing the PPE, which in turn triggers a smart allocation planning model with the Response team. Strong communication, command, and control are essential. Any one team could identify a potential risk in

the process that could be rapidly flowed to the other teams, depending on their role (e.g., if Recovery notes an issue that could have helped it, it would flow back to the Response effort, thereby alerting all the teams).

Strategic human capital is a vital element of a successful acquisition function.[32] The NCSCC teams need data experts to interface with the Data Management team: functional experts, disaster response experts, security experts, acquisition experts (specifically contracting and program management), a financial point of contact, a centralized legal team that supports them all under the Detection and Prevention team, academic/research interface liaisons, and supply chain and operations research experts. In our experience working with the private sector, we observed that a control tower hub should be in a location that (1) enables the government to recruit and retain top talent based on quality of life, (2) includes a large existing and robust acquisition workforce for rotational development, and (3) offers proximity to major enablers such as medical supply firms, research labs and universities, national labs, and federal agencies. For example, two top areas that come to mind for our team are Dayton, Ohio, and San Antonio, Texas, as they have access to a hub of professional acquisition personnel.

We believe that control towers work best when they are connected to mobile networks of field personnel who are kept abreast of key metrics and data wherever they are working. The use of mobile federal civilians and military would support this strategic human capital infusion effort. Regional cells would be established and staffed with Teams 2, 3, and 4 based on FEMA's current 10-region construct or in other forms such as time zones or modified over time as critical distribution hubs evolve to support a globally independent supply chain model. Of course, cyber-security measures would need to be in place to prevent hacking and fraud.

Our proposed framework for governance and response requires a determined leadership effort with a commitment to stewardship that cannot be designated solely by Congress. Important stakeholders' perspectives on data exchange and supply chain design must also be captured, to ensure that the system is designed in accordance with all the constituents' interests, challenges, and issues. The proposed system must therefore be designed to be flexible enough to accommodate the state and county health systems for receiving and distributing material. This will require hearings and consulting with these parties to understand the variety of systems for distribution at state and county levels

and to ensure that the distribution is fair and equitable. The creation of a national material "control tower" can help improve transparency and access to material information but will also require collaboration with all the states to share information in a time of emergency to enable effective and aligned planning and action.

If transparency and visibility are indeed essential to success, hospitals' age-old strategy of hoarding material cannot be allowed and will require regulatory changes. Significant changes in federal contracting guidelines are necessary to allow the Data Management and the Detection and Prevention teams to create bills of agreement with vetted and audited suppliers, to ensure their capability to replenish the SNS. The SNS itself will require on-site management to drive appropriate turning of inventory and avoid large lot buying and concurrent expiration dates for large parts of its contents (which occurred in January 2020 right before COVID hit). These changes will require a different set of capabilities, which will mean working with qualified supply management professionals with experience and knowledge in applying the tools of category management, strategic sourcing, contracting, specification and statement of work development, supply market research, and inventory management.[16] A proposed model for supply monitoring and management is described in more detail in the Online Appendix. While some of the details of our framework are not yet complete, we believe that it is a useful framework on which to construct a national pandemic response policy in our federal government.

Conclusions

As we think through an optimal governance structure for a commons to meet national supply chain contingencies, we must recognize that resilience cannot be obtained without persistence and that persistence cannot be maintained without a sensor to detect disruptions and shortages or a vantage point from which to observe what is happening in the stockpiles and other inventories. Because the commons we propose is constituted of multiple parties and locations, we will need a suite of sensors that can be observed and managed by a strong central governing body. We cannot organize global supply chain networks in a linear fashion. Our federal government must recognize that global opportunities and risks need to be mapped and managed with a constellation of

intelligence assets that are working in and across focus areas of supply chain risk (see the Online Appendix).[33]

Indeed, the commons of the future will not be a singular repository but a network of repositories, extant inventories, and participants. This will require a culture of leaderships and leaders who are committed to the stewardship of the commons. It will also require more funding. Given the earlier role of underinvestment in causing the problems evident in COVID-19, it is fair to wonder whether the funding of our recommended system might be any less subject to the usual political and fiscal "tides" than the one it seeks to replace.

COVID-19 has demonstrated how both suppliers and providers can innovate during a crisis. During the COVID-19 epidemic, we have learned that organizations across the globe that were involved in manufacturing non-PPE materials were quick to augment their ability to produce PPE. What they lacked was access to distribution systems for their products, leading to providers searching for disorganized introductions to those in need. A coordinated effort might have channeled these new suppliers to meet the demand and eliminate hoarding and other behaviors that took place outside the commons. Many of these organizations quickly found themselves in need of one or two critical components that were not part of their normal supply chains. While such responsiveness may well signal the resilience of organizations to provide supplies in times of need, they are not, of course, a substitute for a commons composed of national stockpiles and predictable and reliable reserves within commercial supply chains.

In addition, if organized and rationalized, many rival organizations may well want to draw on these stockpiles for the good of their organization, employees, and patients. Although we did not explore the hoarding of products in this article, it is just one of several behaviors that can undermine the availability of products to those most in need. The mere presence of a commons will not guarantee strong stewardship, trust in fairness, and iron-clad rules surrounding access or use. Thus, the design of the commons must continually be assessed to watch out for the dangers of Hardin's tragedy of the commons: "the eventual overexploitation or degradation of all resources used in common."[6(p1)]

We recognize that this article comes early in what will be many assessments of the US response to the COVID-19 pandemic, that future research will uncover other issues, and that investigators will make other recommendations for reforming an ailing system. Instead, we

offer a perspective from the discipline of supply chain management. Economists have already begun to estimate the cost and benefits of preparedness.[34] It is our hope that this article has laid a foundation for such work by those disciplines that constitute health services research.

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Supplementary Material

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