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CENTERING ON CORONAVIRUS

MEDICAL SUPPLY SHORTAGES

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Centering on Coronavirus: Critical Supply Shortages

Several months into the coronavirus crisis, hospitals are still reporting shortages of testing kits, personal protective equipment, medical devices, and other critical medical supplies—all indispensable in the fight against COVID-19. In a Washington Post-Ipsos Poll from May 2020, 66% of health care workers reported shortages of N95 respirator masks, 36% reported shortages of protective gowns, and 35% reported shortages of cleaning supplies and face shields.

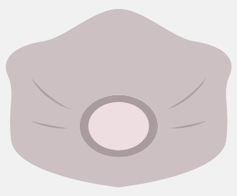
Widespread public health crises are bound to test existing policies and infrastructures, but the novel coronavirus has revealed longstanding deficiencies in medical supply acquisition, distribution, and coordination across all levels of government and in many parts of our economy.

For decades, companies and governments have prioritized efficient global supply chains and "just-in-time inventory," which have helped decrease prices for consumers and increase profits for companies. But it has become clear that some of this happened at the expense of resilience as American hospitals and doctors simply have not been able to get the supplies they need during the COVID-19 crisis.

In this issue brief, The New Center outlines steps the federal government and states have taken to address supply shortages, and what America can and should do in the future to ensure access to critical medicines and supplies when we need them.

AMERICA'S TROUBLING DEPENDENCE ON FOREIGN MEDICAL SUPPLIES

The United States currently sources 40% of its finished product drugs from overseas.



Over 90% of N95 respirators sold in the United States were made abroad.

The parts required to make a complete ventilator are sourced from over a dozen countries.

Recent Actions

FDA Expands Regulatory Flexibility

Since January 2020, the U.S. Food and Drug Administration has issued several Emergency Use Authorizations (EUA) and updated its policies to promote increased availability of testing kits and critical medical supplies and equipment.

Testing Kits and Supplies: On February 4, 2020, the FDA allowed Centers for Disease Control and Prevention (CDC)-qualified labs across the country to use the 2019-nCoV Real-Time RT-PCR Diagnostic Panel; previously, the test was only allowed to be used at CDC laboratories. That same month, on February 29, 2020, the FDA issued a new policy allowing certain laboratories to develop and use COVID-19 diagnostic tests before the FDA completes a review of their Emergency Use Authorization requests. In order to localize test development and use, on March 16, 2020, the FDA announced that states and their individual departments of health could set up a system within which they would be responsible for authorizing tests from laboratories within their respective states.

Respirators: On March 2, 2020, the FDA and CDC issued a joint statement saying that certain respirators approved by the National Institute for Occupational Safety and Health (NIOSH), which had previously only been designated for use in industrial settings, could now be used in health care settings as well. It is important to note that these devices are not meant to assist patients with breathing but, rather, are respiratory protective devices intended to be worn by medical personnel to filter out airborne particles. On March 27, 2020, the FDA issued an EUA allowing imported non-NIOSH-approved respirators that meet specific standards to also be used in health care settings. And on April 10 and April 12, 2020, the FDA issued EUAs to the STERIS Corporation and Advanced Sterilization Products (ASP) for the use of their decontamination machines in health care settings to sterilize N95 respirators and allow for safe reuse.

Ventilators: In another effort to ease the burden on ventilator manufacturers, the FDA announced on March 22, 2020 that it would not be enforcing premarket review requirements for modifications to ventilator devices. On March 27, 2020, it issued an Emergency Use Authorization (EUA) allowing certain ventilators, modified anesthesia gas machines, positive pressure breathing devices, ventilator tubing connectors, and ventilator accessories that meet FDA standards to be used in health care settings. Even NASA is working to address the ventilator shortage. On April 30, 2020, the FDA included a NASA prototype ventilator, which NASA developed in 37 days, called the VITAL (Ventilator Intervention Technology Accessible Locally) under the ventilator Emergency Use Authorization.

Food Supply: Beyond issuing EUAs and enacting policy changes for medical supplies and testing kits, the FDA announced on March 17, 2020 that, in an effort to prevent disruptions in the food supply chain, it would no longer enforce supplier verification onsite audit requirements in food industry settings.

