Assuring Essential Medical Supplies During a Pandemic: Using Federal Law to Measure Need, Stimulate Production, and Coordinate Distribution

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SUMMARY. The global COVID-19 pandemic has temporarily increased demand for basic medical equipment and supplies, and disrupted global supply chains. Governments at all levels and the private sector have found themselves scrambling — and often competing — for the supplies they need. Federal law anticipates that emergencies can generate this kind of sudden demand for medical equipment. Federal agencies not only have ample legal authority to respond to shortages, but also the duty and the authority to prepare for emergencies by planning, supply-chain monitoring, investment and partnership with the private sector, and stockpiling. Perhaps the most important federal law for preventing and ameliorating shortages, and the primary focus of this Chapter, is the federal Defense Production Act (DPA). The DPA provides a menu of powers to stimulate production, strengthen supply chains, coordinate expertise, and resolve market failures. Although the shortfall in personal protective equipment and other basic medical equipment was anticipated by planners and demonstrated in simulation exercises, federal action to address the problem in the face of the pandemic have landed somewhere between failing and making matters worse. This Chapter recommends an independent commission be established to investigate and draw lessons from the federal public health response, but in the meantime points to two core, fixable problems related to law and administration: (1) the failure of Congress and successive administrations to provide sufficient resources to staff and maintain a vigorous infrastructure to prepare for surges in demand, and (2) the failure of the current administration to use its legal authority to lead, manage, rationalize and stimulate production and distribution of needed equipment.

Introduction

By the end of March 2020, health care entities were facing a severe shortage of personal protective equipment (PPE) and fearing a ventilator shortage. Health care workers — and patients and residents in nursing homes, prisons, and other congregate settings — experienced higher risks of infection, and the shortage of PPE led states to halt elective medical procedures. The shortage was the result of a sudden and substantial increase in global demand, as well as short-term interruption of exports as producing countries tried to redirect products to meet surging domestic demand. Similar shortages have continued to arise with respect to other supplies, including swabs, reagents, and pipettes.

The shortage of PPE and basic medical supplies was not a surprise. In August 2019, the federal government had concluded an exercise called "Crimson Contagion" simulating a novel respiratory virus emerging in China and quickly spreading across the globe. The exercise revealed sizable shortages in PPE. The leaked report concluded that "[t]he current medical countermeasure supply chain and production capacity cannot meet the demands imposed by nations during a global influenza pandemic" (HHS, 2019).

Crimson Contagion was a *response* story. It suggested that when a pandemic hit, state and federal officials would be uncertain of their powers and unable to act effectively in concert. But that dramatic

story is embedded in a *preparation* story, in which the confusion of the response stemmed from a set of failures to have staff, resources, innovations, and information ready for the predicted pandemic crisis. From the preparation point of view, the federal government was capable of foreseeing its dangerous incapacity; it just wasn't able to do anything about it.

The pandemic shortages are a market failure – supply is not keeping up with demand – but not a sign of a failing market: global production capacity is sufficient to meet usual demands. This defines the challenge for government: companies that invest in new production capacity to meet surge demand will be left with excess capacity when demand returns to normal. Companies, particularly U.S. companies, that enter or expand their place in the market will find themselves, when the pandemic is over, competing with Chinese and other foreign producers that are well-placed for many reasons to out-compete them. While it is perhaps comforting to imagine the U.S. government somehow nationalizing the production of medical equipment, in reality its task is to use its resources to manage the private sector within the confines of a global production system.

This Chapter looks through the lens of the law at the role of the federal government in meeting this challenge. The Department of Health and Human Services (HHS) has the authority under federal emergency law (the Stafford Act) and the Defense Production Act (DPA) to prepare for and manage shortages during medical emergencies that threaten national security (for a discussion of legal issues related to safety and quality of medical products and clearing regulatory hurdles to innovation, see Chapter 20). We first look at the issue of planning and preparation, with attention to the authority for supply chain monitoring and planning under emergency law and the DPA. We then look at the response – what happened and what, looking at legal authority and the public good, should have happened. We conclude with recommendations.

