



Senate Committee on Homeland Security & Governmental Affairs
COVID-19 Part II: Evaluating the Medical Supply Chain and Pandemic Response Gaps
May 19, 2021
2:30 P.M., Dirksen Senate Office Building SD-342

PURPOSE

The purpose of this hearing is for the Senate Homeland Security & Governmental Affairs to examine the vulnerabilities in the US medical supply chain.

MEMBERS PRESENT

Chairman Peters, Ranking Member Portman, Hassan, Johnson, Hawley, Rosen, Ossoff.

WITNESSES

- **Shereef Elnahal, M.D.**, President and Chief Executive Officer, University Hospital, Newark, New Jersey
- **Robert Handfield, PH.D.**, Professor, Poole College of Management, North Carolina State University
- **Stephen Schondelmeyer, Pharm.D., PH.D.** Professor, College of Pharmacy, Co-Principal Investigator, Resilient Drug Supply Project, University of Minnesota
- **Kimberly Glas**, President and Chief Executive Officer, National Council of Textile Organizations

KEY TAKEAWAYS

- The U.S. personal protective equipment (PPE) shortage during the pandemic is attributed to many factors: reliance on textile imports, unprepared stockpile, supply chain opacity.
- Senators and witnesses supported a public-private collaboration to address these supply chain issues moving forward.
- The textile industry responded quickly to the need for PPE, yet concern remains on reversion to off shore manufacturing.
- The lack of transparency regarding the supply chain for drugs and devices creates a substantial barrier to U.S. systems.

OPENING STATEMENTS

Chairman Peters (D-MI) Our nation was unprepared to address the spread of COVID-19. The Trump Administration failed to have an effective federal response to the emergency. The COVID-19 pandemic took 500,000 lives in the United States (US), and resulted in economic destruction, and created long term health effects for those still suffering from the disease. The Biden Administration has change the course of the COVID-19 pandemic. Swift decisions and actions from the last Administration could have helped combat the pandemic. To prevent medical supply shortages, the government should increase production of supplies, and have a coordinated federal response, instead of relying on state. The lack of action from the last Administration forced states to bid against each other for medical supplies. Moreover, adequate access to personal protective equipment (PPE) could have helped save lives. Even though we had limited information when the virus started to spread, the warning signs for our medical supply chain were there. In Dec 2019, I released a report on the national security risk of reliance on foreign countries for these critical medical supplies. I have introduced bills to address the medical supply chain and its vulnerabilities. I look forward to the testimony and discussion today from the witnesses.

Ranking Member Portman (R-OH) Last month we did hold an oversight hearing on this topic, and this is a continuation of our examination on this topic. Today's hearing will focus on the pandemic response, specifically the medical supply chain response. We owe it to those who lost their lives due to the COVID-19 pandemic to get this right. We saw a convergence of forces on the supply chain: the spike in demand for medical supplies was too high, available supplies were too low, and the Strategic National Stockpile (SNS) was unprepared. Preparation for the pandemics should be done years in advance. Many factors contributed to the lack of preparedness. The SNS is chief among the issue. For more than a decade, SNS focused on nuclear response, but that focus came at the expense of pandemic responses. The SNS was not replaced after H1N1. Moreover, there has been an off shoring of medical supplies. There are three major questions I seek to answer: 1) What steps should the country take to reduce reliance on foreign reliance on medical supplies? 2) How do we foster strong response in the US, and strong supply chain network in the US? 3) How do we ensure we have the right supplies for future crisis? I am concerned about inadequacies of the SNS and seeking to resolve them. Thank you to the witnesses for bring their testimony today and I am looking forward to a non-partisan response to this.