Creation of the Supply Chain Stabilization Task Force

In late March 2020, the Federal Emergency Management Agency (FEMA) and the Department of Homeland Security (DHS) created the Supply Chain Stabilization Task Force. The task force, headed by Rear Adm. John Polowczyk, was created in response to the COVID-19 outbreak as a way to bridge the supply gap between the private sector and health care end-users. The Supply Chain Stabilization Task Force announced its four-pronged "Whole of America" approach to addressing health care supply chain gaps: preservation of supplies, acceleration of manufacturing and distribution, expansion of the critical supply industry, and allocation of supplies. Rear Adm. Polowczyk says policymakers have been urging him to "do all the buying, all the distributing, and all the allocation" to centralize the medical supply chain; Polowczyk, however, has resisted calls to nationalize, instead noting that he is "looking to break down barriers…to help them feed product where it needs to go."

As of June 3, 2020, FEMA has reported that, through the "Whole of America" response and with the help of inter-agency collaboration, 13.9 million face shields, 149.2 million surgical masks, 6.2 million coveralls, 1 billion gloves, 92.2 million N95 respirators, and 36.8 million gowns have been delivered to locations across the country.

Use of the Defense Production Act

The Defense Production Act (DPA) was enacted in 1950 during the Korean War as a mechanism for the federal government to ensure an adequate supply of essential materials and supplies. Since March 2020, the DPA has been invoked by the White House and the Department of Defense to increase the supply of ventilators, N-95 respirators, and testing swabs.

- March 27, 2020: President Trump invokes the Defense Production Act to require General Motors to produce ventilators.
- April 2, 2020: President Trump invokes the Defense Production Act to direct the Secretary of Health and Human Services to facilitate the supply of materials to the General Electric Company, Hill-Rom Holdings, Inc., Medtronic Public Limited Company, ResMed Inc., Royal Philips N.V., and Vyaire Medical for the production of ventilators.
- April 3, 2020: President Trump invokes the Defense Production Act to direct 3M to manufacture N95 respirators. The authorization originally barred 3M from exporting masks to other countries, but 3M and the Trump Administration subsequently struck a deal allowing 3M to continue exporting masks to Latin America and Canada.
- April 11, 2020: The Department of Defense, under the Defense Production Act, entered into a $133 million contract with 3M Co., Honeywell International Inc., and Owens & Minor Inc. to produce 39 million N95 respirators.
- April 19, 2020: During a coronavirus task force briefing, President Trump announced that he would be invoking the Defense Production Act to compel Puritan Medical Products to manufacture nasal swabs. The DPA has not officially been invoked, and President Trump's trade advisor Peter Navarro clarified that "the White House plans to use the act to give Puritan Medical Supplies federal funding to boost production."

Distribution of Supplies from the Strategic National Stockpile

The Strategic National Stockpile (SNS) serves as a multi-location repository for essential pharmaceutical and medical supplies that can be deployed in the event of a national emergency.

At the onset of the U.S. COVID-19 pandemic response, it became clear that the supplies in the Strategic National Stockpile could not fully meet state requests for this given outbreak and it was quickly depleted. Sometimes, when states did receive supplies, they were unusable.

The state of California, for example, announced that 170 of the ventilators it received from the SNS were "broken," and New York-Presbyterian Hospital claimed that 220 ventilators it received from the SNS "needed repair." Most recently, the University of Michigan reported that 22,000 surgical masks that it received from the Stockpile were "less durable" and "removed as many as possible from inventory and are not distributing the rest."

State officials requested a stronger response and contribution from the federal government but President Trump pushed back, urging states to take the lead on acquiring medical supplies they needed. Seven states in the Northeast—New York, New Jersey, Connecticut, Delaware, Massachusetts, Pennsylvania, and Rhode Island—announced they would be forming a consortium to avoid continued bidding wars and provide a more organized distribution mechanism.

On May 14, 2020, the Trump Administration announced that it would be initiating an overhaul of the Strategic National Stockpile in order to prepare it for a potential COVID-19 resurgence in the fall and for other outbreaks down the line. According to administration officials, the goal is to restock the SNS with 90 days worth of critical medical supplies.

Federal Legislative Initiatives

As of April 2020, three pieces of legislation have been signed into law to address the COVID-19 outbreak in the United States: The Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSAA) passed on March 6, 2020, the Families First Coronavirus Response Act passed on March 18, and the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) passed on March 27. Two of them provided resources to deal with America's medical supply chain problems.