The Preparation Failure

Crimson Contagion was just the latest in a long chain of reports, assessments and plans raising the same red flags. The basic challenges to be overcome in preparing for the expected pandemic surge in demand for basic medical supplies were well known, and indeed were described in detail by Centers for Disease Control and Prevention preparedness staff (Patel et al., 2017):

- A market based on meeting demand just in time, with little capacity for meeting sudden large increases;
- A complex supply chain involving many producers and distributors, most based overseas;
- Lack of a system-wide monitoring of needs, consumption, production and distribution;
- Unpredictable distributor management of shortages (e.g., ad hoc rationing to customers);
- Effects of market uncertainty on manufacturer willingness to ramp up production; and
- Huge amounts of equipment required in a national emergency.

Given that the nature of the challenge was well known, true preparation would have entailed significant investment. Ideally, this would have included building an up-to-date database of domestic manufacturers and distributers of all essential supplies, with an assessment of the short-term capacity of each manufacturer to increase production; an assessment of the likely national need; and a plan for allocating equipment to prevent crisis competition and take advantages of regional differences in the timing of peak demand. This information would have informed the inventory needs of a properly stocked Strategic National Stockpile (SNS), and efforts to support new technology and innovation that would increase readiness or help meet a surge. Preparation like this requires leadership and staff who are equipped to analyze and monitor the supply chain and to work creatively to develop solutions to the supply problems that can be implemented, or set in readiness, before the emergency arises.

There were no legal barriers to this work. Both the Stafford Act (the national emergency preparedness law) and the DPA contemplate ongoing preparation to include

> assess[ing] on an ongoing basis the capability of the domestic industrial and technological base to satisfy requirements, ... specifically evaluating the availability of the most critical resource and production sources, including subcontractors and suppliers, materials, skilled labor, and professional and technical personnel; ... prepar[ing] in the event of a potential threat ... to take actions necessary to ensure the availability of adequate resources and production capability ... ; ...improv[ing] the efficiency and responsiveness of the domestic industrial base ...; and ... foster[ing] cooperation between the defense and commercial sectors for research and development and for acquisition of materials, services, components, and equipment to enhance industrial base efficiency and responsiveness. (Executive Order 13603, 2012).

The DPA has three titles that provided the president considerable authority to plan and respond quickly, without further congressional approval. Title I authorizes the government to jump to the front of the line in purchasing goods and empowers the president to allocate resources as "necessary or appropriate" (this "priorities" or "line-jumping" authority is commonly invoked, especially in defense contracting, but "allocations" power has not been invoked since the 1970s). Title III authorizes the government to assist private manufacturers, either by supporting existing supply chains or stimulating new technologies or modes of production. This allows measures like funding new machinery or making purchase commitments to ameliorate financial risks of ramping up production during a demand surge. Title III also authorizes the president to assess the industrial base, with power to get information by subpoena if necessary. Title VII authorities facilitate partnerships with the private sector, including in the form of voluntary agreements, to build capacity.

So how did HHS, the designated agency for this work in the case of health resources, do? Not well. Preparation was chronically neglected. In 2008, Congress directed the Government Accountability Office to examine whether key agencies had created guidance and regulations to implement the DPA. The resulting report noted that "the process for implementation is unclear and

could potentially cause delays in emergencies as agencies navigate the process" (GAO, 2008). When HHS finally issued a regulation for exercising its DPA supply chain management seven years later, it was "little more than cut-and-pasted from an antiquated, pre-existing rule the Department of Commerce first developed in 1984" (Brown, 2020). On the eve of the COVID-19 pandemic, the Crimson Contagion report found that officials "were not clear" on "the applicability or use" of the DPA in the face of these challenges (HHS, 2019).

