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Rethinking Industry's Role in a National Emergency

The shortcomings of U.S. Strategic National Stockpile must be remedied before the next large-scale public health emergency. Here's how.

ManMohan S. Sodhi and Christopher S. Tang

Author Bio, including Twitter handle: ManMohan S. Sodhi (@MohanSodhi) is professor of operations and supply chain management at City, University of London in the business school (formerly Cass). Christopher S. Tang (@christangucla) is a distinguished professor at UCLA and holds the Edward W. Carter Chair in Business Administration at UCLA Anderson School of Management.

The Analysis

- Our analysis derives from our working paper “Preparing for future pandemics with a reserve of inventory, capacity, and capability,” < https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3816606 > which calculates optimal levels of inventory and the unit costs in inventory tradeoffs with domestic capacity for the SNS.
- Our proposed solution draws upon good risk-management practices for supply chains outlined in our book *Managing Supply Chain Risk* (Springer, New York, 2012).

Photographs of doctors and nurses wearing garbage bags to protect themselves from infection are among the most indelible images of the COVID-19 pandemic. They also testify to the limitations the U.S. Strategic National Stockpile (SNS).¹ By the end of March 2020, as the first surge of COVID-19 exceeded 20,000 new detected cases per day, it was woefully clear that the United States' emergency stockpile of essential medical supplies could not meet the demand for personal protective equipment (PPE), ventilators, and other materials urgently needed to battle the pandemic and save lives.

Since then, there has been plenty of finger-pointing regarding the inability of the U.S. Strategic National Stockpile (SNS) to live up to its mandate. But none of that acknowledges the reality that, because of the scale and rarity of pandemic-level public health crises, no national reserve can reliably provide the materials needed from inventory alone.

In the decade prior to COVID-19, flu-related hospitalizations in the U.S. averaged 440,000 annually, but, in 2020 alone, COVID-19-associated hospitalizations reached 4.1 million. This is a huge spike in need that is nearly ten times the flu hospitalization annual mean.² Moreover, public health emergencies of COVID-19 magnitude are highly unusual in the U.S. or anywhere else, occurring decades apart, making the demand spike massive but rare.

After all, the *demand challenge* for the SNS is to be able handle:

1. More severe flus occurring every 2-3 years with demand for medical products and equipment being, say, twice the average annual flu hospitalization mean,
2. Epidemics and minor pandemics that may occur, say, once every 5-10 years with demand being as much as 3-4 times the mean, although the spike may be regional rather than nationwide, and,
3. Severe pandemics occurring once every 20-40 years with demand as high as ten times the annual mean occurring nationwide.

No manufacturer launching a product could handle such a distribution of demand by simply having a huge pile of just-in-case inventory, and neither can the SNS. Instead, it needs a strategically balanced approach to meeting future calls for help, especially keeping in mind that the outcome is counted in human lives.

Ventilators exposed the flaws in the inventory-based approach of the SNS

The inability of the SNS to meet a spike in demand for ventilators was recognized long before the emergence of COVID-19,^{3 4} but efforts to build up inventory⁵ were unsuccessful.⁶ Thus, in early 2020, when COVID-19 struck and the estimates of ventilator demand reached as high as 115,000 additional units, the SNS had only 12,700 ventilators on hand, more than 2,000 of which were unusable. Moreover, the *global* capacity of ventilator manufacturers at the time, estimated at 40,000-45,000 units per year, was nowhere near enough to make up the shortfall in a timely fashion even for the U.S. alone.⁷

Against this backdrop, the federal government invoked the Defense Production Act of 1950 in an effort meet the need for ventilators by tapping the domestic manufacturing capabilities of other

sectors. As a result, by September, the SNS had an estimated 140,000 ventilators in its inventory. However, of these, half are seen by physicians as unsuitable for acute respiratory conditions, such as those created by COVID-19, and multiple models are not FDA-approved for children. Only a tenth were the most commonly needed full-featured ventilators.⁸

The inability of the SNS to fulfill the states' requests for ventilators during the first peak of the COVID-19 pandemic exposed a number of flaws in its approach to fulfilling its mission.