The CPRSAA provided $6.7 billion in funding for the Public Health and Social Services Emergency Fund, the Infectious Disease Rapid Response Reserve Fund, and the Food and Drug Administration. The CARES Act had several provisions that sought to address medical product, emergency drug, and medical device shortages. It also provided appropriations for agencies and programs to address shortages, including $1 billion for Defense Production Act purchases.

Beyond Borders: Sourcing Medical Supplies from Abroad

In December 2011, the U.S. Department of Commerce prepared a report on American reliance on foreign sourcing in the health care and public health sectors for pharmaceuticals, medical devices, and surgical equipment. Included in the report's findings was the conclusion that there is a "very high degree of foreign sourcing and dependency for critical components, materials, and finished products required for U.S.-based manufacturing operations."

Today, American over-reliance on foreign-sourced medical supplies remains unchanged, and has become more severe in certain sectors. For example, according to a 2019 report from the Senate Committee on Homeland Security and Governmental Affairs, the United States currently sources 40% of its finished product drugs from overseas. And data from the Peterson Institute for International Economics shows that the "U.S. imports almost half its personal protective medical equipment, including masks, goggles and gloves, from China."

New Center Solutions: How Can America Secure its Supply Chain?

While confronting issues with global supply chains will be a long and complex process, The New Center has identified several possible ways medical supply shortages can be addressed right now by Congress:

Implementing a National Emergency Medical Supply Inventory Reporting Database

Hospital systems are not required to disclose medical supply stockpile data with the federal government. If a national medical supply inventory reporting database existed, the federal government could ensure that supplies were being distributed to hospitals that needed them the most. The federal government could create a data-sharing requirement for hospitals, activated during times of crisis, in exchange for assistance with sourcing, purchasing, and distribution.

Increase Funding for the Strategic National Stockpile

Without increased funding, the Strategic National Stockpile will always be playing catch-up to restock from previous pandemics. In a recent interview with The New Center, the former director of the SNS Greg Burel said that he believes "the Stockpile's response [to the COVID-19 outbreak] has been outstanding based on what it has and the funds it's received to be prepared for this. But I think what this raises is, if the nation expects the Strategic National Stockpile to continue to grow its mission, and it expects it to be prepared for these kinds of events, then it's going to have to fund it to be able to do that."

Confirming a Director for the Strategic National Stockpile

Right now, the Strategic National Stockpile is headed by Acting Director Steven Adams, who previously served as Deputy Director of the SNS and has been involved with the SNS program since its inception in 1999. Confirming a Director for the Strategic National Stockpile will ensure that this critical program is headed by someone with permanence and full authority.

Implementing Distributed Product Tracking

The Department of Health and Human Services developed the Inventory Management and Tracking System (IMATS) to help states and local governments manage and track medical countermeasures. While the SNS offers the program free of charge, states can still choose to use their own inventory management systems.

If states and localities operated under one uniform management and tracking system, they could be more effective in not only identifying inventory gaps, but also learning about how product travels to better inform preparedness measures in the future. State and local public systems should receive SNS supplies contingent on their participation in the IMATS.

Addressing Our Over-Reliance on Foreign Sourcing

Increased reliance on foreign-sourced medical supplies poses a national security threat and, as evidenced by COVID-19, prevents the United States from quickly manufacturing and deploying critical equipment to patients. Any plan to counter COVID-19 (and future epidemics) will have to address this growing reliance. Congress could consider a plan like the bipartisan Made in America Emergency Preparedness Act which, if passed, would establish a National Commission on United States Preparedness for National Emergencies and establish procurement requirements that prioritized American-made products.

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ABOUT CENTERING ON CORONAVIRUS

Centering on Coronavirus is a new policy series from The New Center that provides insights and analyses of how coronavirus is progressing, how it is impacting our health system, economy and workers, and the extraordinary human, policy, and technological resources that are being mobilized to fight it.

ABOUT THE NEW CENTER

American politics is broken, with the far left and far right making it increasingly impossible to govern. This will not change until a vibrant center emerges with an agenda that appeals to the vast majority of the American people. This is the mission of The New Center, which aims to establish the ideas and the community to create a powerful political center in today's America.

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