Stockpiling was grossly inadequate in volume and range of supplies. The SNS, which like many public health services got a boost after 9/11, was neglected after contributing 85 million masks in the 2009 N1-H1 emergency. By March, 2020, it held only 12 million N-95 masks to help meet an estimated 3.5 billion mask demand (Whalen et al., 2020).

Finally, efforts to develop new technologies and capacities were conceived without sufficient ambition and implemented without necessary diligence. The Obama administration invested several million dollars to promote private sector development of a machine that could spit-out 1.5 million masks a day, but the project fell apart amid corporate take-overs, budget finger-pointing, and unrelated litigation. The Trump administration invested in a reusable N-95 mask, work on which is proceeding but will not likely be done in time to help with COVID-19. The total investment for both projects was about $10 million, a small part of the reported $1.5 billion budget of the HHS Biomedical Advanced Research and Development Authority (BARDA) overseeing the project (Swaine, 2020). There was no concerted effort to investigate other options, like truly "permanent" masks, or to address easily foreseeable shortages of ventilators, swabs, and reagents.

The Response Failure

The Crimson Contagion story became real life at the end of 2019. Having failed to prepare for the emergency, the first step for the administration in late December or early January should have been a rapid assessment of PPE, ventilators, and other supplies in public and private possession, backed as necessary by the powers conferred by Title III of the DPA. The second step should have been using Title VII of the DPA to convene a partnership of private and government sectors to organize a federal response to shortages that would have invoked authority to oversee allocation by the Federal Emergency Management Administration (FEMA) or another appropriate agency based on need. As inadequate supplies became apparent, the federal government should have issued huge purchase commitments, paying higher unit prices for earlier delivery and making long-term commitments to incentivize companies to assume the risks of jumping into the market or significantly increasing capacity. Federal coordination and procurement leadership would not have instantly solved the shortages, but it would have saved states money and effort by unifying purchasing in one buyer.

What happened instead was what Crimson Contagion predicted. By early January, the State Department's epidemiologist had advised that a global pandemic was likely, the HHS had organized a task force, and the president was getting detailed briefings about the

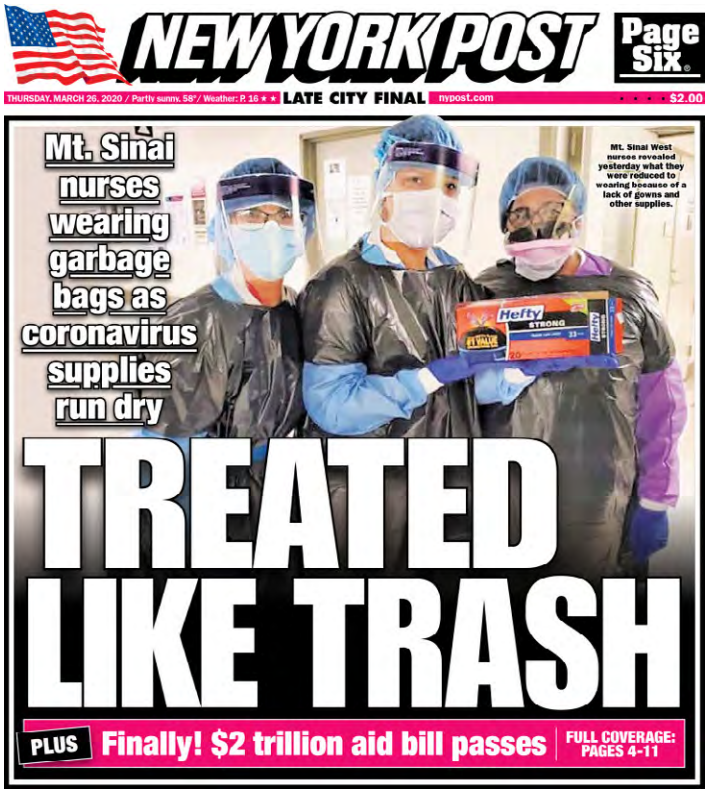

Figure 21.1. *The New York Post* cover from March 26, 2020 (Bowden et al., 2020).