- Maintaining a large inventory of goods such as ventilators over a long period of time requires a large and continuing investment in inspection, repair, and replacement to ensure its viability. Unfortunately, the SNS had cut costs in this area, sacrificing the long-term efficacy of its ventilator inventory on the budgetary altar.
- The prospect of high demand combined with inventory shortages leads to the panic-driven amplification of need and the misallocation of already meager supplies. The SNS not only shipped unusable ventilators to states but also issued contracts for ventilators that were neither needed nor suitable.
- When large amounts of inventory must be purchased in a rush, quality and specification are often compromised and costs can rise precipitously. The rush to meet the demand for ventilators resulted in under-specified units, and the SNS purchased ventilators in various configurations from at least 11 different manufacturers, giving rise to questions regarding their utility in future emergencies especially around having enough trained personnel nationwide for all the models, and raising the specter of even more mishandling of inventory and much higher maintenance costs.⁹
- While tapping manufacturing capability in other sectors is a sound idea, it cannot be done on the fly. Using auto companies to make ventilators on short notice was unrealistic because the time and expertise needed to design, develop, and make medical equipment.¹⁰

Managing surges in demand with inventory, capacity, and capability

There is a better way to meet huge but rare demand spikes than holding massive amounts of just-in-case inventory. Consider a snow-shovel manufacturer that faces a demand challenge similar to that of the SNS except that instead of flu, the demand depends on the size of snowfall each

winter: most winters are typical, but every 5-10 years, demand may be 3-4 times that in a typical year, and every 20-30 years, ten times.

Maintaining an annual inventory sufficient to cover the demand generated for a typical year is necessary, but that for a spike occurring only every five years or so would be prohibitively expensive. And the more inventory the manufacturer holds and longer it is held, the greater the cost as expenses related to obsolescence, purchase, storage, inspection, stock rotation, and replacement rise. Instead, the manufacturer could pay upfront to reserve backup capacity in its supplier network to ensure that sufficient materials and secondary suppliers are available on short notice if the coming winter turned out to be atypical so that demand could be met.

What about the one in twenty winters when the spike shoots up to ten times that of a typical year? The economics of reserving or maintaining backup capacity cannot be stretched to cover such a demand, since the cost of holding parts or raw materials will rise and designs and manufacturing equipment may become obsolete.

Instead, the manufacturer turns to a "just-in-case" standby capability, which is put in place years and decades in advance of demand. It requires creating relationships, identifying supply sources, and researching new technologies every year to develop and maintain standby capability that can be turned into the capacity for filling demand, possibly with alternative products, in case demand does rise tenfold or even more.

Transforming the SNS into a Strategic National Emergency Reserve (SNER)

The demand challenge facing the SNS can be met in a similar way to how the snow-shovel manufacturer meets in our hypothetical example above: using a combination of inventory, capacity, and capability. Taking this approach would transform the national stockpile into a *strategic national emergency reserve* (SNER), which entails government and industry working together.

For the more frequent severe illnesses or local epidemics, public health needs would be fulfilled – as they are now – using *inventory*. For the less frequent minor pandemics, in which the need exceeds inventory, domestic *backup capacity* would be used to quickly manufacture more

inventory. It must be domestic because the ability to import goods from lower-cost countries may be disrupted — or purposely interrupted — in such troubled times. On the extremely rare occasions when need outstrips even backup capacity by a huge margin, a situation like the one with COVID-19, a domestic *standby capability* would be employed. Such a capability would comprise already identified players from diverse industry sectors who can continually develop products and production technology to be able to manufacture the necessary goods on a timely basis.

This three-tier approach using inventory, backup capacity, and standby capability dramatically reduces the high costs of trying to address all three levels of crises using inventory alone. Developing domestic capacity and capability has benefits beyond meeting the life-and-death demands that arise during the worst public health crises – it enables existing domestic manufacturers to continually upgrade their products and production capacity over time.

Here’s how such a response system could work to ensure adequate supply of ventilators:

Tier 1 — Inventory: Like the SNS, the SNER would first use inventory to meet needs nationwide. But rather than having more ventilators in inventory, the SNER would have far fewer units, possibly in line with the 12,700 units in stock before COVID-19. This is because U.S. hospitals have long had more than enough ventilators for even a severe flu season.¹¹ Moreover, SNER would plan only for the peak number of ventilators needed at the same time, which would likely be in only one part of the country versus nationwide. The ventilators in the SNER should all be full featured, so they can be used in a wide variety of situations and both children and adults. Moreover, these ventilators should operate in the same way to minimize training requirements across the country and have swappable parts to ensure that maintenance is easier and less expensive than is the case today.