TESTIMONY

Dr. Elnahal: Thank you Chairman Peters, Ranking Member Portman, Senators, and follow panelist for the opportunity to share my experiences. I first want to start by saying that the PART Act and HOME Act would have helped my hospital during the COVID-19 pandemic. University Hospital is a New Jersey public hospital, an academic medical center, and trauma 1 medical center. We serve a critical and vulnerable populations in New Jersey. During the COVID-19 pandemic we found ourselves running out medical supplies, including PPE and ventilators. These were the same recourses that other hospitals across the country needed. As a result, suppliers and vendors were supplying hospitals and other providers with the highest bids for medical supplies. This was a big

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problem for safety net like University Hospital. We worked around the clock to protect patients. We had find providers we had suppliers in which we no track record with, and at the same time were concerned about fraud among supplies. The SNS needs to be an important focus in improving the supply chain. The CARES Act funding we received supported our hospital and allowed us to keep our doors open. Hospitals cannot fail during a pandemic, especially safety net hospitals. Additionally, the state response helped us get needed equipment. We conducted Moderna vaccine clinical trials in minority communities. We also did many virtual town halls on the vaccine, and encouraged uptake in minority communities. Now we focus on access and are implementing mobile clinics for vaccine distribution. We are in not prepared for next pandemic. Additionally, financial solvency for hospitals is an issue and needs meaningful payment reform. Thank you for the opportunity and I look forward to the discussion.

Dr. Handfield: Thank you to the Committee to the opportunity to speak today. I have studied supply chains for more than 30 years. As a consultant with the Department of Defense (DoD) I provided advice on the PPE, drugs, and medical supplies. Our team presented recommendations to the DoD in May of 2020. During my testimony I will describe the state of SNS and the events that occurred in 2020, and recommendations to prevent future shortages. Prior to COVID-19 the SNS was a secret organization, did not publish what they did or the inventory, and its focus was on nuclear situations, and not ready to respond to pandemics, such as the COVID-19 pandemic. There were a number of problems in the first half of 2020, this included: 1) lack of supply market intelligence, and a multiple agency supply market analysis is needed; 2) lack of ability to track supplies; 3) the US health care system relies on suppliers overseas; 4) lack of governance among public agencies resulted in failure to respond, and we need a structured response; 5) states were competing against each other for supplies, instead we need equity in distribution among states; 6) the SNS was unprepared. The system failure to response is a failure to respond by multiple agencies. I've outline a set of solutions and I am looking forward to the discussion.

Dr. Schondelmeyer: Thank you Chairman and to the Committee for the opportunity to provide input today on the US pharmaceutical supply chain. First, I will start by discussing the state of the pharmaceutical supply chain before the COVID-19 pandemic. In that we expect that essential medicines are available at local pharmacies. My team has tracked and reported on drug shortages. We have found that more than 170 drugs are in short supply at every point in time. This current and ongoing rate of pharmaceutical shortages is unacceptable. What was the impact of pandemic on supply chain? Prescription drugs demand increased, while supply decreased. Over 40 critical COVID-19 drugs were in short supply as of January 2021, and are still in short supply. The rate of drug shortages in unacceptable. The pharmaceutical supply chain saw shutdowns at manufacturing facilities as well as trade shutdowns. Heavy dependence on foreign countries, outdated drug manufacturing system, lack of visibility, and a lack of national coordinated policy approach of the pharmaceutical market. In 2018, University of Minnesota examined the drug supply chain. We looked at top pharmaceutical brands. Nearly all brands have US brand, but looking in upstream supply chain most of products and ingredients are foreign made – mostly in Europe and India. Including with starting materials in China. Critical access drugs are mostly made in China and India. The current level of dependence on

foreign countries is concerning and long term vulnerabilities are concerning. This reliance can result in political and economic leverage, and we can be held hostage by other countries.

Ms. Glas: Thank you for the opportunity to testify. Our strong over reliance on China's production posed a significant threat. As supplies broke down and China's price controls were exercised, we saw the effects of this in the lack of access to the necessary equipment. It as if we were on the frontlines and the equipment supply was cut off. Supply chains broke down, and this is why we exist and should exist in America. We must obtain support, otherwise our companies and industry will go back off shore. I commend the Make PPE in America Act. We need long term contracts and procurement rules for domestic products. We need to ensure vertically integrated supply chains for health care PPE. A strong industrial base for the textile industry means a strong base for healthcare PPE. We need to reinforce a strong industrial base for textiles and implement the strengthening of the PPE stockpile. We need public incentives to buy domestic PPE, and we must centralize U.S. government contracts. In addition, we need to advance key investments in PPE, and address sub standard imports. We should expedite regulatory approvals to strengthen the industry. If we can endure grow and create self sufficiency domestically, then the industry stands ready for the next public health crisis. Thank you.