global spread of the disease – but action was lacking. At BARDA, future whistle-blower Rick Bright was already "alarmed about the scarcity of critical resources and supplies, including N95 masks, swabs, and syringes, and began clashing with HHS leaders as he pressed for them to take appropriate action to address these shortages" (Bright, 2020). HHS officials actually prevented the Food and Drug Administration commissioner in January from reaching out to industry to discuss increasing PPE production because, the Wall Street Journal reported, "such calls would alarm the industry and make the administration look unprepared." Only at this point, with the fire lit, did the chief preparedness official at HHS order his staff to draw up plans to invoke the DPA.

Federal agencies only started to seriously respond to shortages in March, placing bulk orders for N95 masks and ventilators. On March 18, the president issued both an Executive Order "allowing" for the use of the DPA and a tweet that he did not plan to actually use his DPA power. Somewhere around this time, Jared Kushner created his own supply management team drawn from hedge funds and consulting firms, which, after its short run, would be criticized for its "delays, incompetence, confusion, and secrecy" in Congressional hearings. As even wealthy hospitals like New York's Mount Sinai were leaving nurses to wear trash bags for gowns and purchase their own masks (see Figure 21.1), the president blamed state governors for failed procurement and dismissed an Inspector General report of pervasive shortages as "Another Fake Dossier!"

In late March, the president addressed concerns about the supply of ventilators, issuing a statement that directed HHS "to use any and all authority available under the [DPA] to require General

Motors to accept, perform, and prioritize Federal contracts for ventilators." General Motors responded with a bewildered press release, noting that the president's statement lacked specific requirements and that the company was already working as quickly as possible to ramp up production of ventilators. Although there was some loose tweeting about invoking the DPA to mandate specific companies to produce supplies, and even some media references to nationalization, there was no evidence – and quite a bit of skepticism – that direct government control would increase production given how little government understood about the capacity of different firms (Watney & Stapp, 2020). Pushing federal contracts to the head of the line was actually the easy part of the DPA compared to the job of understanding the amount and location of existing equipment. In late March, the senior Navy official leading FEMA's supply chain efforts admitted that he was "blind to where all the product is" (Muller & Swan, 2020).

Spasmodic and confused federal behavior added to the burden of states trying to get supplies from the SNS or on the open market. States' SNS requests were processed through an opaque (and quite possibly politically influenced) process. FEMA and HHS publicly announced different prioritization schemes, and in practice allocations varied tremendously. Florida received all the masks it requested in March; other states received a fraction of their requests (Table 21.1).

State procurement on the open market devolved into bitter competition between individual states and the federal government. Predictably, scarcity and competition increased prices for PPE across the board. Masks that once sold for $0.85 were suddenly $7. Then FEMA stepped in, invoking DPA priority to supersede state and private orders, and in at least one case seizing three million N95 masks on their way to Maryland. The governor of Kentucky voiced the general state lament: "The federal government says 'States, you need to go find your supply chain,' and then the federal government ends up buying from that supply chain." In the face of federal coordination and supply failure, many states began to cooperate and even share equipment in formal and informal ways, like the purchasing consortium set up in New York and six other Northeast states.

The final federal initiative in the story so far was to add prevarication and insult to injury. In early April, presidential tweets blamed governors for supply shortages noting that "Some have insatiable appetites & are never satisfied (politics?)." The White House then moved to redefine the whole idea of the SNS, with Jared Kushner proclaiming that the SNS is "supposed to be our stockpile. It's not supposed to be states' stockpiles that they then use." The next day, this mission shrink was formalized by changing the public definition of the SNS, from a resource that "ensures that the right medicines and supplies get to those who need them most during an emergency" to a "short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available."