Tier 2 — Capacity: When need is growing at a rate that is likely to exceed inventory, the SNER would tap the capacity of manufacturers, already reserved for this eventuality with the contractual obligation to use this capacity produce the needed goods on short notice. In the case of ventilators, whether under the Defense Production Act or by contract, the SNER would order full-featured ventilators in batches, as the pandemic evolves. It would still serve demand at the

outset from inventory, moving ventilators (and other stocks, except for consumables) from one region to another as the pandemic moves across the country. In the meantime, inventory would be replenished by manufacturers as the need grows from different parts of the country.

Tier 3 — Capability: In a pandemic-level emergency, when need is growing rapidly and threatens to exceed not only inventory but also backup capacity, or, when the need develops for goods that are quite different from those in inventory, the SNER would turn to standby domestic capability for creating additional capacity. In the case of ventilators, the consortia – created on the fly during COVID-19 – would have already been formalized years before the need emerged. Over the years, consortia members would have access to appropriate designs, technologies, and production methods, which would be upgraded over time by university and private sector researchers. Production facilities, such as 3-D printing farms or alternative capacity in adjacent manufacturing sectors, would also be available to the consortia. In short, the resources, protocols, and responsibilities of the consortia would be well defined and understood years before a major pandemic struck. Such capability is afforded by developing an *industrial commons*.

Building standby capability at the national level

The ability to tap standby capability – or even reserved capacity – on a timely basis is the crucial missing link in the SNS’s current approach to its mission. To forge this link, the SNS – in its proposed form as SNER – will need to develop an industrial commons that is specifically designed not only to respond to the outsized needs of extremely large public health emergencies, but also to foster product and production innovation among domestic medical manufacturers.¹²

Developing an industrial commons will take an ecosystem of expertise to develop and manage a standby capability for pandemics and other major emergencies. It will require public health professionals to specify goods, and manufacturers outside the sector to design and make them. More than that, it also should include suppliers of the advanced materials, tools, production equipment, and components that shape industries; researchers in universities and university hospitals to create and share knowledge; and data analysts to monitor events and provide timely alerts.

To speed the development of its industrial commons, SNS could partner with existing organizations such as America Makes, an Ohio-based non-profit. America Makes and its member community of more than 170 organizations, including government departments, private companies, and universities, share a common goal: to serve as a *national accelerator* for *additive manufacturing* (AM) and 3D printing technologies. During the pandemic, its members used their 3-D printing capabilities to produce PPE for the Veterans Health Administration.¹³ America Makes also stores and compiles FDA-approved designs for 3-D printing, instigates capability building using open call projects, and shares knowledge among its members through its Digital Storefront platform.

Technologies such as 3-D printing should play an essential role in the SNS's efforts to fill needs using capability.¹⁴ Sensing systems enabled by big data and analytics can detect emergencies earlier and help design responses that are more tailored to local needs than a fifty-ton shipment of generic medical equipment. AM and 3-D printing can help lower the higher unit costs of capability, as well as response times, and drones and other mobility technologies can help speed delivery.

This new approach would have the SNER shoulder the existing responsibilities of the SNS and undertake new ones, such as developing a domestic capability and encouraging stress tests or competitions to ensure that it could create capacity in the needed amounts and the right timeframe. It would also have visibility of resources – inventory, capacity, and capability – wherever they are. And at all times, not just in time of need, the SNER would serve as the central point of contact for federal agencies, non-governmental organizations, commercial partners, and the industrial commons as a whole. In public health emergencies, the SNER would ship inventory to the states and coordinate the creation of additional inventory from capacity and capability.

* * *

In March 2021, the SNS was back in the headlines: A *New York Times* investigation exposed questionable purchasing practices and the Biden Administration announced a comprehensive review and audit of the stockpile.¹⁵ Whether or not this review and audit will address the systemic flaws in way in which the SNS fulfills its mission remains to be seen. But if the SNS is

going to fulfill the urgent needs of the states in the large-scale public health emergencies that will inevitably occur in the coming years, it will have to reinvent its approach to meet demand and begin using a balanced mix of inventory, capacity, and capability to fulfill its mission. Lives are at stake, and government and industry must work together before the next large-scale public-health emergency strikes.

End Notes

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