QUESTIONS AND ANSWERS

Chairman Peters stated that as the pandemic spread, we know that first responders were facing dire shortages of critical drugs, and doctors and other health professionals were forced to reuse masks and ponchos. This situation was startling, and providers were scrambling to find critical drugs and ventilators. Sen. Peters asked Dr. Elnahal to describe the impact of the lack of PPE and equipment during the pandemic. **Dr. Elnahal** stated that providers saw the sickest patients coming in at rates of twenty to thirty patients a day. They expanded pediatric units and asked staff to take care of these patients, nine to ten at the same time. There was a tremendous amount of stress that piled onto an already difficult situation. Two units themselves were on the phone with suppliers, but they were up against goliath health systems obtaining equipment for their systems. Dr. Elnahal stated that they relied on the national stockpile and contended with increases in prices of medications and lack of access of drugs. Oftentimes, physicians were the only people beside a dying patient. **Sen. Peters** stated that the men and women are the frontline heroes and asked what actions should have been taken to support state and local hospitals. **Dr. Handfield** stated early on that SNS did have early indicators on January 29. A logistics summary revealed an ask for response from key distributors. They were slammed with requests for PPE. SNS didn't understand how that supply chain was designed, and there was a lot of overseas dependence. Money previously had been spent on Anthrax vaccines and not on response preparation for a pandemic. He stated there needs to be a portfolio built based on future risk.

Ranking Member Portman stated that we know from the data that 70% of needed PPE was based in China. In 2020, they nationalized supplies and exerted controls of exports.

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He asked whether the U.S. was too dependent on China. All witnesses stated yes. Ranking Member Portman stated that controls in place made the situation worse. He stated the dependence impeded our COVID response. He asked what we do about it. He stated that we need to make more PPE and use market forces to do so. He said that we need market to convert plants to production. Ms. Glas said that the textile industry needs guaranteed investment in the U.S. and needs a demand signal, such as long term contracts. Canada is doing so and some of these contracts last up to ten years. Sen. Portman asked what the Department of Defense's role here was. Ms. Glas stated that there were many fits and starts. She stated that under a short-term contract, there were millions of yards of cloth wasted and unused because the DoD decided they wanted disposable gowns, not reusable gowns. Sen. Portman stated that 80% of drugs are made elsewhere. He asked whether cheaper costs are the primary reason for manufacturing moving to China. Dr. Handfield stated that China has set goals to become leaders in this space. We've seen the price increases. India did limit export of certain drugs to the U.S. Dr. Schondelmeyer stated that there are green and clean processes to turn this around, but there must be a concerted policy. The FDA approves drug but does not look at economic factors.

Sen. Hassan (D-NH) stated that it became apparent that the strategic national stockpile did not have the equipment or distribution processes to respond. Sen. Hassan asked how we can ensure that the stockpile has adequate equipment at all times. Dr. Handfield stated that the challenge is that the stockpile sits there and gets old. There is a need for fresh inventory. He recommended a living stockpile, in which inventory can be kept in hospitals across the country, including VA hospitals and tracked through inventory tracking methods. This is not expensive and would entail use of barcodes and monitoring. Sen. Hassan asked how we add resiliency by expanding domestic manufacturing and production. Dr. Handfield stated that active ingredients are made in India and raw ingredients come from China. We have to take a look at the supply chain but also how these products are reimbursed. Dr. Schondelmeyer stated that there are many things we can do. There are non profit organizations that bring low cost generics to market, however pharmaceutical companies cannot beef up as quickly as the textile industry.