Conclusion

The DPA provides a flexible set of powers that enables the executive branch to assume responsibility to plan, instigate and strategically coordinate public-private collaboration as part of a national program to assure necessary health supplies to every state. The federal government can still bring to bear its human and economic resources to identify shortages and nudge suppliers to ramp up production with investment and purchase orders; it can coordinate the purchase and distribution of existing supplies to get material where it is most needed. Long-term purchasing and investment deals will ultimately yield a surplus of basic supplies that can be used to rebuild a truly adequate SNS.

The law allows this, but it does not ultimately mandate action. Emergency powers obviously raise a potential problem of over-reach, an executive exploiting crisis authority for improper ends. The federal response to COVID-19 shortages has been a surprising and tragic example of the opposite – executive underreach (Pozen & Scheppele, 2020). The federal government has failed miserably and must at once bear grave responsibility for the harm it has failed to prevent and for rebuilding its preparation and response capacities. Congress may need to consider reshaping emergency law to create more binding duties for the executive branch.

There is blame to share. States have been complicit in the long-term underfunding of public health infrastructure, including state stockpiles. Shortages of equipment also demonstrate some shameful attributes of a health care industry that only Rube Goldberg would call a system. Hospitals and health care organizations live in a market that provides little incentive for emergency risk-assessment and response – or even protecting their workers.

There are fundamental equity problems in this mess. Mount Sinai staff to the contrary notwithstanding, when a product costs more the haves get more of it than the have-nots. Richer hospitals and health systems, in wealthier states, will all things being equal get

Table 21.1. Requested and Received N-95 Masks

STATE (POPULATION)	REQUESTED	RECEIVED	PERCENTAGE RECEIVED
Florida (21 million)	180,000	180,000	100%
Oregon (4 million)	400,000	40,000	10%
New Jersey (9 million)	2,900,000	85,000	3%
New York City (8 million)	2,200,000	78,000	4%
Notes: All of the NYC masks received were marked expired (DePillis et al., 2020).			

more and better PPE than poor institutions. Urban will generally beat rural. And in the health care workforce, the doctors, nurses, and other care staff in medical centers will do better than people working in nursing homes and prison infirmaries and other institutional or home care functions. The have-nots in this story are lower paid and more likely to be people of color, yet they are as at-risk and as essential as the workers fortunate enough to get the PPE they need. All these problems and the deeper inequities they reflect are solvable, but not without effective collective action by and through a government that expresses our shared responsibility and solidarity. On top of everything else, the failure to properly prepare and respond is just one more way in which COVID-19 has demonstrated the fundamental moral and political challenges of the "social determinants of health" in the United States (Berwick, 2020).

Recommendations for Action

Federal government:

- The president should empower and equip with the necessary resources competent career government staff to use federal emergency and DPA authority:
  - o Identify and assess the availability of all basic medical equipment required for COVID-19 response;
  - o Assess domestic and international production capacity and supply chains;
  - o Use investment and purchasing to incentivize manufacturers to add necessary capacity;
  - o Develop and implement a strategy for federal procurement and need-based distribution to states.
- Congress and the White House should jointly convene an independent commission of inquiry to conduct a thorough public investigation of the federal and state government preparation for and response to COVID-19.
- Congress should reaffirm the role of the SNS as the primary resource for the nation during emergency surges in demand, and institute a long-term funding plan for assuring supplies commensurate with predicted need.
- Congress should fund and HHS should properly implement and manage the long-term staff and infrastructure to monitor, track, and use the resources of BARDA to proactively address deficiencies in the supply chain for essential medical equipment.
- HHS should develop, with real attention, new regulations on emergency supply chain management including developing and implementing "stress tests" for supply chains for key products, and reorganize accordingly.

State governments:

- In the near term, as long as federal coordination lags, states should continue to formalize and extend interstate cooperation in procurement and sharing of resources.
- As revenues return to normal levels, and we see how federal government goes forward, states should make substantial investments in human resources, infrastructure, and procurement to create state stockpiles and ensure competent staff and leadership for emergency response.

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