Sen. Johnson (R-WI) stated that if there is a demand for a product, there will be a buyer. He stated that the regulatory environment for health care, specifically with medicine and Medicare formularies are among the reasons for the shortages. He said we need to do as much as possible to rely on the pricing signals from the market. He stated that we did not replenish the stockpile, and we need government help to support private corporations. He asked rather than a government inventory system, why not spend money to contract with private contractors and integrate this into their systems. Dr. Handfield stated that this is definitely something we can do. We need to make sure they are held to accountability and transparency. Sen. Johnson stated that first the intermediate precursor is developed in China, then the product is developed in India. He said that there are environmental issue related to emissions in this supply chain as well. He stated that not all manufacturing has to come back to the U.S. as long as it is diversified globally and we are not completely dependent on one nation. Dr. Schondelmeyer said that when it comes to drugs market will respond long term, but for the patient that needs the drug today, they will die without

it. Sen. Johnson said that if you have a steady demand for drugs, the market will respond. No one was prepared for COVID, but he asked outside of COVID how demand spikes. Dr. Schondelmeyer stated that variations are not all totally predictable.

Sen. Hawley (R-MO) asked why the U.S. textile industry competes in an unbalanced playing field. Ms. Glas stated that there was significant off-shoring of this industry. 100 companies have taken on the textile mask production in the U.S. and the orders are dwindling. There are products coming in that are below cost. The U.S. industry has investment and no long-term demand signal from the U.S. government. She stated that there are factories in China that have arisen exploiting forced labor and the industry is subsidized. That is hard to compete with. She stated we need to get policies over the finish line to say yes we can be competitive.

Sen. Rosen (D-NV) stated that we saw health providers scrambling for globes, masks, and PPE. She stated that we need to bolster non-profit drug production by providing support for non-profit drug and device development. She asked what impact do these costs have on Dr. Elnahal's ability to treat patients. Dr. Elnahal stated that it impacts patient care significantly. Resorting to lower standards of care is not acceptable. He stated that costs can be prohibitive, and this is the case for many drugs that are necessary for patients. This is also a challenge when these drugs are available only on the sole-source basis. There needs to be greater availability of generics and alternatives, especially for safety net hospitals. Sen. Rosen asked whether cyber attacks were a concern and how they are accounted for. Dr. Schondelmeyer stated that there are lists of threats and concerns and cyber attacks are among them. Everyday any disruption can be deadly. He stated that they have to work with private markets. If they can't get drugs out to hospitals and pharmacies, patient die. Sen. Rosen asked whether it would be helpful to designate a drug manufacturer as critical infrastructure. Dr. Schondelmeyer stated that it would be helpful for all critical access hospitals and rural hospitals and all healthcare provider institutions.

Sen. Ossoff (D-GA) stated that in the early months, shortages impaired the medical response and put them at unnecessary risk in the early days. Ad hoc homemade solutions were found through trash bags, and sewn masks. He asked whether we have taken the necessary steps since those early months to ensure those are never forced to sew their own face masks and use trash bags as protection. Ms. Glas states that these types of homemade solutions were endemic across the country. She stated that she is concerned that the supply chain constructed to respond to COVID will go off shore again. The government needs to show support and show a demand signal to these textile manufacturers. There are many textile manufacturers who want to respond. Sen. Ossoff asked what key products are included in a list of critical products necessary for another public health crisis. Dr. Elnahal stated that respiratory viruses are not the only types of viruses. Ebola is one example. Other pathogens can effect the gastro intestinal system. There are various characteristic needs depending on the pathogen. Disposable and reusable gowns are key. Making sure the stockpile is there is important. Sen. Ossoff requested a list submitted for the record of itemized lists of medical equipment and products that may be in high demand in the next public health crisis.

Chairman Peters stated that we don't have a good handle on what we manufacture. Manufacturing reporting requirements are unclear as well as reporting on active ingredients, and there is no clear picture of what's out there. Dr. Shondelmeyer agreed and stated that we know little about the drug supply chain. Though you can find information on where the drug is marketed and distributed, you can't find information on where it is manufactured and drug companies are reluctant to make that public. Chairman Peters stated that the U.S. needs to put into place the right contractual incentives that would lead companies to be clear on supply chain. There is no question that there is a long standing reliance on overseas manufacturing, and the Trump Administration was slow to act. Chairman Peters stated that the Committee will continue investigation on the response. As we have seen the cost of inaction is far too great to bear, he said.